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ATTD 2022 Invited Speaker Abstracts

IS001 / #938

PLENARY - PREVENTION AND CURE OF TYPE 1 DIABETES (PART 1)

CAN WE ARREST TYPE 1 DIABETES?

C. Mathieu

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After 100 years of insulin therapy, our insights in the pathogenesis of type 1 diabetes (T1D) have evolved and using the combination of genetic risk and presence of autoantibodies in the blood has allowed us to progress in the prediction of risk. Consortia worldwide are exploring the value of novel biomarkers and evaluate interventions targeting arresting progression of beta-cell destruction in people with newly diagnosed T1D or in those at risk of T1D. In Europe, the IMI2-funded projects INNODIA and INNODIA HARVEST focus on novel biomarker discovery and the consortium is executing 4 clinical trials in people with newly diagnosed T1D. An overview of activities, as well as the evolution of novel therapies for prevention and arrest of T1D will be discussed.

IS002 / #824

PLENARY - ARTIFICIAL INTELLIGENCE AND PERSONALIZED MEDICINE IN DIABETES CARE

BIG DATA IN DIABETES CENTERS AND HOSPITALS – WHAT DO WE DO WITH IT?

M. Clements

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Diabetes centers, healthcare systems, and individuals with diabetes generate many types of data about diabetes-related outcomes and about self-management behaviors, comorbid medical conditions, and clinical care-related events. Yet only a small fraction of these data are used by clinicians regularly for decisionmaking. Risk-based management protocols can help diabetes centers to improve both the quality and cost-efficiency of care. These protocols may be driven by biomarkers of risk extracted or derived from electronic health records, diabetes self-management devices (or the cloud services that receive their data), and digital patient reported outcomes platforms; protocols may alternately be driven by forecasting of negative outcomes via Artificial Intelligence/Machine Learning approaches. The participation by diabetes centers in Learning Health Networks, with data sharing to a central data repository, can accelerate Big-Data-driven quality-improvement of care delivery. The presenter will review examples of risk-based management approaches using each technique, including novel biomarker-based risk indices like the 6 Habits of self-management, the Diabetes Care Index, and the Risk Indexes for Poor Glycemic Control and for Diabetic Ketoacidosis (RI-PGC and RI-DKA, respectively). The presenter will further examine the current state of algorithms and AI/ML to manage population health in diabetes clinics, including a population health dashboard to reduce deterioration in glycemic control in the post-diagnostic period for type 1 diabetes, a precision medicine project for type 2 diabetes incorporating multiple -omics biomarkers, and the Rising T1DE Alliance, which seeks to implement multiple ML models to predict outcomes in clinical care, and to test remote patient monitoring along with multiple digital and behavorial health interventions to improve those predicted outcomes via a risk-based management approach.

IS003 / #825

PLENARY - ARTIFICIAL INTELLIGENCE AND PERSONALIZED MEDICINE IN DIABETES CARE

TELEHEALTH USE ACROSS THE LIFESPAN WITH DIABETES

L. Laffel

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The COVID-19 pandemic required the urgent deployment of a telehealth approach to deliver diabetes care across regions and across the lifespan. A number of observational studies have documented the use of telehealth in people with type 1 and type 2 diabetes from childhood through the older adult population. While the pandemic brought multiple inconveniences to all of us, it permitted health care delivery systems and providers to utilize remote care delivery in a previously unprecedented manner. As a result, a number of these observational studies have a demonstrated that provision of telehealth services maintained needed care processes and some studies have even demonstrated either

maintenance or potential improvement in glycemic outcomes. Data from the Joslin Diabetes Center offer observational information on how telehealth was deployed either via telephone or video modalities in various age groups. In addition, these data help us to evaluate the utility of telehealth services in different segments of the population living with diabetes, for example, according to age or modality of their diabetes treatment. Finally, telehealth services provided opportunities even to initiate diabetes treatment in those newly diagnosed and to implement changes in diabetes management for those with established diabetes, including the implementation of advanced diabetes technologies. These issues will be discussed in the symposium.

IS004 / #828

PARALLEL SESSION - UPDATE ON GLUCOSE AND KETONE MONITORING

NEWER CONTINUOUS GLUCOSE MONITORING SYSTEMS

S. Garg[1,2]

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''**Newer Continuous Glucose Monitoring Systems'' Satish K. Garg, MD** Professor of Medicine and Pediatrics, Director of adult Diabetes program, University of Colorado Denver and Barbara Davis Center for Diabetes, Aurora, Colorado. Over the past decade there have been many advances in diabetes technologies, such as Continuous Glucose Monitoring devices/systems (CGMs), insulin-delivery devices, and hybrid closed-loop systems. There have been significant advances in CGMs in the past decade. In fact, ten years ago very few people use to believe in the use of CGMs, even though they had been available for the past two decades. Many providers used to question who, why, and when will patients ever use CGMs similar to the questions asked about Self-Monitoring of Blood Glucose (SMBG) about four decades ago. At the time of this writing, more than five million people world-wide are using a CGM for their diabetes management, especially those who require insulin (all patients with Type 1 diabetes (T1D) and about 20% of patients with Type 2 diabetes (T2D)). Total sales of all CGMs now exceeds more than $7 billion and the use of SMBG is going down every day. Most of the CGMs have improved their accuracy significantly in the past two decades. I still remember doing studies on the GlucoWatch and earlier versions of Dexcom STS where mean absolute relative difference (MARD) used to be in the range of 15-26%. Now most of the CGMs (Guardian by Medtronic, G6 by Dexcom, and Libre 2 by Abbott) have single-digit MARD. In addition, the majority of the new CGMs do not require calibrations and the newer CGMs last for 10-14 days. An implantable CGM by Senseonics (Eversense®) is approved in the USA for 3 months and a different version is approved in Europe for 6 months. FDA has still not approved the 6-month version of Eversense® implantable sensor in the USA, which also has single-digit accuracy. The newer CGMs that are likely to be launched in the next 3-6 months; hopefully around the ATTD Conference, include 10.5-day Dexcom G7 (60% smaller than the existing G6), 7-day Medtronic Guardian 4, 14-day Libre 3, and 6-month Eversense®. Most of the newer CGM data can be viewed on Android or iOS/iPhone smart devices, and in many instances they have several features like predictive alarms and alerts, easy insertion, automatic initialization (in some instances down to 27 mins, Dexcom G7) with single-digit MARDs. It has also been noticed that arm insertion site might have better accuracy than abdomen or other sites like the buttock for kids. Lag time between YSI and different sensors have been reported differently, sometimes it's down to 2-3 mins; however, in many instances, it's still 15-20 mins. Diabetes effects communities of color disproportionately higher. For example, the highest prevalence of diabetes in the USA is amongst Native Americans (14.7%), which is nearly two times higher than Caucasians. African Americans and Hispanics also have higher prevalence of diabetes in the USA. It's also known that LatinX, African Americans, and Native Americans are much less likely to be offered new technologies like continuous subcutaneous insulin infusion (CSII/insulin pumps) and CGMs. Use of technology, especially CGMs, is expected to remove many of the social barriers and disparities in care for people with diabetes. A large database during the COVID-19 pandemic recently reported better Time-in-Range (TIR) in patients with diabetes irrespective of their ethnic background. However, the baseline TIR was significantly lower for minorities as compared to Caucasians. I believe the future will bring a larger increase in the use of CGMs for people with insulin-requiring diabetes (estimated at more than 100 million people globally) and those with T2D on non-insulin therapies (estimated at more than 400 million people globally). I also envision an increase in the number of pre-diabetes patients (estimated at more than 200 million people globally) using CGMs so that early medical intervention for diabetes management can be entertained. The intermittent or continuous use of CGM would depend upon the clinical needs. Needless to say, healthy individuals without diabetes (who can afford CGMs) might even use these technologies for self-evaluation of their glucose profiles after meals.

IS005 / #830

PARALLEL SESSION - UPDATE ON GLUCOSE AND KETONE MONITORING

IMPLANTABLE GLUCOSE AND KETONE MONITORING

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Living with type 1 diabetes (T1D) is challenging as it requires intensive monitoring of glucose levels, nutritional intake and physical activity, and correct titration of insulin in order to obtain near-normal glucose levels. The Endocrine Society has proposed real-time continuous glucose monitoring (RT-CGM) as the gold standard for people with T1D. RT-CGM devices display interstitial glucose levels around the clock and are designed to set off alarms to warn people when glucose levels are trending too high or too low. The evolution in pump and CGM technology has led to the development of hybrid closed loop (HCL) systems where basal insulin delivery is automatically guided by sensor glucose values using an algorithm. CGM and HCL systems have demonstrated improvements in HbA1c, time spent in hypoglycaemia, hospitalisations for severe hypoglycaemia or ketoacidosis, and quality of life. However, there are still some shortcomings with currently available CGM devices. Firstly, currently available sensors rely entirely on continuous glucose measurements and do not provide an alert for high ketone levels or impending diabetic ketoacidosis (DKA). Monitoring ketones is also advised for sick-day management, but in

reality many at-risk patients do not have ketone test strips at home. Production of ketone bodies may occur as a result of insulin deficiency (e.g. in case of pump failure or inadequate bolus dosing), sickness, insufficient intake of carbohydrates (very low calorie diet), or sodium-glucose co-transporter-2 inhibitors (SGLT2-i) therapy. Continuous ketone monitoring (CKM) may facilitate earlier detection of ketones, thereby possibly reducing hospitalisations for DKA in high-risk patients. The first-in-human results obtained in 12 volunteers of a CKM device were published in 2021 by Alva et al. The electrochemical sensor used wired enzyme to measure β-hydroxybutyrate (BHB), the major pathologic analyte. This sensor delivered a linear response over the 0-8 mM range with good accuracy and stability, both in vitro and in vivo, for 14 days. With a single retrospective calibration the mean absolute difference (MAD) for BHB concentrations <1.5 mM was 0.129 mM and 91.7% of the sensor results were within ±0.3 mM of the reference. For BHB ≥1.5mM the mean absolute relative difference (MARD) was 14.4%. Teymouran et al. reported data of a new real-time CKM microneedle platform based on the electrochemical monitoring of BHB alongside with glucose. This sensor detects BHB based on the NAD-dependent dehydrogenase enzyme and a selective low-potential fouling-free anodic detection of NADH using an ionic liquid-based carbon paste transducer electrode. In vitro data showed that the sensor had a high sensitivity (with low detection limit, 50 μM), high selectivity in the presence of potential interferences, along with good stability. The BHB microneedle sensor has been coupled with an oxidase-based glucose microneedle sensor on the same array platform, leading to an attractive sensor array towards the simultaneous real-time continuous monitoring of both glucose and ketones. The ability to detect lactacte has also been demonstrated based on lactate oxidase catalyzed lactate oxidation to pyruvate. A third sensor that has been developed by Indigo Diabetes nv is an implantable continuous multimetabolite sensor monitoring glucose, BHB, and lactate using near-infrared (NIR) spectroscopy technology with an expected lifetime of 2 years. In a first-in-man study, exploratory data on accuracy were promising (95.6 % of all data points for glucose ranging between 40-400 mg/dl were located in zone A, a MAD of 10.5 mg/dl for values between 40 and 70 mg/dl and a MARD of 10% for values between 70-180 mg/dl and of 4% for values >180 mg/dl were observed). Administration of paracetamol, acetylsalicylic acid, ibuprofen, sorbitol, caffeine, fructose, aspartame and vitamin C did not significantly influence the accuracy of glucose measurements. Also for BHB good accuracy was observed. Continuous measurement of ketones was compared to blood strip measurements over a physiological range of 0-4 mM; the sensor showed a MAD of 0.19 mM. The lactate concentrations measured over a range of 0-20 mM showed an MAD of 0.53 mM in relation to Biosen EKF reference measurements in blood. A second area of concern relates to the design of current sensors, patient's experiences and costs. The short sensor lifespan, the likelihood of accidental sensor dislocation, the occurrence of skin reactions, and privacy reasons (keep their diabetes hidden), limit the implementation of these sensors. The Indigo Diabetes nv sensor is a miniaturized near-infrared spectrometer on a silicon photonics chip that measures optical transmittance in the interstitial fluid at up to 24 wavelengths between 1680 and 2400 nm. The sensor is covered by a biocompatible silicone envelope. It is implanted subcutaneously in the abdominal region and has an expected lifespan of 2 years or more. In summary, there is a compelling need for a patient tailored device that is implantable, has a long lifespan and continuously monitors multiple biomarkers thereby helping to prevent episodes of hypoglycaemia or ketoacidosis under all circumstances (exercise, illness, SGLT2i therapy, very low carb diet), and possibly increasing quality of life.

IS006 / #835

PARALLEL SESSION - HYPOGLYCEMIA

USING TECHNOLOGY AND BEHAVIOR CHANGE TO ADDRESS THE HYPO AVERSE PATIENT

W. Polonsky

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Individuals with type 1 diabetes and type 2 diabetes often harbor excessive worries and concerns regarding hypoglycemia, which can impair their quality of life as well as their ability to achieve favorable glycemic outcomes. Technological interventions, such as the introduction of RT-CGM or hybrid closed-loop pumps, as well as behavioral interventions, such as BGAT (Blood Glucose Awareness Training), have been shown to reduce hypoglycemic fear and/or enhance hypoglycemic confidence, though the effect sizes are typically modest. This presentation will describe how new clinical interventions that integrate the two approaches, both technological and behavioral, may be even more efficacious, especially in those cases where hypoglycemic fears and worries are overwhelming. Through the description of actual cases, practical tips for addressing excessive hypoglycemic worries will be introduced and suggestions for future research investigations will be presented.

IS007 / #836

PARALLEL SESSION - HYPOGLYCEMIA

LOW-DOSE GLUCAGON – FOR "OPEN-LOOP" HYPOGLYCEMIA PREVENTION

K. Nørgaard

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When striving for strict metabolic control to reduce late-onset diabetes complications, episodes of mild hypoglycemia occur frequently in type 1 diabetes (T1D) due to relative insulin overdosing. Strategies aimed at preventing mild hypoglycemia have traditionally been limited to lowering the insulin dose and increasing the consumption of oral carbohydrates. Since obesity is a growing problem in T1D, it has been hypothesized that avoiding the extra caloric intake associated with supplementary carbohydrates to prevent hypoglycemia can help maintain a positive weight balance. In the last few decades, where the development of closed-loop treatment has taken place, several academic research groups have gathered experience with dual-hormone (glucagon and insulin) closed-loop treatment. Systematic reviews have shown superiority of dual-hormone to single-hormone closed-loop systems in lowering the incidence of hypoglycemia. Yet, no dual-hormone closed-loop system has been brought to market and used in clinical practice. Until recently, glucagon was only available in powder form, but several companies have now developed soluble glucagon. Soluble glucagon is available not only in vials but also in injection pens. This opens up the possibility for people with T1D to self-administer low-dose glucagon as a means to prevent and/or treat mild hypoglycemia, independent of their insulin regime *per se*. The objective of this talk is to present studies in which the efficacy, safety, and feasibility of injecting low-dose native or soluble glucagon on different causes of hypoglycemia in T1D have been assessed.

IS008 / #842

PARALLEL SESSION - COVID-19 AND DIABETES

OVERALL DIABETES MORBIDITY AND MORTALITY WITH COVID-19

V. Shah

University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America

Overall Diabetes Morbidity and Mortality with COVID-19
Viral N. Shah, MD Associate Professor, Barbara Davis Center for Diabetes, University of Colorado Denver On December 12, 2019, a pneumonia cluster of unknown causes was identified in Wuhan in the Hubei province of China. Later on, it was confirmed to be caused by novel coronavirus (COVID-19) probably linked to seafood wholesale market in Wuhan. Within three months of the first case in Wuhan, many countries reported cases of COVID-19. There has been a large amount of publications since the first case of COVID-19 in December 2019. Per a PubMed search (using the search strategy COVID-19 [tiab]), in the year 2020 alone there were 79,593 publications related to COVID-19. Earlier publications from China and other countries reported a higher frequency of diabetes patients in the hospital setting. Earlier studies reported a two- to three-fold increased risk for severe disease and mortality in patients with diabetes compared to non-diabetic patients. This higher mortality among patients with diabetes was confirmed across different geographic locations, cross-sectional studies, as well as cohort or nationwide studies. Moreover, diabetes was associated with a higher risk for hospitalization, longer hospital stays, and ICU admissions. The majority of earlier studies reported an association between diabetes and COVID-19 morbidity and mortality without specifying diabetes type. A large population-based study from the United Kingdom, mortality in patients with type 1 diabetes was three-fold higher (OR 3.51; 95% CI 3.16-3.90) and in patients with type 2 diabetes was two-fold higher (OR 2.03; 95% CI 1.97-2.09) compared to the general population. This suggested a higher mortality among patients with type 1 diabetes compared to type 2 diabetes. However, another population-based study from Sweden reported a two-fold increased but similar mortality between patients with type 1 diabetes and type 2 diabetes. Similarly, studies from the United States reported similar outcomes in patients with type 1 and type 2 diabetes. The published studies suggest mortality and morbidity is higher among patients with diabetes compared to patients without diabetes. However, there are many limitations and confounders of which we should be cognizant. Timing and virus strain may have confounded the results of many studies. For example, during the first wave of COVID-19 in many countries, health care systems were unprepared to deal with the huge surge of this new viral infection leading to rationalization of health care. In addition, there were no drugs or vaccines available during the first wave leading to higher mortality in older adults with multiple comorbidities such as diabetes. Moreover, different strains of the virus overtime had varied infection severity. For example, the alpha and delta strains of the virus led to more severe infections and increased mortality compared to a wild virus and the newer omicron variant. Higher mortality in people with diabetes was attributed to old age (>70 years) and the presence of other comorbidities such as hypertension and cardiovascular diseases. In summary, the present evidence indicates higher mortality and morbidities in patients with type 1 diabetes and type 2 diabetes. There is no data on morbidity and mortality of COVID-19 in patients with other types of diabetes such as monogenic diabetes. Higher mortality may be attributed to advanced age and presence of comorbidities. The COVID-19 disease is evolving and future studies will provide a greater understanding on the pathophysiology of COVID-19 in patients with diabetes and drugs to prevent disease severity in this patient population.

IS009 / #962

PARALLEL SESSION - COVID-19 AND DIABETES

THE DANGER OF HYPERGLYCEMIA DURING COVID-19

A. Ceriello

IRCCS MultiMedica, Diabetes Research, Milan, Italy

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an RNA beta-coronavirus responsible for the coronavirus disease 2019 (COVID-19). COVID-19 encompasses a large range of disease severity, from mild symptoms to severe forms with Intensive Care Unit admission and eventually death. The severe forms of COVID-19 are usually observed in high-risk patients, as those with type two diabetes mellitus. Acute hyperglycemia at hospital admission represents a risk factor for poor COVID-19 prognosis in patients with and without diabetes. Acute and chronic glycemic control are both emerging as major determinants of vaccination efficacy, disease severity, and mortality rate in COVID-19 patients. Mechanistically, it has been proposed that hyperglycemia might be a disease-modifier for COVID-19 through multiple mechanisms: 1- induction of glycation and oligomerization of ACE2, the main receptor of SARS-CoV-2; 2- increased expression of the serine protease TMPRSS2, responsible for S protein priming; 3- impairment of the function of innate and adaptive immunity despite the induction of higher pro-inflammatory responses, both local and systemic. Consistently, managing acute hyperglycemia through insulin infusion has been suggested to improve clinical outcomes while implementing chronic glycemic control positively affects the immune response following vaccination. Here, we review the available evidence linking acute and chronic hyperglycemia to COVID-19 outcomes, describing also the putative mediators of such interactions and proposing glycemic control as a potential route to optimize disease prevention and management.

IS010 / #845

PARALLEL SESSION - COVID-19 AND DIABETES

WORLDWIDE EFFECTS OF COVID-19 PANDEMIC ON CHILDREN WITH DIABETES: RESULTS FROM THE SWEET REGISTRY

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Background: SWEET (Better control in Pediatric and Adolescent diabeteS: Working to crEate CEnTers of Reference), a large international multicentred pediatric diabetes registry for children with diabetes, was launched in 2008. Presently it contains data from 90,000 participants and 1 Million visits from 120

centers on all continents As the COVID-19 pandemic has been global, registries collecting data from around the world are particularly well suited for analyzing the impact and outcomes in children with established diabetes and on the cases of new-onset of type 1 diabetes (T1D).

Methods: Aggregated data per person with T1D ≤ 18 years of age were analysed in 2018 – first half of 2021. Hierarchic linear and logistic regression models were applied. Models were adjusted for gender, age- and diabetes duration-groups**.**

Results: Across all country quartiles of COVID-19 mortality in the background poulation, HbA1c and rate of severe hypoglycaemia remained comparable to the year prior to the first wave, while DKA rates increased significantly in the centres from countries with the highest mortality rate but returned to baseline after the first wave. CGM use decreased slightly during the first wave (53 vs. 51%) and increased significantly thereafter (55 vs. 63%, $p < 0.001$). The total number of new onset T1D cases in 88 centers worldwide increased from 3242 (2018), 3967 (2019) to 4302 in 2020. The average number of new-onset T1D per center increased from 11.5 [95%-confidence interval: 10.3-12.8] in 2018 to 16.8 [15.6-18.1] in 2020 in the youngest age group <6, from 13.6 [12.9-14.3] in 2018 to 21.5 [20.8-22.2] in 2020 in children 6 to <12 year and from 12.0 [11.4-12.6] to 19.3 [18.7-19.9] in adolescents 12 to 18 years (all $p < 0.001$) These increases remained within the expected increase with the 95%-confidence interval of the regression line and tended to continue during the first half of 2021. However, in Europe and North America following the lockdown early in 2020, the typical seasonality of more cases during cold season was delayed with a peak during the summer and autumn months.

Conclusions: This real-world data analysis of the worldwide impact of the COVID-19 pandemic on pediatric T1D indicates that children cared for in large pediatric diabetes centres maintained glycemic control during the challenges of the first wave of the COVID pandemic. Possibly the widespread use of diabetes technology contributed to this. The major concern relates to the observed rise in DKA in those countries with the highest COVID-19 mortality. In contrast to other findings the slope of the rise in pediatric new-onset T1D in SWEET centers remained unchanged during the COVID pandemic in all age groups. However, the lockdown caused a change in the seasonality at onset possibly related to lockdown measures.

Trial Registration: NCT04427189

IS011 / #856

PARALLEL SESSION - CLOSED-LOOP USERS' EXPERIENCE

CLOSED-LOOP IN VERY YOUNG CHILDREN

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It is well recognised that hybrid closed-loop insulin delivery improves glycaemic control and quality of life in older children and adolescents with type 1 diabetes, but data in very young children is limited. As a result, the majority of commercially available closed-loop systems are not licensed for use in this age-group. While challenging to manage at any age, maintaining recommended glycaemic control is particularly difficult in very young children, due to their high variability of insulin requirements and unpredictable eating and activity patterns. In this talk we discuss the specific challenges of diabetes management in very young children and how hybrid closed-loop therapy might address these. We review most recent published evidence in this age-group, including results of the longest randomised closed-loop study in very young children to date, which showed significant improvements in glycaemic control with closed-loop therapy. Finally, we identify areas for future research with regards to closed-loop technology tailored for very young children and how these might alleviate disease burden.

IS012 / #855

PARALLEL SESSION - CLOSED-LOOP USERS' EXPERIENCE

PARENTS' EXPERIENCES OF, AND VIEWS ABOUT, USING A HYBRID CLOSED-LOOP SYSTEM TO CARE FOR A VERY YOUNG CHILD WITH TYPE 1 DIABETES: QUALITATIVE STUDY

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Objectives: We explored parents' experiences of using a hybrid closed-loop system (CamAPS FX) when caring for a very young child (aged 1-7 years) with type 1 diabetes to better understand how this technology can affect their own, their child's and wider family life. Methods: We interviewed n = 33 parents of 30 children who used the closed-loop system during a randomised controlled trial (KidsAP02 study). Data were analysed using a descriptive thematic approach. Findings: As well as highlighting clinical benefits to using the closed-loop system, parents reported wide-ranging quality-of-life benefits. Parents described sleeping better and worrying less about their child due to the system's ability to help keep glucose in range and their own ability to remote monitor insulin and glucose data. Parents also described being better placed to get on with their own lives (e.g., returning to employment) as caregiving demands were lessened, other people felt more confident caring for their child, and parents felt more confident entrusting their child's care to others. They also noted how their child had more opportunities to socialise with peers and experienced improved concentration and mood due to better glucose control, improved sleep and not being distracted by diabetes management tasks. Siblings also benefited from parental time and effort no longer being so focused on

diabetes management. Discussion: Our findings suggest that, alongside clincal benefits, using a closed-loop system can have life changing consequences for parents, young children with type 1 diabetes and their siblings.

IS013 / #858

PARALLEL SESSION - CLOSED-LOOP USERS' EXPERIENCE

TEAMWORK, TARGETS, TECHNOLOGY, AND TIGHT CONTROL (4T PROGRAM): PERSONALIZED MEDICINE AT POPULATION SCALE, TECHNICAL, FINANCIAL, AND ADVOCACY CHALLENGES

D. Maahs

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Translation of optimal diabetes outcomes from the Diabetes Control and Complications Trial and diabetes technology research to routine clinical care has been suboptimal. The Stanford Pediatric Diabetes Team designed, implemented, and iterated on a pragmatic research study: 'Teamwork, Targets, Technology, and Tight Control (4T Program)' with the goal of improving care after diagnosis of type 1 diabetes in pediatric patients. We hypothesized that early introduction of CGM and systematic education combined with reducing the friction of CGM analysis to allow for more timely education interventions and dose adjustments would result in improved glucose metrics and quality of life. Pilot study data will be reviewed as well as approaches to technical and financial challenges to scaling the 4T program to a larger patient population in our clinic and to share the 4T program with other diabetes centers. Future directions include systematically implementing automated insulin delivery, scaling the 4T project to a wider population within our clinic and in collaboration with external colleagues, incorporating an exercise education sub-study, and advocating for better insurance coverage for diabetes care for all. We would like to thank the other members of the 4T Study Group for their help with this project. Study team members include: Brianna Leverenz, BS, Julie Hooper MPH, RD, Ana Cortes, BS, Franziska Bishop, MS, CDCES, Natalie Pageler, MD, Jeannine Leverenz, RN, CDCES, Piper Sagan, RN, CDCES, Anjoli Martinez-Singh, RD, CDCES, Barry Conrad RD, CDCES, Annette Chmielewski, RD, CDCES, Julie Senaldi RN, CDCES, Nora Arrizon-Ruiz, Erica Pang, BS, Carolyn Herrera, BS, Victoria Ding, MS, Rebecca Gardner, MS, Kim Clash, NP, Erin Hodgson, RD, CDCES, Johannes Ferstad BS, Ryan Pie, MS, Michael Gao, BS, Annie Chang, BS, Simrat Ghuman, PhD, Priya Prahalad MD, Ananta Addala MD, Dessi Zaharieva PhD, Korey Hood PhD, Manisha Desai PhD, Ramesh Johari PhD, David Scheinker PhD and Esli Osmanlliu, MD

IS014 / #839

PARALLEL SESSION - BRAIN AND DIABETES

DEVELOPING BRAIN IN CHILDREN: A LONGITUDINAL DIRECNET STUDY

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It has been increasingly appreciated that chronic exposure to hyperglycemia is detrimental to the brain, particularly during the critical periods of growth and development in young children. The Diabetes Research in Children Network conducted a longitudinal study focused on neuroanatomical and cognitive consequences of type 1 diabetes (T1D). Over six years of study, we conducted unsedated MRI, cognitive testing batteries, and continuous glucose monitoring assessments in 144 children with diabetes and 72 age-matched controls, beginning at the age of 4-9; compared anatomical and cognitive outcomes between groups; and within the T1D group, correlations with measures of glycemia. Total brain, gray and white matter volumes, and full-scale and verbal intelligence quotients were lower in the T1D group at all assessment points, and rates of growth of cortical and subcortical gray and white matter were consistently slower in T1D children over this time period spanning childhood and early puberty. Within the T1D group, brain volumes and cognitive scores were negatively correlated with higher CGM-measured glucose levels and a calculated lifetime A1c index. Resting-state fMRI demonstrated increased functional connectivity in executive function control areas in the T1D group, suggesting a mechanism to compensate for the adverse effects of dysglycemia to maintain cognitive and behavioral performance. The need for improved control of hyperglycemia during the developmental window of childhood and puberty is clear. A recently completed six-month pilot study utilizing automated delivery systems in adolescents with T1D may help to determine the potential impact of improved short-term glycemic control on these critical anatomic and cognitive outcomes.

IS016 / #851

PARALLEL SESSION - SPORTS AND DIABETES

EXERCISE AND TYPE 1 DIABETES: PRELIMINARY RESULTS FROM THE TYPE 1 DIABETES EXERCISE INITIATIVE (T1DEXI)

M. Riddell

York University, School Of Kinesiology And Health Science, Toronto, Canada

Regular exercise has numerous health and fitness benefits for people living with type 1 diabetes, however the acute management of glycemia during and after a bout of exercise remains a major clinical challenge. The Type 1 Diabetes Exercise Initiative (T1Dexi) is a real-world study designed to create a shareable dataset that will help researchers better understand modifiable and non-modifiable factors that may influence the glycemic responses to different types of exercise in those living with type 1 diabetes. This session will highlight results of a one-month observational study of exercise-related glycemia from 497 adults in the US living with type 1 diabetes (n = 183 on standard pump therapy; n = 226 on hybrid closed loop; n = 88 on multiple daily injections). Participants self-reported physical activity events, including randomized assignment to study-designed aerobic, resistance or interval type exercise, and food intake using a custom smart phone application. Data collection also included insulin delivery and activity monitors (Polar heart rate chest strap, Verily Health Watch) to contextualize each activity event and relate to exercise-associated changes in glycemia as assessed by continuous glucose monitoring (Dexcom G6).

IS017 / #852

PARALLEL SESSION - SPORTS AND DIABETES

SEPARATING INSULIN-MEDIATED AND NON-INSULIN-MEDIATED GLUCOSE DISPOSAL DURING AND AFTER DIFFERENT FORMS OF EXERCISE IN DIABETES. PHYSIOLOGICAL EFFECTS THAT MAY IMPACT AUTOMATED INSULIN DELIVERY

J. El Youssef[1], A. Nguyen[2], J. Castle[3], L. Wilson[1], G. Young[4], R. Dodier[5], R. Narayan[4], D. Branigan[6], V. Gabo[6], J. Eom[6], P. Jacobs[4]

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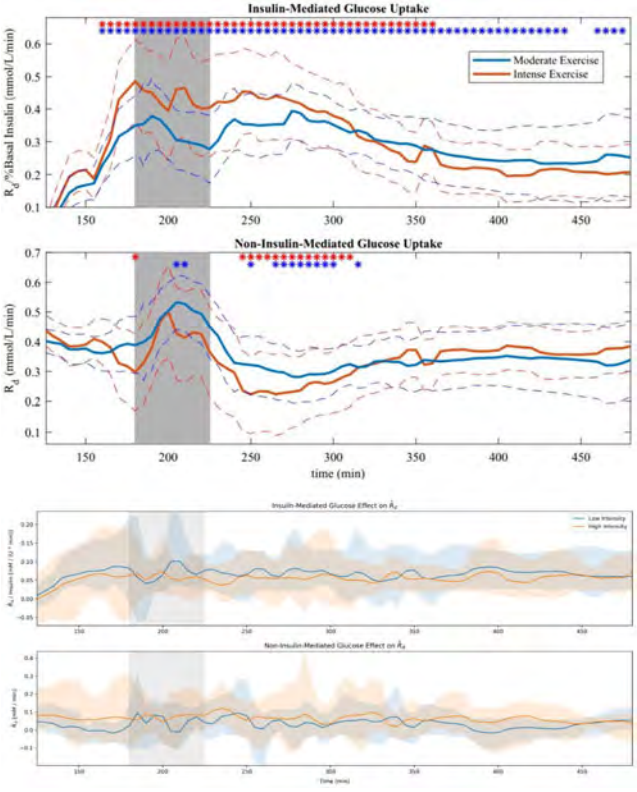
Background: Exercise in type 1 diabetes (T1D) remains challenging. Intensity and duration impact glucose levels but this varies with exercise type. Separating increased glucose uptake due to muscle action from increased insulin effectiveness allows us to model glucose changes and better adjust insulin delivery.

Methods: Participants with T1D performed aerobic (n = 26) and resistance exercise (n = 25) during two clamp studies to obtain rate of appearance (Ra) and disappearance (Rd) of glucose. Participants were divided into 2 cohorts, moderate and intense exercise, and engaged in three experiments at different, constant insulin infusion rates (basal, 1.5* basal, and 3*basal). A model of glucose dynamics estimated Ra and Rd, and linear regression across the three experiments per participant obtained insulin-mediated effect. Non-insulin mediated effect was the intercept. We determined area under the curve for endogenous glucose production (AUC_{EGP}) and Rd (AUC_{Rd}) over 45 min of exercise.

Results: During aerobic exercise, AUC_{Rd} increased 12.45 mmol/L and 13.13 mmol/L ($P < 0.001$) whereas AUC_{EGP} increased 1.66 mmol/L and 3.46 mmol/L ($P < 0.001$) above baseline during moderate and intense exercise, respectively. AUC_{EGP} increased during intense exercise by 2.14 mmol/L ($P < 0.001$) compared with moderate exercise. Insulin-mediated glucose uptake rose during exercise and persisted hours afterward, whereas non-insulin-mediated effect was limited to the exercise period (figure 1). Preliminary data from resistance exercise is shown in Figure 2.

Conclusions: Separating insulin and non-insulin glucose uptake during exercise in T1D has not been done before. This method allows visualization of these changes for the first time.



IS018 / #853

PARALLEL SESSION - SPORTS AND DIABETES

INTEGRATING METABOLIC EXPENDITURE DATA FROM WEARABLE SENSORS INTO AN AUTOMATED INSULIN DELIVERY SYSTEM: CLINICAL STUDY RESULTS

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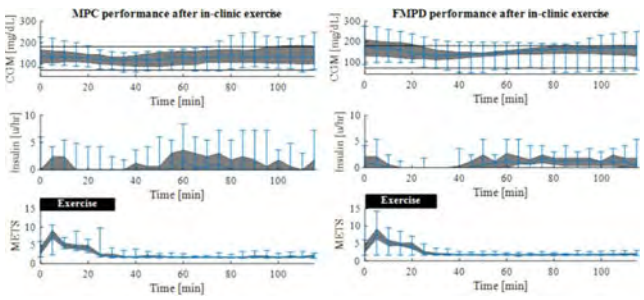
Background: The objective was to evaluate an automated insulin delivery (AID) system that responds automatically to physical activity.

Methods: We evaluated an exercise-aware model predictive control (ExMPC) AID using iPancreas developed at OHSU, which includes a Dexcom G6 CGM, an Insulet Omnipod, a control algorithm running on a Samsung S9 smart-phone, and a Polar M600 smart watch. Another exercise-aware algorithm, fading-memory-proportional-derivative (FMPD) was also evaluated. Heart rate and accelerometer data from the smart-watch were combined to calculate metabolic equivalent of task (MET). METs were continuously used in ExMPC to adjust insulin delivery. FMPD notified when METS exceeded a threshold of 4 METs and then shut off



insulin for 30 minutes, then reduced insulin by 50% for 1-hour. We compared ExMPC with FMPD in a 2-arm, randomized 3-day outpatient study that included an in-clinic 30-minute aerobic exercise video on day 1. Wilcoxon rank-sum test determined difference in % time-in-range (TIR: 70-180 mg/dL), % time-low (TL: <70 mg/dL), and % time very low (TVL: <54 mg/dL) between algorithms during in clinic exercise and across the entire study.

Results: From start of in-clinic exercise to 2-hours post-exercise, ExMPC (n = 18) had higher TIR than FMPD (n = 20), (87.5% vs. 76.3%, P = .046) and trended towards less TVL (0.0% vs. 1.5%, P = .09). Across the entire study, TIR (74.5% vs. 75.7%) and TL (1.0% vs. 1.4%) were comparable between algorithms.

Conclusions: An exercise-aware MPC AID can safely control glucose levels during exercise and under free-living conditions without the need for notifications and confirmations from a user.

IS019 / #854

PARALLEL SESSION - SPORTS AND DIABETES

GLUCOSE CONTROL DURING EXERCISE USING AUTOMATED INSULIN DELIVERY IN TYPE 1 DIABETES

K. Dovc[1,2]

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While the benefits of regular physical activity are well established for individuals with type 1 diabetes, glucose control remains a challenge with conventional therapeutic tools, especially during and after physical activity. Factors affecting glycemic control include activity type (aerobic, anaerobic or mixed), intensity and duration of the activity, level of hydration, the secretion of counter-regulatory hormones as well as the amount of insulin and nutrients in the body, when the physical activity is performed. Glucose-responsive automated insulin (and glucagon) delivery is now a routine clinical reality for many individuals living with type 1 diabetes. There are several automated insulin delivery systems are already available, at the same time there are several other devices extensively evaluated at home, mainly unsupervised, and for longer periods. The performance of automated insulin delivery devices has been challanged with different types of physical activity, using different exercise settings and duration, adding additional signals to detect physical activity, such as activity and heart rate monitoring, and including individuals with type 1 diabetes of different ages. In this presentation, we will present current data on automated insulin delivery in type 1 diabetes challenged by physical activity.

IS020 / #942

PARALLEL SESSION - JDRF SESSION - UTILITY OF PROS IN THERAPY DEVELOPMENT FOR TYPE 1 DIABETES: PUTTING THE END-USER UPFRONT

PRO WORK ON THE INTANDEM STUDIES AND PROPOSE A FORWARD-LOOKING STRATEGY ON PROS FOR DKD

C. Granowitz

Lexicon Pharmaceuticals, Inc., Chief Medical Officer, The Woodlands, United States of America

PATIENT-REPORTED OUTCOMES IN THE inTANDEM STUDIES AND PROPOSAL FOR A FORWARD-LOOKING STRATEGY ON PATIENT-REPORTED OUTCOMES FOR DIABETIC KIDNEY DISEASE IN TYPE 1 DIABETES Presenter: Craig Granowitz Affiliation: Lexicon Pharmaceuticals, Inc., The Woodlands, Texas, USA

Background and aims: Patient-reported outcomes (PROs) provide insight into disease burden. In type 1 diabetes (T1D), treatment satisfaction and diabetes distress are associated with glycemic control. In the inTandem 1 and 2 trials, sotagliflozin, a dual inhibitor of SGLT 1 and 2, was associated with improved glucose control and renal-related measures, reduced hypoglycemia, and increased DKA when added to insulin in patients with T1D. PROs were assessed with sotagliflozin in these trials.

Methods: Diabetes Treatment Satisfaction Questionnaire status (DTSQs) and the 2-item Diabetes Distress Scale (DDS2) were evaluated at baseline and 24 weeks in the inTandem trials. PRO results were pooled for both studies and various analyses were performed including changes in the overall scores and in the individual PRO components.

Results: Sotagliflozin 200 and 400 mg significantly improved DTSQ and DDS2 scores overall and for each component compared to placebo. Among patients at high risk of diabetes distress (DDS2 score ≥6) at baseline, significantly more patients receiving sotagliflozin compared to placebo shifted from high to low risk. In blinded exit interviews, improved glycemic stability (ie, lower HbA1c and less hypoglycemia) was frequently cited by more patients on sotagliflozin, which was consistent with the improvements observed in the DTSQs and DDS2.

Conclusions: The inTandem trials showed that improved glycemic control with sotagliflozin reduced disease burden in T1D. Given the renal complications associated with T1D and the beneficial effects of sotagliflozin on renal-related outcomes, it would be of interest to understand if sotagliflozin impacts PROs applied to kidney disease.

IS021 / #944

PARALLEL SESSION - JDRF SESSION - UTILITY OF PROS IN THERAPY DEVELOPMENT FOR TYPE 1 DIABETES: PUTTING THE END-USER UPFRONT

PATIENT-REPORTED OUTCOMES ASSOCIATED WITH CELL THERAPY IN T1D

M. Jaiman

ViaCyte, Head Of Clinical Development, San Diego, United States of America

Some patients living with type 1 diabetes (T1D) are participating in clinical trials of cell therapy. As these trials advance, Physician Investigators and clinical trial Sponsors are learning more about outcomes desired and experienced by patients. Three themes that emerge in this setting are fear of hypoglycemia, a reduction of the burden of daily management of T1D, and a desire for better glycemic control in order to reduce the risk for micro- and macro-vascular complications. Hypoglycemia has a major impact on patients and their behavior,[1] and a history and fear of severe hypoglycemia may be a prominent concern driving interest in cell therapy; these issues are even more pronounced for parents and their offspring. For others, cell therapy may be attractive because it does not require daily monitoring. HbA1C control is recognized as important by patients, yet its

improvement has to be tempered by reducing hypoglycemia risk and improving glucose time in range, in the context of simplifying the burden of T1D management. Recent experience suggests that patients with T1D and hypoglycemia unawareness in particular have a strong interest in cell therapy. The interest exists despite the availability of continuous glucose monitoring and advancements in diabetes technological tools. Patients suggest that cell therapy can be successful in several dimensions other than A1C control, and it can be attractive without offering complete insulin independence. Patient personal experiences may not always be related to changes in traditional clinical indicators[2] including A1C. Questionnaires used in clinical trials help capture real-time feedback from patients with T1D and can help illuminate both benefits and burdens associated with these interventions. Given the diversity of perspectives and the lack of PRO questionnaires specific to diabetes cell therapy, additional research should include qualitative interviews of patients receiving cell therapy and validation of these instruments. Interviews in the clinical trial setting may be a good supplement for capturing clinically meaningful patient-reported outcomes.
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IS022 / #900

PARALLEL SESSION - SOCIOECONOMIC BARRIERS & DISPARITIES TO DIABETES TECHNOLOGY

EXPERIENCE IN THE UNITED STATES

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Stanford University, Pediatric Endocrinology & Diabetes, Stanford, United States of America

Diabetes technology has improved quality of life, increased time-in-range, and decreased hypoglycemia over the past decade. Healthcare in the US is inequitable, including care for people with diabetes. Recent data on disparities in diabetes technology use and outcomes will be reviewed. Local and national efforts to improve access to diabetes technology and to improve outcomes with the goal or reducing socioeconomic disparities will be described.
We would like to thank the other members of the 4T Study Group for their help with this project. Study team members include: Brianna Leverenz, BS, Julie Hooper MPH, RD, Ana Cortes, BS, Franziska Bishop, MS, CDCES, Natalie Pageler, MD, Jeannine Leverenz, RN, CDCES, Piper Sagan, RN, CDCES, Anjoli Martinez-Singh, RD, CDCES, Barry Conrad RD, CDCES, Annette Chmielewski, RD, CDCES, Julie Senaldi RN, CDCES, Nora Arrizon-Ruiz, Erica Pang, BS, Carolyn Herrera, BS, Victoria Ding, MS, Rebecca Gardner, MS, Kim Clash, NP, Erin Hodgson, RD, CDCES, Johannes Ferstad BS, Ryan Pie, MS, Michael Gao, BS, Annie Chang, BS, Simrat Ghuman, PhD, Priya Prahalad MD, Ananta Addala MD, Dessi Zaharieva PhD, Korey Hood PhD, Manisha Desai PhD, Ramesh Johari PhD, David Scheinker PhD and Esli Osmanlliu, MD

IS023 / #902

PARALLEL SESSION - SOCIOECONOMIC BARRIERS & DISPARITIES TO DIABETES TECHNOLOGY

EXPERIENCE IN GERMANY

M. Auzanneau[1,2]

[1]German Center for Diabetes Research, Dzd, Neuherberg, Germany, [2]University of Ulm, Institute Of Epidemiology And Medical Biometry, Zibmt, Ulm, Germany

Efficacy and safety of diabetes technology improve continuously. As a consequence, established technologies, like insulin pumps and continuous glucose monitoring systems (CGM), now benefit from improved reimbursement that facilitates their wider use in high-income countries. Nevertheless, ethnic and socioeconomic disparities continue to be reported. Based on the DPV registry, the use of CGM in patients aged under 26 years increased from 5% in 2009 to 76% in 2021 and the use of insulin pump increased from 32% to 58% in the same period in Germany. Despite increasing use, disparities based on patient's characteristics persist. In 2021, the use of insulin pumps was still significantly higher in girls than in boys (61% in girls vs. 55% in boys, $P < 0.001$), whereas the gender difference for the use of CGM remained negligible (77% in girls vs. 76% in boys, $P = 0.02$). The gender difference in pump use has been observed above age 10 years and increased with age. Poorer metabolic control, variable insulin requirement during the menstrual cycle, and possibility of pregnancy, are factors that contribute to the higher use of insulin pump in female adolescents and young adults compared to males of the same age. Regional disparities in the use of diabetes technology also persist in Germany. Whereas the use of insulin pumps was still associated with area deprivation until 2019, the association with CGM use disappeared in the last years. Nevertheless, in 2021, both technologies were still more frequently used in the former Western Germany, compared to the Eastern part of the country (Pump: 55 vs. 52%, CGM: 76 vs. 71%, both $p < 0.001$). Independent of area deprivation, the effect of migration background on CGM use decreased over the last years in Germany. However, patients without migration background still use both insulin pump and CGM more frequently. In 2019, 58% of the patients up to age 26 years without migration background used an insulin pump compared to 52% of the second-generation migrants (at least one parent born outside Germany) and 38% of the first-generation migrants (patient himself born outside Germany). Similarly, 77% of the patients without migration background used a CGM, compared to 68 and 60% for the second and first-generation migrants, respectively. Besides complex discriminatory reasons which cannot be excluded, language and cultural barriers may limit the access to diabetes technology. To conclude, our findings raise the concern that inequitable access to diabetes technology in Germany continues to systematically disadvantage some patients, on the basis of their gender, migration history or socioeconomic situation.

IS024 / #904

PARALLEL SESSION - SOCIOECONOMIC BARRIERS & DISPARITIES TO DIABETES TECHNOLOGY

EXPERIENCE IN INDIA

V. Mohan

Madras Diabetes Research Foundation & Dr. Mohan's Diabetes Specialities Centre, Diabetology, Chennai, India

SOCIOECONOMIC BARRIERS & DISPARITIES IN DIABETES TECHNOLOGY : EXPERIENCE IN INDIA DR.V. MOHAN, M.D., FRCP (London, Edinburgh, Glasgow & Ireland), Ph.D., D.Sc. D.Sc (Hon. Causa), FNASc, FASc, FNA, FACE, FACP, FTWAS, MACP, FRSE **Chairman & Chief of Diabetology,** Dr. Mohan's Diabetes Specialities Centre & Madras Diabetes Research Foundation, Chennai, India Email : drmohans@diabetes.ind.in, Websites : www.mdrf.in & www.drmohans.com The number of people with diabetes globally, is rising at an alarming rate. South Asia is one of the hot spots of the diabetes epidemic. In India alone, there are over 74 million people with diabetes today. Unfortunately, 70% of the doctors in India practice in urban areas while 70% of India's population lives in rural areas. This mismatch between the availability of health care professionals and the rapid spread of diabetes in rural areas, provides an opportunity to use technology to deliver the diabetes care to remote rural areas. The first part of this presentation will talk about a model of successful delivery of diabetes health care in rural India. The Chunampet Rural Diabetes Program was carried out in a group of 42 villages in Kancheepuram District in Tamilnadu. Using a Mobile van, a population of 27,014 individuals (86.5% of the adult population) were screened for diabetes. All those detected with diabetes were offered a follow up care at a rural diabetes centre which was set up during the project. The results were very impressive and led to good improvement in A1c levels using low cost generic drugs. The second use of technology was during the COVID – 19 pandemic and the lock down which was enforced in India. Thankfully, Telemedicine was also legalized in India at that time. Using technology, a system was created whereby the doctor and the patient stayed at home but blood tests were arranged at home for the patient. With the results, teleconsultation was done by doctors using the Electronic Medical Records which were made available on their mobile phones. Thus, despite the lockdown, patients managed to get their tests and diabetes consultations done remotely. The third use of technology which will be presented is through our network of diabetes clinics across India. Even at centres where there was no ophthalmologist, retinal photographs were obtained using a low-cost retinal camera and were uploaded for centralized diabetic retinopathy grading unit where the images were read by trained retina specialists. The eye reports were sent back to the peripheral clinics in real time. Over one year period, 25,316 individuals with diabetes could have their eyes screened for diabetic retinopathy. Only 11.4 % needed referral to an ophthalmologist for further management. In conclusion, judicious use of technology can help to bridge the socioeconomic and geographical challenges in delivering diabetes health care in developing countries.

IS025 / #859

PARALLEL SESSION - SENSORS IN HOSPITALS

ACCURACY OF GLUCOSE SENSORS IN PATIENTS WITH ACUTE OR CHRONIC COMORBIDITIES

G. Freckmann

Institut für Diabetes-Technologie, Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Scientific Operations, Ulm, Germany

Continuous glucose monitors (CGMs) have become part of routine diabetes care in the last years. The use of CGM for the management of diabetes in special patient groups with co-morbidities, in hospitals and nursing homes is of great interest and gets additionally stimulated by coronavirus disease that necessitates remote monitoring. However, these patient groups or settings are usually not represented in large studies on reliability and accuracy of CGM devices. Different physiological processes and possibly interfering medication might impair CGM performance. In the last years a couple of small studies that evaluated the accuracy of CGM in different patient groups and settings, like patients undergoing dialysis or ICU patients, were published. The presentation will provide a brief overview about studies and study results and will discuss the consequences of these results for CGM use in such patient groups.

IS026 / #861

PARALLEL SESSION - SENSORS IN HOSPITALS

CLOSED-LOOP INSULIN THERAPY IN HOSPITALS

C. Boughton

University of Cambridge, Wellcome Trust-mrc Institute Of Metabolic Science, Cambridge, United Kingdom

Fully automated closed-loop insulin delivery in the inpatient setting has been shown to be safe and effective. The use of inpatient closed-loop therapy is associated with significantly improved glycaemic control compared to standard insulin therapy without increasing the risk of hypoglycaemia, including in those requiring nutrition support (enteral and parenteral nutrition) or haemodialysis during their admission. Closed-loop systems may provide an important opportunity to address the challenges associated with inpatient diabetes management. In this talk we review the available evidence from randomised clinical trials, and report on our experience of implementation of inpatient closed-loop technology in a real-world setting. We will discuss key considerations for healthcare providers to adopt inpatient closed-loop technology.

IS027 / #863

PARALLEL SESSION - METHODS AND REGULATORY ISSUES IN DIABETES

IS POC HBA1C ADEQUATE?

D. Sacks

NIH, Dlm, Bethesda, United States of America

Hemoglobin A1c (HbA1c) is used very widely both to monitor patients with diabetes mellitus and to diagnose diabetes. An International Expert Committee recommended that HbA1c ≥6.5% rather than fasting glucose be used to diagnose diabetes (Diabetes Care 2009; 32:1327). Since 2010 when HbA1c was advocated by the American Diabetes Association (ADA) for both

screening and diagnosis of diabetes (and endorsed in 2011 by the World Health Organization), there has been a dramatic increase in the use of HbA1c for diagnosis. Initially HbA1c was measured only in central laboratories, but subsequently smaller point-of-care testing (POCT) devices became commercially available to analyze HbA1c in doctors' offices and clinics. At present, the ADA cautions that POCT devices for HbA1c should not be used for diagnosis. Although several point-of-care HbA1c assays are NGSP-certified, the test is waived in the USA and proficiency testing is not necessary. Therefore, no objective information is available concerning their performance in the hands of those who measure HbA1c in patient samples. Nevertheless, some advocate for use of POCT HbA1c devices for diagnosis and the topic remains highly contentious. Numerous publications have evaluated performance of HbA1c POCT devices, with many shown to have inadequate analytic performance (eg, Clin Chem 2010; 56:44; Clin Chem 2014; 60:1062). The use of HbA1c POCT in diabetes diagnosis has also been addressed in both the clinical and laboratory published literature (eg, Clin Chem 2013; 59:1790; Prim Care Diabetes. 2017;11:248; Ann Fam Med. 2017;15:162; JAMA 2019; 322:1404). This talk will provide a current perspective on these issues.

IS028 / #862

PARALLEL SESSION - METHODS AND REGULATORY ISSUES IN DIABETES

THE IMPACT ON POLICY OF THE CHANGING SCIENCE IN T1D

P. Kar

NHS England, Diabetes, Portsmouth, United Kingdom

The introduction of the clinical use of HbA1c in the early 1980s was a revolutionary step for the modern management and eventually the diagnosis of diabetes. The use of this objective and relatively inexpensive biomarker allowed both researchers and clinicians to track diabetes control. In fact, the Diabetes Control and Complications Trial (DCCT) would not have been possible if not for the use of HbA1c. The test now is standard of care for all types of diabetes for assessment of glycemic control. While limitations of HbA1c (anemias, hemoglobinopathies, etc.) have been understood for 40 years, it has been more recently that the real limitations of HbA1c have been reported due to the use of continuous glucose monitoring (CGM). This was first observed in a population with no anemia, renal disease, or liver disease in 2008- an individual with a HbA1c of 9% could have the same mean glucose as someone with a HbA1c of 7%. For a population, the test is robust, but for any given individual, there may be major discordance between mean glucose and HbA1c. While more factors have been found to impact HbA1c since the 1980s, we have also learned that race/ethnicity may impact this biomarker. For example, on average we now know that in African Americans, HbA1c runs 0.4% *higher* than in Caucasian Americans. The introduction of glucose management indicator (GMI) has resulted in many clinicians wondering if we need to measure HbA1c moving forward. While using GMI during the pandemic when it was not possible for patients to get blood work was helpful, HbA1c will remain as part of our standard of care. First, the majority of people with diabetes do not use CGM, so GMI is not possible. Still, in an ideal world it would be good to know if there is discordance between mean glucose and HbA1c tested with a one-time professional HbA1c for at least 14 days. Secondly, many clinicians and patients feel HbA1c is an important piece of information they want for routine clinic visits. It should also be noted that regulatory agencies are still dependent on HbA1c as an objective measure to confirm the efficacy of a pharmaceutical therapy. Still, it is also true HbA1c does not provide the granularity of someone's diabetes control, particularly as it pertains to hypoglycemia. After four decades of the use of HbA1c, it is not realistic that it will go away and more importantly, it will continue to have a role in the immediate future. Given the cost of CGM, it likely will continue to be used in the long-term future too.

IS029 / #951

PARALLEL SESSION - RCT EVIDENCE ON TIME-IN-RANGE IN TYPE 1 DIABETES

RCT EVIDENCE ON TIME-IN-RANGE IN TYPE 1 DIABETES

T. Battelino[1], T. Danne[2], S. Edelman[3], P. Choudhary[4], E. Renard[5], J. Westerbacka[6], B. Mukherjee[6], P. Picard[7], V. Pilorget[8], R. Bergenstal[9]

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Background: Suboptimal glycaemic control among people with type 1 diabetes (T1D) is known to lead to long-term micro- and macrovascular complications and, unfortunately, it is still prevalent even in the most affluent societies. Although glycated haemoglobin monitoring is considered to be the gold standard for assessing glycaemic control, such monitoring is unable to reliably measure acute glycaemic excursions. Continuous glucose monitoring (CGM) has been shown to improve glucose control and reduce the incidence of hypoglycaemia, and also allow a more complete assessment of overall glycaemic control and hyper- and hypoglycaemic excursions. The use of CGM has led to time-in-range, which is the time that a patient is within the glycaemic range of 70 to 180 mg/dL, to be adopted as a treatment target. To date, only limited data comparing the second-generation insulins glargine 300 U/mL (Gla-300) and degludec 100 U/mL (IDeg-100) in people with T1D are available, and there is no CGM literature on comparisons of the use of CGM results to assess primary, secondary and tertiary endpoints. The aim of the InRange study was to address this unmet need.

Methods: InRange is a multicentre, randomised, active-controlled, parallel-group, 12-week, open-label, phase 4, comparative study. Adults with T1D will be randomised to receive once-daily Gla-300 or IDeg-100 by subcutaneous injection in the morning. Following an 8-week titration period, CGM data will be collected over 20 consecutive days.

Planned outcomes: The primary objective is to demonstrate that Gla-300 is noninferior to IDeg-100 in terms of glycaemic control [time-in-range ≥70 to ≤180 mg/dL (≥ 3.9 to ≤10 mmol/L)] and variability, as assessed using CGM, in adults with T1D. The results are expected to help confirm the utility of

CGM in clinical practice in this population and provide insight into its application as an outcome measure in clinical practice.

Trial registration: NCT04075513<http://clinicaltrials.gov/show/NCT04075513

Reference: https://doi.org/10.1007/s13300-020-00781-6

IS030 / #868

PARALLEL SESSION - CONNECTED PENS: NEEDS, EXPECTATIONS, VARIETIES AND EXPERIENCE OF USE

CONNECTED PENS: NEEDS AND EXPECTATIONS

E. Wilmot

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Connected insulin pens are the latest technology to be introduced to the diabetes clinic. These pens use Bluetooth or Near Field Communication to transfer insulin dosing data from the pen to an app or online platform, allowing for the review of both glucose an insulin data in the clinic. This lecture will explore the concept of connected pens, unmet needs and expectations of both health care professionals and people living with diabetes. Just a decade ago, paper diaries were central to an effective diabetes consultation. They contained information on insulin doses, glucose levels and carbohydrate intake to enable informed shared decision making. Fast forward 10 years and the diabetes consultation has evolved with paper diaries largely replaced with uploaded or 'in the cloud' glucose data. For those on insulin pumps the ability to have the glucose, insulin and carbohydrate data available to review is an advantage. However, this data is not readily available for those on multiple daily injections. A data gap exists between multiple daily injection and insulin pump therapies. Connected pens bridge this gap by providing insulin data alongside glucose data, essential for optimisation. For those living with diabetes, connected pens may support therapy and behaviour change, for example, providing insight into the impact of mealtime insulin timing on postprandial glucose levels or the ability to identify missed insulin doses. This new technology is promising. Future feedback from both people living with diabetes and the health care professionals supporting them will determine their future role in diabetes services.

IS031 / #869

PARALLEL SESSION - CONNECTED PENS: NEEDS, EXPECTATIONS, VARIETIES AND EXPERIENCE OF USE

THE INDUSTRY APPROACH: SMART PENS: THE NEED, OUTCOMES, AND FUTURE APPLICATIONS

R. Vigersky

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Major milestones in non-automated insulin administration include plastic syringes, pre-filled insulin pens, and smart insulin pens. The InPen™ smart insulin pen enables users to capture both the time and amount of insulin delivered and can provide missed bolus reminders to the person with diabetes. The need for such advance technology was found in observational data of over 1.1 million meals where on-time bolusing occurred in just over half of all boluses and that boluses were missed almost one-third of the time. The time-in-range (70-180 mg/dL) was strongly correlated with the frequency of on-time bolusing ($r = 0.59$, $p < 0.001$). When the InPen™ is used with the accompanying smartphone app to calculate the meal dose or correction dose of insulin, the user can safely determine the dose because insulin-on-board is incorporated in the dose calculation. InPen™ use is associated with almost 2% less time-below-range (TBR) in those who had TBR greater than 8% before initiating its use. In adolescents (13-17) and young adults (18-22) using MDI for management of their diabetes, those using InPen™ (with CGM) had significantly lower GMI's compared to those using traditional insulin pens ($p < 0.001$). Combining the data provided by a smart insulin pen and CGM with sensors that capture the duration/intensity of exercise, sleep and meal gestures may allow MDI users to obtain real-time and/or retrospective decision support for their diabetes management.

IS032 / #870

PARALLEL SESSION - CONNECTED PENS: NEEDS, EXPECTATIONS, VARIETIES AND EXPERIENCE OF USE

THE INDUSTRY APPROACH: VALUE OF BASAL INSULIN CONNECTIVITY IN THE DIABETES MANAGEMENT ECOSYSTEM

A. Bode

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Development of effective technologies supporting patient self-care behaviors, real-time monitoring or optimization of treatment regimen is essential for people living with chronic health conditions, such as diabetes, where suboptimal adherence to medication and lifestyle modification can compromise patient outcomes. When people living with diabetes receive basal insulin, as part of their treatment regimen, it is assumed that basal insulin treatment is adapted and personalized. However, only ~25% of those on basal insulin achieve glycemic control, indicating that a significant gap remains. Since basal insulin is a foundational pilar for management of people with diabetes, we believe it is imperative to address the gaps in treatment regimen optimization and improve adherence to basal insulin using effective technologies. The suggested strategies include the use of digital devices amongst which the connected insulin pen plays a key role. However, at Sanofi we believe that the game-changing determinant for adoption of next-generation pens is user experience. The question we asked ourselves is – what matters most to people with diabetes: Convenience of use? Live data? Device autonomy? Interoperability with digital companions? Fit into existing life and care routines? Or health outcomes? In this context and as part of its commitment to help people with diabetes, Sanofi will present its connected solutions designed with the intention to support basal insulin management in fitting user expectations and guided by strict user safety standards. We believe such solutions could provide greater convenience for people with diabetes and support improved patient-healthcare provider interaction.

IS033 / #875

PARALLEL SESSION - DUAL AGONIST

MECHANISMS OF ACTION OF TIRZEPATIDE IN HUMANS: BETA AND ALPHA CELLS EFFECTS AND INSULIN SENSITIVITY

A. Mari

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Tirzepatide, a novel dual GIP/GLP-1 receptor agonist, has shown in clinical trials consistent efficacy as treatment for type 2 diabetes, with marked improvement of glycemic control, decrease of HbA1c and weight loss. These changes have been shown to be superior to those obtained with long-acting GLP-1 receptor agonists. A recent study has been performed to clarify the mechanisms underlying such a marked improvement in glucose control. The study assessments included a euglycemic hyperinsulinemic clamp to measure insulin sensitivity, a hyperglycemic clamp to assess insulin secretion and beta-cell function, and a meal test to evaluate the treatment effects in physiological conditions and in particular the glucagon response. The 28-week randomized controlled study included both placebo and GLP-1 receptor agonist semaglutide 1mg as comparators. The study has confirmed greater improvement in HbA1c and weight loss with tirzepatide compared to semaglutide. Consistently with the superior improvement in HbA1c, both fasting and mean glucose during the meal test were reduced to a greater extent with tirzepatide. The study of the underlying mechanisms of action has revealed a considerably larger improvement in insulin sensitivity with tirzepatide compared to semaglutide, which was paralleled by similar results obtained from the meal-based insulin sensitivity surrogates. Enhancement of insulin secretion from the hyperglycemic clamp, as both first- and second-phase secretion, was larger with tirzepatide vs. semaglutide. During the meal test, both fasting and mean glucagon concentration decreased more with tirzepatide than with semaglutide. The combined effects on insulin sensitivity and insulin secretion, assessed with disposition index (the product of insulin sensitivity and total insulin secretion normalized to glucose, from the clamps), were largely superior with tirzepatide, which showed an almost double disposition index increase compared to semaglutide. In conclusion, large improvements in insulin sensitivity and insulin secretion and glucagon suppression underlie the strong effects of tirzepatide on glycemic control.

IS034 / #876

PARALLEL SESSION - DUAL AGONIST

TIRZEPATIDE ACTIONS ON ECTOPIC FAT ACCUMULATION: RESULTS OF MRI ADDENDUM OF SURPASS-3

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ABSTRACT

Background and aims: The effect of tirzepatide, a novel dual GIP/GLP-1 receptor agonist, vs insulin degludec (IDeg) on liver fat content (LFC) and visceral and abdominal subcutaneous adipose tissue (VAT and ASAT) was assessed with MRI techniques in a subpopulation of participants in the SURPASS-3 trial.

Primary and Secondary Endpoints[a]	TZP 5 mg (N=71)	TZP 10 mg (N=79)	TZP 15 mg (N=72)	IDeg (N=74)
LFC (%)				
Baseline	14.86 (1.108)	14.78 (1.039)	16.65 (1.092)	16.58 (1.053)
Week 52[b]	10.11 (0.795)*	8.16 (0.792)**	8.59 (0.768)**	13.18 (0.791)
Relative change from baseline at Week 52[b]	-29.78 (5.607)*	-47.11 (5.582)**	-39.59 (5.417)**	-11.17 (5.579)
LFC targets: % participants with				
LFC ≤10% at baseline	32.6 (5.813)	38.0 (5.643)	19.9 (4.873)	29.5 (5.372)
LFC ≤10% at Week 52[b]	60.4 (7.979)*	77.9 (6.409)**	73.9 (6.694)**	34.8 (7.865)
≥30% relative decrease in LFC at Week 52[b]	66.9 (7.394)*	81.4 (5.623)**	78.8 (5.970)**	32.1 (7.190)
Visceral adipose tissue volume (L)				
Baseline	6.87 (0.240)	6.21 (0.232)	6.81 (0.238)	6.34 (0.230)
Week 52[b]	5.42 (0.187)**	5.00 (0.178)**	4.88 (0.181)**	6.90 (0.182)
Abdominal SC adipose tissue volume (L)				
Baseline	10.99 (0.506)	10.21 (0.491)	10.34 (0.502)	10.04 (0.485)
Week 52[b]	9.07 (0.247)**	8.22 (0.236)**	8.42 (0.234)**	11.10 (0.240)
Body weight (kg)				
Baseline	98.0 (1.93)	93.4 (1.85)	95.6 (1.92)	91.3 (1.92)
Week 52	86.9 (0.85)**	84.9 (0.83)**	83.5 (0.85)**	97.2 (0.86)
HbA_{1c} (mmol/mol)				
Baseline	66.8 (1.19)	68.4 (1.14)	65.6 (1.18)	65.6 (1.18)
Week 52	44.7 (1.34)**	43.3 (1.32)**	41.2 (1.33)**	53.4 (1.36)
HbA_{1c} (%)				
Baseline	8.27 (0.109)	8.41 (0.104)	8.15 (0.108)	8.15 (0.108)
Week 52	6.24 (0.122)**	6.12 (0.121)**	5.92 (0.122)**	7.04 (0.124)
Liver enzymes concentration (U/L)				
ALT at baseline	28.0 (1.71)	25.8 (1.54)	26.1 (1.59)	24.7 (1.53)
ALT at Week 52[c,d]	21.8 (1.12)	19.1 (0.97)*	17.8 (0.89)**	22.8 (1.20)
AST at baseline	20.7 (0.97)	19.6 (0.90)	20.6 (0.96)	20.0 (0.95)
AST at Week 52[c,d]	18.3 (0.76)	17.8 (0.74)*	16.5 (0.67)**	20.4 (0.87)

Data are estimates (SE), unless otherwise noted. *p<0.05 and **p<0.001 are both vs IDeg.

TZP doses were achieved through stepwise 2.5-mg dose escalation every 4 weeks. IDeg starting dose was 10 U/day and it was titrated to a FSG <5 mmol/l following a treat-to-target algorithm. Mean IDeg dose at Week 52 was 58.8 U/day.

[a]mITT-Efficacy Analysis Set, unless otherwise noted: on treatment data prior to initiating rescue therapy from mITT population excluding patients with baseline and postbaseline data not obtained or not valid. N values vary across primary and secondary endpoints at Week 52.

[b]Missing values at Week 52 were imputed with LOCF using mITT efficacy analysis set (if early termination or unscheduled visit with MRI scan available).

[c]mITT-Safety Analysis Set: all available data from mITT population including safety follow-up regardless of adherence to study drug or use of rescue therapy including patients with non-missing baseline and at least one non-missing post-baseline record.

[d]Statistical significance based on percent change from baseline vs IDeg.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; FSG = fasting serum glucose; HbA_{1c} = haemoglobin A_{1c}; IDeg = insulin degludec; LFC = liver fat content; LOCF = last observation carried forward; mITT = modified intent-to-treat (all randomised patients who took at least one dose of study drug); N = number of patients in specified dataset; SC = subcutaneous; SE = standard error; TZP = Tirzepatide.

Methods: Insulin-naive participants with type 2 diabetes and Fatty Liver Index ≥60 had an MRI scan performed before randomisation (1:1:1:1) to once-weekly tirzepatide (5, 10, 15 mg) or once-daily IDeg as add-on to metformin with/without sodium-glucose co-transporter-2 inhibitors (SGLT-2i). The primary outcome was the change from baseline in LFC at Week 52 using pooled data from tirzepatide 10/15-mg arms vs IDeg. Secondary outcomes compared the individual tirzepatide doses vs IDeg at Week 52 for LFC, VAT and ASAT volumes; proportions of participants achieving LFC targets.

Results: A total of 296 participants had evaluable MRI data during the study (mean baseline age, 56.2 years; diabetes duration, 8.3 years; HbA_{1c}, 8.2%; weight, 94.4 kg; BMI, 33.5 kg/m^2; 30% on SGLT-2i). The reduction from baseline in LFC at Week 52 was significantly greater for the pooled tirzepatide 10/15-mg arms vs IDeg arm and for all individual tirzepatide doses vs IDeg. The proportions of participants achieving LFC targets were significantly greater in each tirzepatide arm vs IDeg arm. All tirzepatide doses reduced VAT and ASAT volumes at Week 52 while IDeg increased both. The results were similar regardless of the concomitant use of SGLT-2i.

Conclusions: Tirzepatide demonstrated clinically meaningful reductions in LFC and VAT and ASAT volumes compared to IDeg in this SURPASS-3 substudy.

IS035 / #881

PARALLEL SESSION - DIABETES TECHNOLOGY ONBOARDING – ONE SIZE FITS NOBODY – EASY WAYS TO GET BEST FROM YOUR DEVICE

CGM TOP TIPS - BALANCING THE BENEFIT/BURDEN SEESAW

K. Barnard-Kelly

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Continuous glucose monitoring (CGM) is increasingly used amongst people with type 1 diabetes, type 2 diabetes and pre-diabetes as a tool to visualise glycemic patterns and excursions. The are widely reported clinical benefits across different systems and study designs. There are also a number of downsides that contribute to discontinuation of CGM use including increased visibility of disease state, alarm fatigue and interference in daily living. Effective onboarding of such systems, including exploration of personalised expectations and goals can mitigate these downsides. This presentation will explore benefits and burdens of CGM systems, as well as provide practical tips and advice on how to get the best out of them for improved physical and mental wellbeing.

IS036 / #883

PARALLEL SESSION - DIABETES TECHNOLOGY ONBOARDING – ONE SIZE FITS NOBODY – EASY WAYS TO GET BEST FROM YOUR DEVICE

WHY IS MY TECH NOT GIVING ME THE RESULTS I WANT

W. Polonsky

Behavioral Diabetes Institute, N/a, San Diego, United States of America

When individuals grow discouraged or disappointed with their personal diabetes devices, such as an insulin pump or RT-CGM, it increases the possibility that they will at some point choose to quit their devices altogether. To address this potentially harmful decision in a proactive manner, we must seek to understand the the individual's underlying reasoning and, when needed, develop clear strategies for intervention. This presentation will review how such factors as unreasonable device expectations (e.g., 100% CGM accuracy), history of hypoglycemic fear, and problematic device-related hassles (e.g., alarm fatigue) can all lead to worry, discouragement and potential discontinuation. In addition, practical strategies for addressing these issues will be discussed.

IS037 / #886

PARALLEL SESSION - PREGNANCY AND DIABETES TECHNOLOGY

USING TEMPORAL CGM PROFILES TO UNDERSTAND CLINICAL OUTCOMES IN DIABETES PREGNANCY

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Clinicians are increasingly familiar with using the visual 24 hour glucose profile obtained by CGM to personalise the clinical management of diabetes. However at a population level the temporal profiles are not used to ascertain where clinically relevant differences lie across the 24 hour day and any differences in glucose are often masked by summary statistics. This talk will highlight the importance of examining the full 24 hour temporal glucose profiles and illustrate the relevance of this to understanding pregnancy outcomes in women with diabetes.

IS038 / #888

PARALLEL SESSION - PREGNANCY AND DIABETES TECHNOLOGY

IS THERE A ROLE FOR MORE DIABETES TECHNOLOGY USE IN TYPE 2 DIABETES PREGNANCY

H. Murphy

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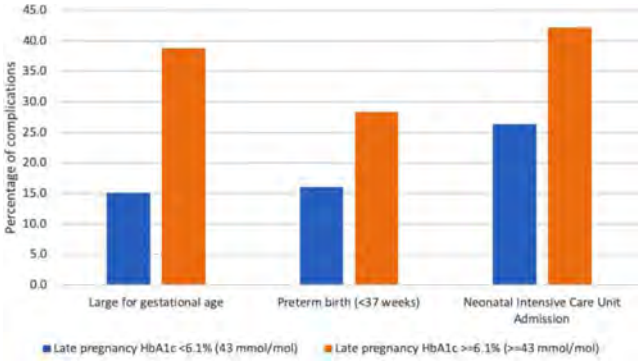
During 2019-20, there were 5,085 pregnancies in women with T2D and 4,175 in those with T1D, making T2D now the commonest form of pregestational diabetes in pregnancy in England and Wales. This represents a doubling in the prevalence of T2D pregnancies in the past two decades. Compared to pregnant women with T1D, those with T2D are older, have higher BMI, with more metabolic comorbidities (hypertension, dyslipidemia) and are more likely to belong to minority ethnic groups, and live in higher deprivation areas. There were seven times more pregnancies (>40% vs <6%) among women with T2D living in the most vs least deprived communities. Fewer than one in four were taking high dose folic acid before pregnancy. Glycaemic management was also inadequate with 25% of women untreated, 50% taking metformin alone, and only 15% taking insulin (10 % metformin and insulin, 5% insulin alone) before pregnancy. Approximately one in seven pregnant women (median age 34 years) were taking ACE-inhibitors, statins (13%) or other potentially harmful therapies (7%). Pregnant women with T2D had higher rates of perinatal death across all HbA1c categories compared to pregnant women with T1D. After adjusting for relevant confounding risk factors, an above target HbA1c after 24 weeks was associated with a four-times increased risk of perinatal death in T2D. Rates of preterm births, LGA and neonatal intensive care unit admissions are all significantly reduced in women with T2D who achieve HbA1c < 6.1% (43mmol/mol) after 24 weeks gestation (Figure 1), emphasizing the crucial importance of antenatal glucose levels during T2D pregnancy.



IS039 / #890

PLENARY - CLOSED-LOOP UPDATES

THE USE OF REAL WORLD DATA TO OPTIMIZE THE PERFORMANCE OF AUTOMATED INSULIN DELIVERY DEVICES

O. Cohen

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Real-world evidence (RWE) of a new therapy provides insights into whether or not results from relatively small and highly structured clinical trials can be generalized to a wider user and provider populations. While randomized controlled trials provide a standardized mean to isolate an attribute, so the effect of a single therapy, can be deduced, in real-world situation , myriad of interaction and differing care structures occur that effect outcomes. Analyzing RWE from large data bases can, therefore, provides a more realistic scenario to assess the outcomes of therapeutic interventions. In this presentation, the use of RWE driven insights to drive therapy recommendation for the individual user of automated insulin delivery systems, and the care provider, will be demonstrated . Harnessing the objectively and unbiased collected data requires attention to technical, analytical and privacy issues to ensure data quality and analytic integrity. The limited individual data and challenges of anonymization of RWE will be discussed as well. The clinical outcome effect of applying the insights from the prediction analysis of RWE, will be demonstrated in the case of the MiniMed™ 780G Advanced Hybrid Closed Loop (AHCL) system.

IS040 / #891

PLENARY - CLOSED-LOOP UPDATES

LONG-TERM, REAL-LIFE USE OF CLOSED-LOOP CONTROL

B. Kovatchev

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After years of development and testing of system components and algorithms, closed-loop control (CLC) of diabetes, known as the ''artificial pancreas,'' is a clinical reality. Two CLC systems, Medtronic's 670G/770G and Tandem's Control-IQ, have FDA clearance for clinical use in the U.S. and CE mark for clinical use in Europe. Insulet's Omnipod 5 received FDA clearance in January 2022, but has no CE mark and is not available in Europe. Another two systems, Medtronic 780G, and CamAPS FX, received CE mark for use in European countries. These systems are at different stages of their clinical use: while 670G/770G and Control-IQ already have hundreds of thousands of users around the world, 780G, Omnipod 5, and CamAPS FX are making their first strides in real-life application. Several other systems have passed extensive testing and are along their ways to regulatory approval, including Diabeloop, Tidepool Loop, the bi-hormonal (insulin plus glucagon) Inreda, and iLet, in two configurations – insulin only and insulin plus glucagon. Real-life data began to emerge. The MiniMed 670G helped with improved glycemic control and quality of life, but also resulted in frequent discontinuation of system use due to suboptimal user experience: approximately one-third of those starting on the 670G system discontinued use within months. It was concluded that ''While auto mode utilization correlates with improved glycemic control, a focus on usability and human factors is necessary to ensure use of auto mode. Alarms and sensor calibration are a major patient concern, which future technology should alleviate.'' Thus, it is not a surprise that more advanced systems enjoy better user acceptance. In a clinical trial, the 780G (known as Advanced Hybrid Closed-Loop System, AHCL) achieved 86% use in auto mode, compared to 75% for the 670G. Published real-life CLC data for over 9,000 Control-IQ users confirmed almost exactly the glycemic results from the two pivotal trials of this system. In this 2021 report, Control-IQ had 94% use of auto mode throughout a year of observation. To these literature data, this presentation adds new unpublished results of Basal-IQ and Control-IQ use by over 20,000 people with type 1 and type 2 diabetes.

IS041 / #847

PARALLEL SESSION - CGM AND TYPE 2 DIABETES

MEDICAL AND PSYCHOLOGICAL APPROACHES TOWARDS ENHANCING THE VALUE OF PERSONAL CGM IN THE TYPE 2 POPULATION

S. Edelman[1], W. Polonsky[2]

[1]University Of California San Diego, Veterans Affairs Medical Center, Professor Medicine, San Diego, United States of America, [2]Behavioral Diabetes Institute, N/a, San Diego, United States of America

Real-time continuous glucose monitoring (RT-CGM) has become the standard of care for people with type 1 diabetes (T1D) and it is the rare individual who would not benefit greatly from it. With the advent of hybrid closed loop systems, RT-CGM has taken on an even greater level of importance. However, the use of RT-CGM in people with type 2 diabetes (T2D) remains very limited.

Currently, only patients with T2D treated with 3 or more injections a day or insulin pump therapy are able to obtain a CGM that is covered by insurance or Medicare in the United States. However, we believe that every patient with T2D, no matter what their current antidiabetic medication regimen may be, could potentially benefit from RT-CGM. The key will be to provide both HCPs and patients with the necessary guidance, education and support to interpret and respond effectively to RT-CGM data. In this presentation, we will put forward a series of practical strategies designed to promote a more successful introduction to RT-CGM for both HCPs and individuals with type 2 diabetes, and also to enhance ease of use and patient enthusiasm regarding RT-CGM as well as long-term glycemic success.

IS042 / #963

PARALLEL SESSION - CGM AND TYPE 2 DIABETES

THE MEANING OF GLUCOSE CONTROL IN DIABETES TODAY: IT'S TIME FOR A PARADIGM SWITCH

A. Ceriello

IRCCS MultiMedica, Diabetes Research, Milan, Italy

Glycated haemoglobin (HbA1c) is the most used parameter to assess glycaemic control. However, recent evidence suggests that the concept of hyperglycaemia has profoundly changed and that different facets of hyperglycaemia must be considered. A modern approach to glycaemic control should focus not only on reaching and maintaining optimal HbA1c levels as soon as possible, but to obtain this result by reducing postprandial hyperglycaemia, glycaemic variability and to extend as much as possible the time in range in near-normoglycaemia. These goals should be achieved avoiding hypoglycaemia and, if this happens, hypoglycaemia should be reverted to normoglycaemia. Modern technology, *i.e.* intermittently-scanned glucose monitoring and continuous glucose monitoring together with the new available

drug therapies (e.g. ultra-fast insulin, SGLT-2i, and GLP-1RAs) may help to change the paradigm of glycaemia management based on HbA1c in favour of a holistic approach considering all the different aspects of this commonly oversimplified pathological feature of diabetes.

IS043 / #894

VIRTUAL PARALLEL SESSION (PRE-RECORDED + LIVE Q&A) - DIABETES INDIA

PRECISION DIABETES IN INDIA- WHERE ARE WE?

V. Mohan

Madras Diabetes Research Foundation & Dr. Mohan's Diabetes Specialities Centre, Diabetology, Chennai, India

PRECISION DIABETES IN INDIA – WHERE ARE WE?

DR.V. MOHAN, M.D., FRCP (London, Edinburgh, Glasgow & Ireland), Ph.D., D.Sc. D.Sc (Hon. Causa), FNASc, FASc, FNA, FACE, FACP, FTWAS, MACP, FRSE **Chairman & Chief of Diabetology,** Dr. Mohan's Diabetes Specialities Centre & Madras Diabetes Research Foundation, Chennai, India Email : drmohans@diabetes.ind.in, Websites : www.mdrf.in & www .drmohans.com Precision Diabetes includes precision diagnosis, prevention and treatment. Although Precision Diabetes is applicable to all forms of diabetes. Currently, it is more used in type 2 diabetes and Monogenic Diabetes in India. **PRECISION MEDICINE IN TYPE 2 DIABETES** Type 2 diabetes (T2D), is caused by impairment in both insulin secretion and insulin action. Till recently, T2D was considered and treated as one condition. After the work of Alquist et from Sweden describing different clusters of T2D, we also attempted clusters of T2D using clustering. We described 4 clusters of T2D which includes SIDD (Severe Insulin Deficient Diabetes) and MARD (Mild Age-Related Diabetes), which are similar to the Swedish clusters and two new clusters namely IROD (Insulin Resistant Obese Diabetes) and CIRDD (Combined Insulin Resistant and Deficient Diabetes). Insulin secretagogues would obviously be preferred for SIDD and insulin sensitizers for IROD and both groups of drugs for the combined types while MARD is the easiest to treat as it is the mildest variety. An RCT on different drugs to treat these T2D subtypes is currently in progress. **PRECISION DIABETES IN MONOGENIC DIABETES** In the case of monogenic diseases such as Maturity Onset Diabetes of Young (MODY) and Neonatal Diabetes, genetic testing has now come to the realm of clinical practice as these are single gene defects which can be easily identified by genetic testing. Our centre is an ICMR Nodal Centre for India for monogenic diabetes testing (www. http://monogenicdiabetes.in/) Based on genetic testing, **MODY** is a group of clinically heterogeneous forms of beta cell dysfunction that are defined at the molecular genetic level by mutations in different genes (eg., *HNF4A, GCK, HNF1A, HNF1B, etc*). By correctly identifying MODY subtypes like HNF1A & HNF4A, it is possible to avoid life long insulin injections in these patients who are wrongly diagnosed to have type 1 diabetes. One of the most gratifying clinical applications of Precision Diabetes is in the diagnosis of **Neonatal Diabetes** which is defined as diabetes occurring in the first 6 months of life. Several children with neonatal diabetes in India carrying the *KCNJ11* and *ABCC8* mutations have been successfully switched over from insulin therapy to oral sulfonylurea. In conclusion, precision medicine has finally come to the diabetes clinic. Good clinical phenotyping can make genetic testing cost effective. It can also help change the therapy from life long insulin injections to tablets for some forms of diabetes like monogenic diabetes which can be very gratifying to the patient and his / her family.

IS044 / #895

VIRTUAL PARALLEL SESSION (PRE-RECORDED + LIVE Q&A) - DIABETES INDIA

WHATSAPP SUPPORT GROUP FOR 950 CHILDREN AND ADOLESCENTS/PARENTS WITH TYPE 1 DIABETES - PHYSICIAN'S PERSPECTIVE ON MERITS AND DEMERITS

J. Kesavadev

Jothydev's Diabetes Research Centre, Diabetes, Trivandrum, India

During the Covid pandemic, telemedicine(TM) has been more and more accepted by doctors and patients all over the world. Evidence-based research has found telemedicine-based management of type 1 diabetes efficient in delivering equivalent or better care and outcomes when compared to only face to face visits. A year before the covid, Kerala, the most literate state in India, with 96.2% literacy rate, had a community consisting of parents and children with type 1 diabetes. Almost all these parents had access to WhatsApp and were part of the type 1 diabetes community in Whatsapp. This of course doesn't include all of those with type 1 diabetes in the state but included most of those who were economically compromised and didn't have access to the premier hospitals and doctors. There were total of 4 WhatsApp groups, each consisting of 250 parents and children from all over the state of Kerala, receiving treatment from government hospitals or other private hospitals. The groups also included volunteering doctors, nurses, educators and dietitians where we were also part. Our duty was to give them directions and advices rather than to treat them. We in addition, provided the economically disadvantaged families with free supplies including insulin, glucometers, strips and injection needles based on their needs. All the communications in the group were based on updated telemedicine guidelines in India. As a team, we have been providing 24/7 advices and services free of cost to the entire community together with multiple online educational programs via the zoom. Some of these programs were with parents and children together and some other programs incorporated only parents so that counselling can be given to them to specifically address psychosocial issues of these kids. In each WhatsApp group, one of us in the team, always made sure we replied to the questions posted by the parents or grown up children, without any delay. Most frequently asked questions during Covid pandemic were related to stress and anxiety of children including abnormal/aggressive behaviour, uncontrolled glucose, reluctance with insulin injections and glucose monitoring. We also had to arrange exclusive counseling sessions with psychologist to address the multiple emotional issues of the kids/caregivers. We also created educational videos addressing different aspects of type 1 diabetes and Covid based on the frequently raised questions and concerns.

MERITS

1. All their concerns are addressed even during the middle of the night.
2. Could avoid multiple episodes of DKA
3. Could successfully avert/treat multiple episodes of life-threatening hypoglycemia
4. Dietitians in the groups could advise on diet, specific to individual requirements

5. Diabetes nurses could retrain parents and children on injection techniques whenever found essential, multiple times
6. Questions on stopping insulin or Complementary and Alternate Medicines(CAM), side effects of insulin where not only answered but also explained via videos.
6. Whoever is in short of glucometer strips or needles could get it from community itself or from us without any delay.

DEMERITS

1. The patients in the WhatsApp groups are getting treated in different hospitals and not by the volunteering doctors and healthcare providers in the Whatsapp groups and hence the medical history and records are not with them.
2. Many a time, the patients with uncontrolled glucose might be on an insulin formulation or regimen not suitable for them but the team would not be able to commend on it.
3. Hundreds of parents will be messaging or calling via WhatsApp privately to doctors. However,due to legal implications, they are not replied to unless it is posted in community group.
4. Though there is no hesitancy for the type 1 diabetes community members to open up about disease in the group, there would be many concerns and questions which cannot be posted in a group.
5. Since it is an open community, whatever communications are exchanged; including lab reports are not secure or confidential.
6. The health care professionals(HCPs) will not get a remuneration and there is no funding for this activity; so those getting involved should volunteer out of their commitment to the society.
8. The HCPs may be under tremendous pressure since the patients will have easy and free access to the health care professional. The WhatsApp community of type 1 diabetes children and their parents were provided support throughout the day and night by the physicians and allied healthcare professionals in each group. This telemedicine model prevented hospital admissions which was widely appreciated by the patient community and it also reduced the overall cost and burden of treatment. However,this model is not free of demerits which may include the legal implications, the errors and mistakes, which can happen in the process of communication and implementation. This advantageous model may not be applicable in many other health systems.

IS045 / #897

VIRTUAL PARALLEL SESSION (PRE-RECORDED + LIVE Q&A) - DIABETES INDIA

TIR THROUGH PROFESSIONAL CGM - THE INDIA FRIENDLY METRIC

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The Time in Range (TIR) metrics are now accepted internationally and in India as a means of assessing the entire glycemic movement and glycemic variability. The TIR is measured using predominantly CGM devices and also SMBG (although SMBG does have limitations). Professional CGM systems have been available in India for over a decade with the Libre Pro Flash Glucose monitoring being introduced in India for the first time in 2015. Despite the availability of the libre freestyle and other real time CGM devices like Guardian Rt in India, their use is limited in comparison with the retrospective, professional cgms due to cost and poor awareness. Though the Indian CGM guidelines recommend routine use of cgm for patients with type 1 DM and those with type 2 DM with potential for hypoglycemia the uptake is still slow. TIR as supplementary to HBA1C is slowly gaining relevance amongst Indian physicians and as the use of this technology is predominantly intermittent where used the assessment of TIR through professional blinded CGM (does not get influenced by change in lifestyle and drug dose like in case of real time CGM use) seems most appropriate in the Indian population context. An important component of the TIR metrics besides the Time in Target and Time above Target percentage is the Time below Target Range as unrecognized hypoglycemia is one of the biggest drawback and limitation of the current approach towards diabetes management. We have identified significant time spent by patients below range inspite of being in higher hba1c bracket and that is an important indicator for routine assessment of TIR in Indian patients through intermittent professional CGM.

IS046 / #908

PARALLEL SESSION - NUTRITION AND FOOD TECHNOLOGIES

DIGITAL NUTRITION TECHNOLOGIES FOR DIABETES PREVENTION

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Using Digital Technology for Diabetes Prevention Delivery and Engagement Despite medical and technological advances in diabetes care, the prevalence of diabetes continues to rise. It is becoming critically important to use technology not only to improve diabetes management but also for delivery and engagement in Lifestyle Change Programs for the prevention of type 2 diabetes. Based on the Diabetes Prevention Program and the DPPOS, intense lifestyle intervention aimed at weight loss decreased the incidence of type 2 diabetes by 58% at study's end and had a long-lasting risk reduction of 25% by 22 years. The National Diabetes Prevention Program (National DPP) in the United States is a widely available Lifestyle Change Program for people with prediabetes with the goal of 5% weight loss, improvement in food quality and quantity to promote weight loss and an increase in physical activity. Technology can improve access to the program, delivery, engagement, and effectiveness of the National DPP. This seminar will discuss how to use technology to deliver the National DPP, best practices around synchronous delivery and engagement, how asynchronous delivery can augment the program, and how digital technologies can support effectiveness.

IS047 / #909

PARALLEL SESSION - NUTRITION AND FOOD TECHNOLOGIES

PERSONALIZED NUTRITION FOR IMPROVING GLYCEMIC CONTROL IN PEOPLE WITH TYPE 2 DIABETES

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Dietary modifications are crucial for managing newly-diagnosed type-2 diabetes mellitus (T2DM) and preventing its health complications, but many patients fail to achieve clinical goals with diet alone. We previously developed a machine-learning algorithm for predicting personalized postprandial glucose responses (PPGR) to meals using clinical and gut microbiome features, and showed that dietary interventions based on this algorithm successfully lowered PPGRs in adults with prediabetes. Here, we sought to evaluate the clinical effects of a personalized postprandial-targeting (PPT) diet on glycemic control and metabolic health in individuals with newly-diagnosed T2DM. We preformed a short-term randomized controlled crossover trial and compared the effects of an algorithm-based personalized postprandial-targeting ('PPT') diet, to those of a commonly used Mediterranean-style (MED) diet on glucose levels in 23 newly diagnosed T2DM subjects. The PPT diet lead to significant decrease in glycemic parameters as compared to the MED diet, for example, average PPGR (mean difference between diets, -19.8 ± 16.3 mg/dl × h, $p < 0.001$), mean glucose (mean difference between diets, -7.8 ± 5.5mg/dl, $p < 0.001$), daily time of glucose levels >140mg/dl (mean difference between diets, -2.42 ± 1.7 hour/day, $p < 0.001$) and blood fructosamine (mean change difference between diets, -16.4 ± 37μmol/dl, $p < 0.0001$). We further evaluated the long-term clinical effects of the PPT diet in 16 of the participants by an additional 6-month PPT intervention program, and found significant improvements in multiple metabolic health parameters, including HbA1c (mean±SD, -0.39 ± 0.48%, $p < 0.001$), fasting plasma glucose (FPG) (-16.4 ± 24.2mg/dl, $p = 0.02$) , fasting insulin (-2.3 ± 4.0MCU/ml, $p = 0.04$), triglycerides (-49 ± 46mg/dl, $p < 0.001$) and body composition measurements including body fat% (-2.5 ± 3%, $p = 0.005$) and waist circumference (-4.7 ± 3.7cm, $p = 0.001$). Importantly, 61% of the participants exhibited diabetes remission at the end of the intervention, as measured by HbA1c. Finally, we show that some of the improvements in clinical outcomes were accompanied by significant alterations to the gut microbiome composition per person. Our findings suggest that a personalized postprandial-targeting diet may be an effective alternative treatment compared to standard dietary approaches for improving glycemic control in newly diagnosed T2DM.

IS048 / #911

PARALLEL SESSION - EDUCATION AND ADHERENCE TO TREATMENT

DAILY PREDICTORS OF DIABETES ADHERENCE IN ADOLESCENTS AND YOUNG ADULTS WITH T1D

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Glycemic control is typically measured by aggregate glucose data spanning 14 days. Little is known about the daily fluctuations in diabetes self-management, glycemic control, and ability to achieve goals in adolescents and young adults (AYA) with type 1 diabetes. There are likely a myriad of underlying physiological, emotional, and cognitive factors that fluctuate on a day-by-day basis that predict these daily diabetes outcomes. This is important because daily patterns and habits are proximal to the momentary experience of AYA, and may provide unique foci for precision interventions to improve diabetes self-management among AYA with diabetes. Newer health behavior theories such as Two Minds Theory suggest that such momentary biopsychosocial factors require state-level assessment close to the time of the actual behavior rather than trait-level global assessment. We prospectively studied 100 AYA with T1D on a daily basis to determine novel biopsychosocial factors that predict glycemia, adherence, and goal attainment, in an effort to identify novel intervention targets and strategies to improve glycemic control in AYA with type 1 diabetes.

IS049 / #915

PARALLEL SESSION - ISPAD SESSION: USE OF TECHNOLOGY IN VARIOUS POPULATIONS

PATIENT REPORTED OUTCOME WHEN USING AID/ TECHNOLOGY

K. Barnard-Kelly

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Automated insulin delivery (AID) systems are increasingly being used by children of all ages with type 1 diabetes. Glycemic benefits have been widely reported, with a 70% time in target range reported to be clinically beneficial. The impact of such systems on the quality of life and psychosocial functioning of children and their parents, however, is less well understood. This presentation will explore some of the benefits and burdens of AID technology use amongst young children with type 1 diabetes. These will include competing priorities between children and their parents; relationships with other caregivers and balancing diabetes management with simply growing up. Finally, appropriate ways to assess patient reported outcomes will be explored.

IS050 / #916

PARALLEL SESSION - ISPAD SESSION: USE OF TECHNOLOGY IN VARIOUS POPULATIONS

SLEEP AND DIABETES

S. Jaser

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Sleep is a potentially modifiable risk or protective factor for diabetes-related outcomes that has recently gained interest. In addition, new diabetes technology and devices have the potential to both disrupt sleep (with alarms) and improve sleep (through reduced glycemic variability overnight). This session will highlight recent findings from studies of sleep in type 1 diabetes (T1D), with a focus on the role of sleep in self-management, diabetes-specific sleep disturbances, and the potentially modifiable aspects of sleep, as well as emerging evidence from studies of sleep-promoting interventions to improve outcomes in youth with T1D and their caregivers.

IS051 / #917

PARALLEL SESSION - ISPAD SESSION: USE OF TECHNOLOGY IN VARIOUS POPULATIONS

DIABETES IN LOW (MEDIUM) INCOME COUNTRIES (L(M)IMC): WHAT TECHNOLOGY TO PRIORITIZE?

S. Besancon

NGO Santé Diabète, Ceo, Bamako, Mali

Background As in many Low Income Countries (LIMC) countries the situation of type diabetes was catastrophic in Mali a few years ago. In 2003, The International Diabetes Federation (IDF) estimates that there are a total of 790 new people with Type 1 diabetes [1] in Mali. In 2004, the NGO Santé Diabète (SD) and the International Insulin Foundation (IIF) conducted the RAPIA investigation which allowed the barriers to diabetes care and the reality for the type 1 diabetes in Mali with just 10 patients a live with a life expectancy of less than 1 year after diagnosis [2].

Case description As in many developing countries, before thinking about technologies the emergency was to strengthen the health system to give access to care for patients with type 1 diabetes. After this RAPIA study, from 2005 to 2018, Santé Diabète, in collaboration with the Ministry of Health of Mali and the local specialists, developed a comprehensive strategy to address 5 barriers to develop diabetes care in Mali. For the management of type 1 diabetes, the strengthening of the health system, with the support of IDF's LFAC program, has made it possible to detect and manage many children and young adults. The active file has gone from less than 10 DT1 in 2004 to more than 450 in June 2016 [3] and more than 1000 today [4]. With a real active file of type 1 diabetes, since 2015, we started the structuration of type 1 diabetes care with the creation of a sub unit for type 1 diabetes and young adults within the endocrinology and diabetology service in the national hospital and the development of early education tools for T1D. To really achieve better control in the new units we develop also a paper medical record and a logbook for each child to record the first data on T1D in Mali. Once this care was built, we started to think about how to improve the care and the quality of life of patients. For this we have launched a reflection on the technologies that we could use to support this. We started with the availability of the Hba1c in the capital Bamako and the different regions by setting up simple devices that can be easily and inexpensively transported to decentralize the possibility of carrying out the HBA1C. Then, it was through different successive stages to use new technologies to produce quality medical data allowing the production of quality clinical data and research data in connection with the sweet program. Finally, we are currently studying various other technologies and we will present our analyses with technical strengths and weaknesses as well as economic ones. We will present: - The potential availability of insulin analogue compared to human insulins; - The possibility to use pen instead of syringes; - The possibility to use blood glucose meter such as freestyle (as a tool for reading blood glucose or as a therapeutic education tool) ; - The possibility to use pump; - The possibility to use ICT technologies as educational tools (example webdia tool, whatsapp channels, etc.)

Conclusion To develop the management of type 1 diabetes in many Low Income Countries, a three-step strategy must be followed: - Strengthening the health system to lift all the barriers to care for T1D - Construct data collection tools in the country adapted to the national health information system - Add the technologies that are relevant and financially affordable to strengthen this care and the quality of life of - patients

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IS052 / #920

PARALLEL SESSION - THE ITALIAN TECHNOLOGY EXPERIENCE (ENDORSED BY THE ITALIAN TECHNOLOGY SOCIETY)

USE OF DIABETES TECHNOLOGY AT DIABETES ONSET, PROS AND CONS

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Advanced technologies have become an integral part of type 1 diabetes (T1D) management. The aim of this presentation is to review current technologies with emphasis on the advantages and disadvantages of their use from the onset of T1D. Immediate start of pump therapy at the time of diagnosis has been shown to be successful in terms of glycemic control achieved and might help to preserve residual β-cell function, although larger clinical trials would be required to confirm this. In very young children, the advantages are more evident and related to the need for a more physiological delivery of precise doses of insulin through continuous subcutaneous insulin infusion (CSII) rather than multiple daily injections (MDI). Furthermore, parents of children treated with CSII reported superior quality of life for their children compared with parents of children treated to MDI but CSII use is lower in patients from ethnic minorities and those with the greatest socio-economic deprivation. Initiation of technological devices so early in the course of T1D requires highly coordinated teamwork to provide the education needed for youth and families to manage a large volume of data and notions to learn. The use of CSII may be associated with an increased risk of diabetes ketoacidosis (DKA) due to unrecognized malfunction and/or failure of the device. Other potential complications are infusion site infections and lipodystrophies. In our experience, intensive MDI/CSII regimens from the onset of diabetes are both safe and efficient. Data from the SCIPI (subcutaneous insulin: pumps or injections?) study on TID children and young people newly diagnosed, indicate that the use of CSII was neither clinically beneficial nor cost-effective in the first year of type 1 diabetes, concluding that resources could be more effectively invested in other measures to improve glycemic control. Recent studies show instead the importance of closed-loop in the pediatric T1D population, even at the onset. In particular, the ongoing CLOuD study (a randomised parallel study protocol) was aimed at assessing the effect of closed-loop insulin delivery from the onset of type 1 diabetes in youth on residual beta-cell function compared to standard insulin therapy. The future widespread use of an advanced hybrid closed-loop from the onset of diabetes will improve and probably change the metabolic outcomes.

IS053 / #925

PARALLEL SESSION - ADVANCED TECHNOLOGIES AND REGULATORY ADJUSTMENTS IN TREATING DIABETES

A BIONIC FULLY AUTOMATED INTRAPERITONEAL INSULIN DELIVERY SYSTEM: THE EU PROJECT FORGETDIABETES

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The last decade has seen important developments in closed-loop subcutaneous (sc) sensing and insulin delivery closed-loop systems. However major limitations of subcutaneous insulin delivery still exist, including the hyper-insulinemia due to the non-physiologic sc route and need for meal announcement. FORGETDIABETES introduces a radically new approach to Type 1 Diabetes (T1D) treatment, by developing a fully-implantable, fully-automated bionic invisible pancreas (BIP) based on physiological intraperitoneal (ip) hormone delivery, thus enabling an optimal glycemic control. BIP will free individuals with T1D from therapeutic actions and from the related psychological burden. BIP will become a life-condition (like contact lens), allowing T1D patients to live just as everybody else. An interdisciplinary team with top experts in micronano mechatronics, control engineering, biomaterials, endocrinology, surgery and behavioral sciences has been assembled to develop a long-lasting system relying on a physiological glucose sensing and hormone delivery, orchestrated by personalized adaptive algorithms with advanced self-diagnostic capabilities. Pump refilling through a weekly oral recyclable drug pill will free T1D subjects from the burden of treatment actions. Wireless power transfer and data transmission to cloud-based data management system round-up to a revolutionary treatment device for this incurable chronic disease. In this project, the key technologies enabling BIP will be developed. Furthermore, extensive in vivo preclinical experiments along with massive in silico testing will establish the prototype system, paving the way to the ambitious first-in-human inpatient trial of BIP. This paradigm will revolutionize diabetes treatment and stimulate an innovation ecosystem including research bodies, SMEs, patient organizations, diabetes societies and clinicians.

IS054 / #926

PARALLEL SESSION - ADVANCED TECHNOLOGIES AND REGULATORY ADJUSTMENTS IN TREATING DIABETES

PATCH PUMPS: WHAT ARE THE ADVANTAGES FOR PEOPLE WITH DIABETES

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Objective: Patch pumps, i.e. tubeless insulin pumps, are an attractive alternative to conventional insulin pumps for people with type 1 diabetes and type 2 diabetes on insulin therapy. However, to date, the patient-related benefits of patch pumps are not well understood.

Methods: A systematic review was conducted to summarize potential patient-relevant advantages and disadvantages of patch pumps and to assess relevant studies on patient-reported outcomes (PROs). Relevant studies were identified by a systematic PubMed search. In addition, the reference lists of the respective articles and Google Scholar were checked for further references. English-language articles published before June 30, 2021, were included; no other publication date criteria were specified.

Results: A total of 12 studies were included. The results of this analysis demonstrate that patch pumps improve quality of life, reduce diabetes-related symptoms, increase patient satisfaction, and are preferred by patients compared with conventional insulin pumps and daily multiple injection (MDI) therapy. However, several methodological limitations of the identified studies limit the power of this analysis.

Conclusions: Despite the limited number of studies evaluating the benefits of patch pumps in relation to PROs, there is increasing evidence that people with diabetes prefer patch pumps compared to MDI and conventional pumps. It is notable that this aspect has been relatively understudied. More systematic studies evaluating the benefit of patch pumps in relation to PROs are needed.

IS055 / #927

PARALLEL SESSION - ADVANCED TECHNOLOGIES AND REGULATORY ADJUSTMENTS IN TREATING DIABETES

FLASH GLUCOSE MONITORING WITH THE FREESTYLE LIBRE 2: RESULTS FROM THE FLASH-UK RANDOMISED CONTROLLED TRIAL (ON BEHALF OF THE STUDY GROUP)

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Objectives To evaluate whether intermittently scanned continuous glucose monitoring (isCGM) with optional alarms (FreeStyle Libre 2) improves glycaemia as measured by HbA1c and sensor-based gluco-metrics, patient reported outcome measures (PROMS) and cost-effectiveness compared with self-monitoring of blood glucose (SMBG).

Design Flash UK is a multicenter, open-label, two arm, parallel, randomised controlled trial delivered in 7 specialist hospital diabetes clinics and 1 primary care centre.

Participants 156 people with Type 1 diabetes, age 16 years and over treated with either multiple daily insulin injections or insulin pump therapy with HbA1c 7.5%-11% were randomised. **Interventions** Participants were randomised (1:1) to the FreeStyle Libre 2 (n = 72) or standard care with SMBG (n = 69). Participants were reviewed at 4, 12 and 24 weeks post-randomisation. Education and treatment optimisation was provided to both groups at randomisation, 4 and 12 weeks. Participants in the SMBG arm wore blinded glucose sensor (Freestyle Libre Pro) during the last 2 weeks of the study; all participants wore a 2-week blinded sensor prior to randomisation. All study visits were conducted either in-person or virtually owing to the COVID-19 pandemic.

Main outcome measures The primary outcome was HbA1c at 24 weeks, analysed by intention to treat. Secondary outcomes included glucose time in range (3.9 to 10mmol/l), time below and above range and glucose variability. PROMS included EQ-5DL-5L, Type 1 Diabetes Distress Scale, Diabetes fear of injecting and self-testing, Diabetes Eating Problem Survey, Diabetes Treatment Satisfaction, Patient Health Questionnaire and The Glucose Monitoring Satisfaction Survey. Economic evaluation included healthcare resource use, insulin usage and Freestyle Libre 2 utilisation.

Results & Conclusion Results and conclusions will be presented during the 15th International Conference on Advanced Technologies & Treatments for Diabetes, April 27 to 30th Barcelona, Spain and Online.

IS056 / #930

PARALLEL SESSION - ADDRESSING UNIQUE HEALTH CARE NEEDS OF WOMEN WITH DIABETES BY TECHNOLOGY: CHALLENGES AND OPPORTUNITIES

GLYCEMIC CONTROL AND HEALTH COMPLICATIONS IN WOMEN VS. MEN WITH TYPE 1 AND TYPE 2 DIABETES

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While diabetes mellitus affects both men and women, there is limited data regarding gender specific differences in diabetes outcomes. Existing studies, however, reveal several differences between men and women with diabetes. As the impact of personalized medicine on improving clinical outcomes expand, gender specific health needs and treatments for people with diabetes mellitus have come to the forefront. Data regarding gender specific differences in diabetes outcomes and gender-related risk factors would be key to devise customized diabetes management plans to improve diabetes outcomes and quality of life for people with diabetes. This presentation highlights some of the health challenges that are common to women with diabetes and outlines gender-based differences, gender-specific risk enhancers and clinical outcomes in diabetes.

IS057 / #931

PARALLEL SESSION - ADDRESSING UNIQUE HEALTH CARE NEEDS OF WOMEN WITH DIABETES BY TECHNOLOGY: CHALLENGES AND OPPORTUNITIES

PSYCHO-BEHAVIORAL CHALLENGES FACED BY WOMEN WITH DIABETES

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It is well-documented that women with type 1 and type 2 diabetes report significantly higher levels of emotional distress than men with diabetes. Research has documented this for diabetes-related distress, depression, anxiety, and fear of hypoglycemia and shown that these differences occur over a broad age span, with adolescent girls reporting more distress than boys, especially problems with body image and disordered eating patterns. Increased emotional distress is also higher in mothers of children with type 1 diabetes as compared to fathers. Importantly, these gender differences appear to occur pan globally with studies emerging across continents and cultures. This presentation will review some of the psychological issues and challenges that are unique to women with diabetes. In addition, this presentation will examine some of the implications of these gender differences for the adoption and use of diabetes technology in women. To explore the impact of gender, psychological and behavioral data from recent pivotal trials of hybrid closed loop control (CLC) use will be presented, focusing primarily on Diabetes Distress Surveys completed by study participants at baseline and after 24 weeks of CLC use. These data show that more female participants, both adults and adolescents, reported clinically significant levels of diabetes distress at baseline (adult women vs. men = 38% vs 24%, adolescent girls vs. boys = 47% vs. 13%). After use of CLC, higher scores tended to remain high for the majority of participants, indicating that diabetes technology may not be effective in lowering diabetes distress.

IS058 / #932

PARALLEL SESSION - ADDRESSING UNIQUE HEALTH CARE NEEDS OF WOMEN WITH DIABETES BY TECHNOLOGY: CHALLENGES AND OPPORTUNITIES

PHYSIOLOGY OF MENSTRUAL CYCLE AND ITS RELATIONSHIP TO INSULIN NEEDS AND GLYCEMIC CONTROL IN WOMEN WITH TYPE 1 DIABETES

C. Fabris

University of Virginia, Center For Diabetes Technology, Charlottesville, United States of America

Individuals with type 1 diabetes (T1D) need to continuously calibrate insulin therapy, to account for time-varying insulin requirements driven by multiple metabolic and psycho-behavioral factors - eg, meals, physical activity, psychological stress. Among these factors, the menstrual cycle has been documented to impact insulin needs and complicate insulin dosing in women with T1D. According to several studies, women with T1D may experience a decrease in insulin sensitivity during the second half of their menstrual cycle (ie, the luteal phase), which is oftentimes accompanied by an increased exposure to hyperglycemia. Also, increased occurrence of hypoglycemia has been documented during the initial days of the menstrual cycle, as women transition from luteal to follicular phase. These patterns are not consistent across women and elevated inter-subject variability has been observed; further, intra-subject variability has also been documented in some studies. During this talk, we will review the physiology of the menstrual cycle and the effect that phases of the menstrual cycle have on insulin requirements and glycemic control in women with T1D. Further, the talk will discuss how technology in the form of open-loop decision support systems or closed-loop automated insulin delivery systems can support women in the management of T1D across the menstrual cycle.

IS059 / #933

PARALLEL SESSION - ADDRESSING UNIQUE HEALTH CARE NEEDS OF WOMEN WITH DIABETES BY TECHNOLOGY: CHALLENGES AND OPPORTUNITIES

AUTOMATED INSULIN TREATMENT IN WOMEN WITH TYPE 1 DIABETES: EVIDENCE FROM REAL-WORLD DATA

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Automated Insulin Delivery systems (AID) have consistently demonstrated improved glycemic outcomes and therefore have been in increasing use for people with Type 1 Diabetes. Pivotal trials have been completed with several systems that are now available for outpatient use. Although women have been adequately represented in these pivotal trials, it is unclear if women have a different glycemic response to AID treatment. A preliminary secondary analysis of AID trials conducted at UVA identified no significant change in hemoglobin A1c or time in range following AID use comparing female and male participants. In terms of changes across the menstrual cycle, there is little information available regarding the impact of AID systems on glycemic control. Preliminary studies have not observed trends in glycemic control or insulin delivery across menstrual cycle phases during AID use, but these studies are small and uncontrolled. Available real-world data will be discussed to consider whether differences are observed between female and male users of AID systems.

ATTD 2022 Oral Abstract Presentations

OP001 / #393

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 1

INSULIN REQUIREMENTS FOR BASAL AND AUTO-CORRECTION INSULIN DELIVERY IN MINIMED 780G: A REAL-WORLD DATA OF CHILDREN IN 2 DIFFERENT AGE GROUPS

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Background and Aims: Children with T1D have varying insulin needs throughout a day due to factors including age, diurnal rhythms, exercise, food intake. This study investigates the variations in insulin needs for basal and auto-correction of children in different age groups, through MiniMed 780G data.

Methods: Pump and CGM data of 34 children using MiniMed 780G were obtained from Medtronic Carelink. Micro and auto boluses were analyzed on an hourly bases by two age groups as 5-9 and 9.1-18 years old. Glycemic metrics were analyzed based on the International CGM consensus.

Results: Mean age was 12.2 years, mean duration of diabetes was 6.1 years. A total of 4193 patient-days were analyzed. Mean TIR and GMI were 80.5%, 6.6%, respectively. Basal insulin ratio between 05am-07am is significantly higher than those between 10am-03am ($p<0.01$) whereas it was significantly lower between 07pm-09pm than those between 12am-10am ($p<0.001$) (Figure1). Auto-correction insulin ratio between 09pm-12am is significantly higher than those between 03am-05pm($p<0.001$) and 07pm-09pm ($p=0.008$) whereas it was significantly lower between 07am-10am than those between 10am-03am($p<0.001$). Basal insulin ratio is significantly higher in 5-9yo children than those among 9.1-18yo between 9pm-12am($p=0.026$) and 12am-03am ($p=0.003$) (Figure2).

Conclusions: Minimed 780G data show that basal insulin needs are high in all age groups during the night and morning up to 10 am; also children under 9 years of age need more basal insulin around midnight, suggesting the reversed dawn phenomenon. Data obtained from AID systems can guide physicians to adjust insulin doses for MDI and initiation of conventional pumps.

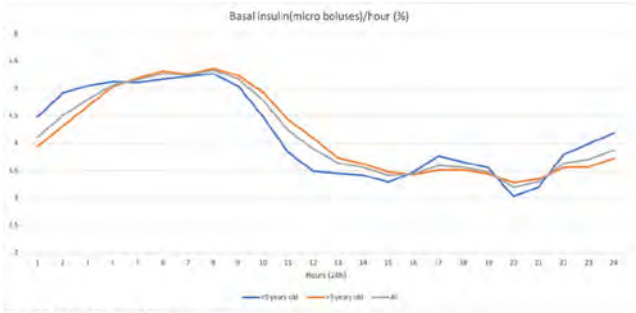

Figure1:Basal insulin/hour(%) for two age groups

Hour Intervals	Basal insulin/hour(%) <9 years (N=11)	Basal insulin/hour(%) >9years (N=23)	p-values
12am-03am	14.04	12.65	0.003*
03-05am	14.91	15	0.913
05-07am	15.14	15.51	0.561
07-10am	14.37	15.20	0.176
10am-5pm	10.31	11.06	0.106
05-07pm	10.51	10.22	0.291
07-09pm	9.08	9.74	0.424
09pm-12am	11.64	10.63	0.026*

Figure2:basal-insulin/hour(%) in time-intervals for two age groups

OP002 / #430

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 1

IMPROVED GLYCAEMIC CONTROL WITH THE MEDTRONIC MINIMED™ 780G ADVANCED HYBRID CLOSED-LOOP SYSTEM IN PEDIATRIC PATIENTS WITH TIPE 1 DIABETES.

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Background and Aims: Glycaemic control in pediatric patients with Type 1 Diabetes (T1D) continues being a challenge. Insulin infusion systems are being developed that optimize and personalize insulin delivery. The Medtronic MiniMed™780G is a new generation closed-loop hybrid system, that automatically adjusts insulin delivery and corrects glucose levels every five

Table 1. Data on glucose control and glycaemic variability before starting treatment with closed-loop system MiniMed™780G and after 6 months (n=28).

	Baseline	6 months MiniMed™780G	p
HbA1c (%)	7,1	6,7	**<0,001**
TIR 70-180 mg/dl (%)	63,4	78	**<0,001**
Time <70 mg/dl (%)	2,9	1,4	**0,004**
Time <54 mg/dl (%)	0,8	0,3	**0,011**
Time >180 mg/dl (%)	25	16,8	**<0,001**
Time >250 mg/dl (%)	7,5	3,5	**<0,001**
Sensor use (%)	94	93,1	0,59
Mean glucose (mg/dl)	158,2	144,5	**<0,001**
SD of glucose (mg/dl)	56	47,1	**<0,001**
CV (%)	46,5	32,5	0,21

minutes to a modifiable target. The aim of the study is to analyse glycaemic control data and glycaemic variability in pediatric patients with T1D after change from their usual treatment to the Medtronic™780G advanced close-loop system.

Methods: This is a prospective study in pediatric patients that begin treatment with the closed-loop system Minimed™780G, from different previous treatments. Data on glucose control and glycemic variability were studied at the beginning and 6 months after treatment.

Results: Twenty-eight patients (15 of them women) with a mean age of 13,5 years were studied. Four patients had previous treatment with MiniMed™640G system (sensor augmented pump with predictive low glucose suspend). The rest of the patients were in treatment with multiple daily injections, 19 of them associated continuous glucose monitoring with DEXCOM™G6 and the other 5 associated flash glucose monitoring with FREESTYLE2™. A statistically significant reduction in HbA1c was observed, as well as an increase in time in range 70-180 mg/dl, a decrease in time in hyperglycemia and a reduction in time of hypoglycemia. An improvement in glycemic variability is also observed. The results of the study are shown in table 1.

Conclusions: The new MiniMed™780G advanced closed-loop system improves metabolic control in pediatric patients with T1D, regardless of previous treatment.

OP003 / #502

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 1

A DUAL-HORMONE ARTIFICIAL PANCREAS IN A PRE-TRIAL VIRTUAL CLINICAL TRIAL

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Background and Aims: Single-hormone closed-loop treatment of type 1 diabetes is becoming more and more common. However, dual-hormone systems are still not available on the market. A dual-hormone artificial pancreas (AP) consists of 1) a continuous glucose monitor, 2) two pumps (one for insulin and one for glucagon) and 3) a control algorithm. The aim of this work is to develop a dual-hormone AP as well as to perform pre-trial in silico tests (of both the closed-loop system and the model identification).

Methods: The AP is based on nonlinear model predictive control (NMPC) and heuristics, and the model is identified using maximum likelihood estimation. In the pre-trial virtual clinical trial, we test the AP in closed-loop simulations of virtual persons. In reality, the AP does not know the true dynamics. Therefore, we generate the virtual individuals from a simulation model that is different from the control model in the AP.

Results: We present the results of closed-loop simulations on virtual persons using the dual-hormone AP as well as model identification. Furthermore, we demonstrate how it can be used to indicate if the system is ready for a real clinical trial. The system achieves time in range (TIR) (3.9 – 10 mmol/L) above the 70% TIR standard of care with a limited number of hypoglycemic events (< 3.9 mmol/L).

Conclusions: The pre-trial virtual clinical trial of the AP shows 1) time in range above the guideline-recommended target, 2) a limited number of hypoglycemic events, and 3) the safety heuristics function as expected and prevent undesired behavior.

OP004 / #521

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 1

IMPLEMENTATION OF FULLY AUTOMATED CLOSED-LOOP INSULIN DELIVERY FOR INPATIENTS WITH DIABETES

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Background and Aims: Inpatient use of fully-automated closed-loop insulin delivery has been shown in randomised clinical trials to be safe and improve glucose control compared with standard insulin therapy. This project investigates the feasibility of implementing the CamAPS HX closed-loop system for inpatients with type 2 diabetes in a tertiary hospital to inform widespread adoption.

Methods: An online training module hosted on the Cambridge Diabetes and Education Program (CDEP) platform was developed, and face-to-face or virtual workshops were used for staff training along with guidelines and policies for out-of-hours escalation. Demographic and glycaemic data were collected using Electronic Patient Records. The project received local approval and was funded by Addenbrooke's Charitable Trust.

Results: Ten healthcare professionals completed the online training module and 29 attended face-to-face or virtual training. In the first 90 days of implementation, 12 inpatients (mean age 63 ± 15 years, 92% male) with complex medical issues on ten wards started closed-loop insulin delivery with a total of 127 days of closed-loop usage. Patients had a mean 57.8 ± 17.1% time in the target range (5.6 to 10.0mmol/L) and 37.9 ± 17.7% time with glucose >10.0mmol/L during closed-loop use. There was 0.1% (0.0, 0.5) time spent in hypoglycaemia (<3.9mmol/L). Mean glucose was 9.7 ± 1.2mmol/L. The median total daily insulin dose was 54 units/day (range 22 to 112 units/day). There were no episodes of severe hypoglycaemia or hyperglycaemic emergencies associated with use of the closed-loop system.

Conclusions: Implementation of fully-automated closed-loop systems in the hospital is feasible and can achieve safe and effective glucose control when delivered by the diabetes outreach team.

OP005 / #636

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 1

FEASIBILITY AND SAFETY STUDY TESTING HYBRID, SEMI AND FULL CLOSED LOOP VERSIONS OF THE AUTOMATED INSULIN SYSTEM DERIVED FROM OPEN SOURCE ANDROIDAPS: PANCREAS4ALL

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Background and Aims: First official random control trial evaluated the feasibility, safety, and efficacy of Pancreas4ALL system derived from open source AndroidAPS in adolescent and young adults in a hybrid, semi and full closed loop version.

Methods: In an open-label randomized crossover study, 16 participants (10 females) on sensor and pump therapy (n = 8) or on an official closed loop (n = 8), with mean age 17 years (range 15-20) and HbA1c 56 mmol/mol (range 43-75) and mean duration of diabetes 9 years (9-15), underwent three 3-day periods in which three different versions of Pancreas4ALL closed loop were compared; hybrid closed loop with premeal boluses (HCL), semi closed loop with meal announcement only (MA) and full closed loop (FCL), MA and FCL in random order. The obtained data were compared with 3-day pre-study period representing usual therapy of participants (UT).

Results: The time spent in hypoglycaemia below 3 mmol/L (HCL-1.05% vs MA-0.63% vs FCL-0.49% vs UT-0.76%; p = 0.16) and between 3 to 3.9 mmol/L (HCL-3.7% vs MA-2.35% vs FCL-1.4% vs UT-2%; p = 0.31) was low and comparable between all interventions and usual therapy. Time spent in target range (TIR) was increased during all three tested versions compared with the usual therapy (HCL-82,88% vs MA-79,85% vs FCL-81,03% vs UT-71%; p = 0.006). However, no significant difference in TIR was found between tested versions and subgroup of UT using official closed loop (p = 0.31). The totally daily insulin dose did not increase during all three interventions(p = 0.9).

Conclusions: Use of Pancreas4ALL in Hybrid, Semi and Full closed loop versions in adolescent/young adults is safe, feasible and efficient.

OP006 / #130

Topic: ***AS03-Artificial Pancreas***

ORAL PRESENTATIONS SESSION 1

PREDICTING 12-MONTH SUCCESS WITH A SECOND-GENERATION HYBRID CLOSED LOOP ARTIFICIAL PANCREAS SYSTEM

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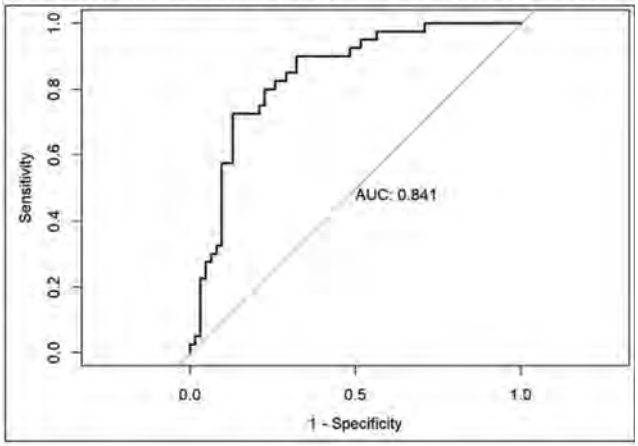
Background and Aims: Hybrid Closed Loop (HCL) systems improve time in range 70-180 mg/dL (TIR) but not all users meet the TIR target of ≥70%. This study developed a model to predict attainment of the consensus TIR target after 12-months of HCL use based on baseline and 1-month data among Tandem Control-IQ (CIQ) users.

Figure. Predictive Model of 12-Month TIR ≥70% for CIQ Users



Term	OR	Standard Error	p-value
Month-1 TIR	1.1397	0.0296	<0.001
Month-1 Meal Boluses	1.1623	0.1215	0.2157
HFS Helplessness/Worry About Low BG Score	1.0630	0.0329	0.0637

Methods: Data from 162 youth (7.6 ± 1.4 yrs., 45.7%F, 7.6% ± 1.4% HbA1c) who began using the CIQ HCL system were included. Lasso model selection was used to develop a predictive model for meeting the TIR goal after 12 months of use. The lasso is a single-step alternative to stepwise selection and includes covariates maximizing area under the curve (AUC) rather than using significance testing. Candidate factors included sex, age, diabetes duration, baseline HbA1c, race/ethnicity, insurance status, history of pump and continuous glucose monitor (CGM) use, and scores on psychosocial questionnaires, as well as percent CGM use, percent TIR, number of meal boluses/day, and percent HCL use at 1-month.

Results: Factors retained in the final model included 1-month TIR, meal boluses/day, and Hypoglycemia Fear Survey Helplessness/Worry About Low Blood Glucose score. The model had very good predictive ability with AUC of 0.84 (Figure). Internal 5-fold cross validation was also very good with an average AUC of 0.803 ± 0.014.

Conclusions: Our prognostic model using clinically accessible baseline, early device-use and psychosocial data can strongly predict users who will meet therapeutic targets with HCL technology. This model may be useful in early identification of barriers so as to promote early intervention prior to behaviors becoming ingrained.

OP007 / #169

Topic: ***AS03-Artificial Pancreas***

ORAL PRESENTATIONS SESSION 1

WHICH CHARACTERISTICS ARE ASSOCIATED WITH ATTAINING AN OPTIMAL GLYCEMIC MANAGEMENT AMONG ADULTS LIVING WITH TYPE 1 DIABETES AND USING AUTOMATED INSULIN DELIVERY SYSTEMS?

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Background and Aims: Automated insulin delivery (AID) systems help people living with type 1 diabetes (T1D) obtain an optimal glycemic management (HbA1c ≤ 7%). However, not every AID user achieved this optimal target. We aim to investigate which characteristics are associated with an optimal glycemic management among adult AID users living with T1D.

Methods: Cross-sectional study using data from the BETTER registry, a registry recruiting participants living with T1D in Quebec, Canada. Inclusion criteria: T1D, aged ≥18 y/o, available HbA1c value and not pregnant. Participants were divided into HbA1c ≤ 7% group and HbA1c > 7% group. Student's t test or chi-square test were used to compare the two groups. Multivariate logistic regression analysis was applied to analyze the associated factors.

Results: The 90 eligible participants (60.0% women) averaged (mean±SD) 43.5 ± 14.5 years old with 26.6 ± 12.5 years of T1D. Comparison between HbA1c ≤ 7% group (N = 44) and HbA1c > 7% group (N = 46) were shown in Table. Logistic regression analysis suggested that participants with bachelor degree or above (OR 4.18, 95%CI 1.45, 12.03) and with shorter duration of pump use (OR 1.12, 95%CI 1.02, 1.23) were more likely to attain an optimal glycemic management when using an AID, after adjusting for age, sex, body mass index and use frequency of AID (Figure).

Conclusions: Special attention should be given to adult AID users who have a lower educational level and a longer duration of pump use.

Table: Characteristics of participants

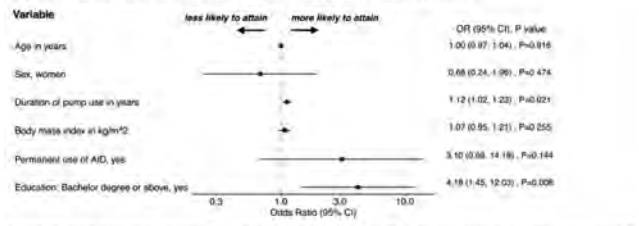
	Total population, (n=90)	HbA1c ≤ 7% group, (n=44)	HbA1c > 7% group, (n=46)	P value
Age in years	43.5±14.5	45.1±13.7	41.9±15.3	0.293
Sex, women	54 (60.0)	26 (59.1)	28 (60.9)	0.863
Ethnicity, Caucasian	86 (95.6)	42 (95.5)	44 (95.7)	1.000
Diabetes duration in years	26.6±12.5	26.9±12.8	26.4±12.3	0.845
Body mass index in kg/m² [a]	26.8±4.7	25.9±3.1	27.8±5.8	0.068
Duration of CGM use in years [b]	2.0 (1.0, 7.0)	2.5 (1.0, 7.0)	1.0 (1.0, 5.0)	0.520
Duration of pump use in years [c]	10.0 (6.0, 14.0)	9.0 (5.0, 13.0)	11.0 (6.3, 15.8)	0.057
Reported diabetes-related complications, yes	33 (36.7)	15 (34.1)	18 (39.1)	0.620
Permanent use of AID system [d], yes	75 (83.3)	40 (90.9)	35 (76.1)	0.089
Annual household income > CA$100,000 [e], yes	37 (46.8)	21 (53.8)	16 (40.0)	0.218
Education: Bachelor degree or above, yes	50 (55.6)	32 (72.7)	18 (39.1)	**0.001**
Employment: full time equivalent [f], yes	66 (73.3)	32 (72.7)	34 (73.9)	0.899
Insurance status				0.129
• Public	12 (13.3)	3 (6.8)	9 (19.6)	
• Private	64 (71.1)	32 (72.7)	32 (69.6)	
• Combined	14 (15.6)	9 (20.5)	5 (10.9)	

Data were presented as mean±SD, median (Q1-Q3) or number (%).

Abbreviation: AID = automated insulin delivery; CGM = continuous glucose monitoring

[a] 5 missing data; [b] 11 missing data; [c] 3 missing data; [d] Permanent use = use at least 75% of the time; [e] 11 missing data; [f] full time equivalent includes participants self-reported as full time, self-employed, students and caregivers.

Figure: Factors associated with an optimal glycemic management



Multivariate logistic regression analysis is performed using variables selected in the bivariate analyses (P < 0.1 and without multicollinearity) as well as age and sex.

Abbreviation: AID = automated insulin delivery;

Permanent use = use at least 75% of the time.

OP008 / #300

Topic: ***AS03-Artificial Pancreas***

ORAL PRESENTATIONS SESSION 1

SUSTAINING IMPROVEMENT IN GLYCEMIC CONTROL FOR YOUTH USING CONTROL-IQ (CIQ) FOR ONE YEAR

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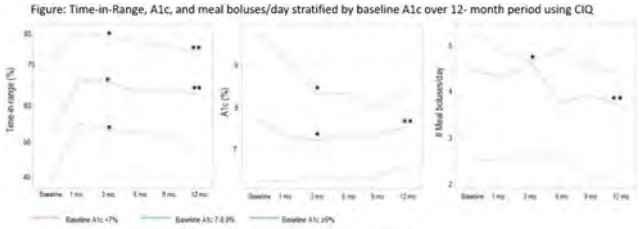
Background and Aims: To investigate the sustainability of glycemic improvements in youth using CIQ for one year

Methods: Youth with T1D starting CIQ enrolled in a observational study, stratified by baseline A1c: low (<7%), middle (7-8.9%), high (≥9%). Linear mixed models were used to compare changes from baseline to month-3 and month-3 to month-12.

Results: One-hundred eight-three youth (13 ± 4 y, 52% M) were enrolled. Baseline TIR was 73 ± 2%, 53 ± 1% and 39 ± 3% for the low, middle,and high groups, respectively, which increased to 79 ± 2%, 67 ± 1% and 53 ± 2% at month-3, p < 0.001 for all (Figure). TIR decreased at month-12 to 74 ± 2% (p = 0.003), 63 ± 1% (p = 0.006) and 49 ± 3% (p = 0.05) respectively. A1c in the high group decreased from 9.8 ± 0.2% at baseline to 8.3 ± 0.2% at month-3 (p < 0.001), with no change at month-12 (p = 0.74). In the middle group, A1c decreased from 7.7 ± 0.1% at baseline to 7.2 ± 0.1% at month-3 (p < 0.001), then increased to 7.5 ± 1.0% at month-12 (p = 0.03). There was no change in A1c in the low group across time (6.3 ± 0.1% to 6.4 ± 0.1%, p = 0.5 to 6.6 ± 0.1%, p = 0.18). Baseline meal boluses/day were 5.3 ± 0.3, 4.5 ± 0.3 and 2.6 ± 0.6 for the low, middle and high groups respectively. Boluses/day decreased to 4.7 ± 0.3 at month 3 (p = 0.02) with no change at month 12 (p = 0.45) in the low group. In the middle group, there was no change at month 3 (p = 0.53), then a decrease to 3.7 ± 0.3 at month 12 (p < 0.001). There was no change in meal bolus frequency for the high group (p = 0.90, 0.21).

Conclusions: Meal bolus frequency is an important factor to achieving glycemic targets with CIQ and sustaining glycemic improvements across time.

Figure: Time-in-Range, A1c, and meal boluses/day stratified by baseline A1c over 12- month period using CIQ



* p<0.05 for the change from baseline to 3-mo **p<0.05 for change from 3-mo. to 12-mo

OP009 / #398

Topic: *AS03-Artificial Pancreas*

ORAL PRESENTATIONS SESSION 1

MEAL ANTICIPATION MAY IMPROVE FULL CLOSED LOOP CONTROL IN ADULTS WITH TYPE 1 DIABETES

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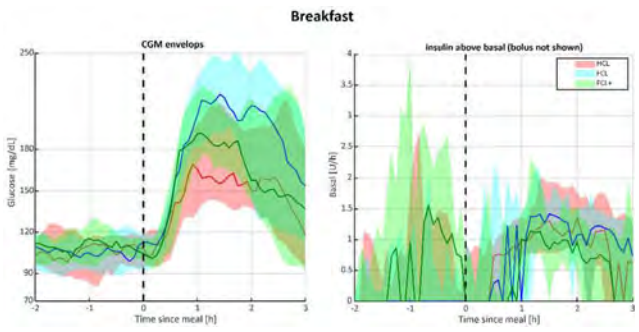
[1]University of Virginia, School Of Medicine, Center For Diabetes Technology, Charlottesville, United States of America, [2]University of Virginia, Department Of Pediatrics, Charlottesville, United States of America, [3]University of Virginia, Division Of Endocrinology, Charlottesville, United States of America

Background and Aims: Hybrid closed-loop (HCL) automated insulin delivery (AID) systems improve glycemic control in people with type 1 diabetes (T1D) but remain largely dependent on announcement and quantification of meals. Full closed loop (FCL) offers to remove this dependency but needs to be clinically validated.

Methods: In a randomized crossover supervised clinical trial of T1D adults, we assess the feasibility of three AID modalities: HCL, FCL, and FCL with anticipation of personalized meal patterns (FCL+). After a 4-week data collection, each modality was tested in random order during three identical 24h periods with standardized meals of different timing: dinner was 90-120min later than usual (per data collection); breakfast occurred as expected; lunch fixed at 1pm. We present an interim analysis (without comparative statistical analysis) of CGM-based outcomes (mean±sd or median[quartiles] as appropriate) overall, 2h-pre-meals, and 5h-post-meal.

Results: 18 adult participants with T1D completed the protocol to date (N = 36 expected at trial end). No serious adverse events were reported. Overall time in range (TIR) was excellent in all modalities (HCL: 86.3 ± 8.2, FCL: 76.9 ± 13.0%, FCL+: 78.1 ± 12.1%), with low time below range (TBR, HCL: 0.7[0-2.8]%, FCL: 0[0-3.8]%, FCL+: 0.8[0-2.1]%). The nominal meal control (breakfast) showed HCL dominating FCL, with FCL+ in between: TIR = 77.6 ± 24.4%, 58.5 ± 25.0%, and 66.3 ± 23.6% respectively; increased insulin delivery pre-breakfast was observed for FCL+ (figure). Delaying meals showed no clear trend towards hypoglycemia, TBR, HCL:0[0-12.5]%, FCL:0[0-0]%, FCL+:0[0-8.3]%.

Conclusions: All modalities provided adequate glycemic control overall in this very controlled environment; meal anticipation appears to be safe and may mitigate some lost postprandial control.



OP010 / #401

Topic: *AS03-Artificial Pancreas*

ORAL PRESENTATIONS SESSION 1

VALIDATION OF A NOVEL MODEL OF GLUCAGON EFFECT INCLUDING GLUCAGON RECEPTOR DYNAMICS

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Background and Aims: Accurate modeling of glucagon effect is essential in dual-hormone artificial pancreas development, both for accurate *in silico* evaluations and the development of model-based control algorithms. Glucagon action models in literature differ significantly among authors and some of them do not provide physiological insight into glucagon behavior. This works aims to propose and validate a model based on glucagon receptors dynamics, which could justify some of the phenomena surrounding glucagon.

Methods: The proposed model was fitted using data from 8 persons with type 1 diabetes. Pharmacokinetic (PK) and pharmacodynamic (PD) related parameters were identified in such a way that the effect of glucagon on endogenous glucose production (EGP) was isolated. In order to provide a more insightful validation, three other models from literature were also fitted to data using the same procedure. A glucose-insulin-glucagon validated model from literature was used as common ground to test the glucagon model structures, only changing the glucagon effect description. This allowed to focus the comparison on the influence of glucagon on EGP.

Results: show that the average root mean square error of the fit with the proposed model was around 6.5 mg/dl. This value was 22.1% lower than the average error obtained with the other model structures.

Conclusions: The glucagon receptor dynamics enables the overall model to successfully fit clinical data. Therefore, this model will be useful in the development and design of dual-hormone artificial pancreas systems, as well as, providing a better understanding of glucagon physiology.

OP011 / #537

Topic: *AS03-Artificial Pancreas*

ORAL PRESENTATIONS SESSION 1

A REINFORCEMENT LEARNING BOLUS CALCULATOR WITH NO MEAL INFORMATION FOR PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: In hybrid artificial pancreas systems (HAPs) insulin boluses are usually calculated based on patient

estimations of the amount of carbohydrates to be ingested. The aim of this study is to calculate the bolus insulin without knowing the patient's carbohydrate intake, thus alleviating the patient's management burden.

Methods: A Q-Learning agent (QLA) was trained to optimize bolus insulin doses for in-silico type 1 diabetic patients. The area under the curve of glucose profile, maximum and minimum glucose values were defined as states. The glucose value before meal was utilized to define the range of bolus values in the action space to restrict the exploration of the QLA in a safe zone.

Results: The algorithm was tested for a cohort of 68 virtual patients and the results were compared to the standard bolus calculator (SBC) in open loop therapy. The results are given as median (interquartile range). A mean glucose value of 153.57 (145.54 - 166.88) vs 154.48 (145.52 - 164.21); $p = 0.0027$, time below range of 0.049 (0.04 - 1.15) vs 1.17 (0.41 - 2.34); $p = 0.000000642$, time in target range of 72.37 (59.99 - 81.94) vs 69.64 (61.56 - 77.40); $p = 0.0096$ and time above range of 1.38 (0.27 - 4.68) vs 1.59 (0.7 - 4.44); $p = 0.645$ were achieved for SBC and QLA respectively.

Conclusions: The reinforcement learning methodology using Q-Learning to compute insulin boluses without information on the amount of carbohydrates in meals showed similar performance as compared to the SBC.

OP012 / #730

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

VIRTUAL ORAL PRESENTATIONS SESSION 1

ALGORITHM-DRIVEN BASAL-BOLUS THERAPY IN HOSPITALIZED PATIENTS WITH TYPE 2 DIABETES: IMPLICATIONS FOR DISCHARGE THERAPY

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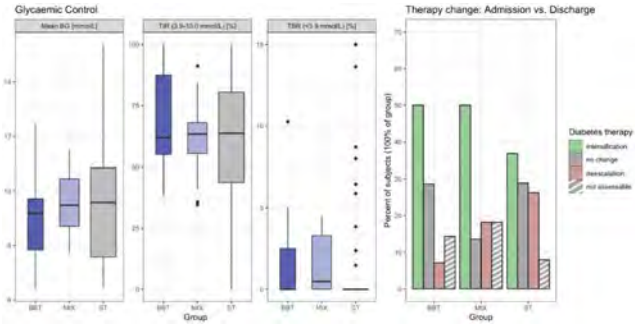
[1]Medical University of Graz, Division Of Endocrinology And Diabetology, Graz, Austria, [2]decide Clinical Software GmbH, -, Graz, Austria

Background and Aims: Diabetes therapy in hospitalized patients with type 2 diabetes (T2D) often fails to improve glycemic control during inpatient stay and beyond. To facilitate inpatient basal-bolus insulin therapy (BBT), an algorithm-based decision support system (GlucoTab®, decide Clinical Software GmbH, Graz, Austria) was developed.

Methods: This retrospective analysis included T2D patients treated during a 6-month-period at a general internal medicine ward. Patients with algorithm-driven BBT throughout the whole inpatient stay (BBT-group) were compared to patients who received a mix (MIX-group) and those with 100% standard therapy (ST-group) provided by physicians. Outcomes included mean blood glucose (MBG), measurements in target range (TIR: 3.9-10.0 mmol/L) and below (TBR: <3.9 mmol/L), and changes in discharge vs. baseline therapy evaluated by three independent assessors.

Results: 74 patients with T2D (age: 74.0 ± 12.5 years, female: 37.8%, Caucasian: 98.6%, diabetes duration: 15.0 ± 10.7 years, BMI: 28.9 ± 5.6 kg/m^2, HbA1c: 70.0 ± 24.0 mmol/mol, stay length: 9.6 ± 5.7 days) distributed as followed: 14 BBT-group, 22 MIX-group, 38 ST-group. MBG [mmol/L] was 9.1 ± 1.8 vs. 9.6 ± 1.1 vs. 9.5 ± 2.2, respectively. TIR [%] was highest in the BBT-group (67.6 ± 21.1 vs. 62.0 ± 15.4 vs. 62.0 ± 25.4). TBR [%] was comparable in all groups (1.6 ± 3.0 vs 1.5 ± 1.8 vs. 1.7 ± 3.8). Discharge therapy compared to baseline showed higher rates of intensification in BBT- and MIX-groups compared to ST-group (50% vs. 50% vs. 36.8%). De-escalation of therapy occurred in 7.1%, 18.2% and 26.3%, respectively.



Conclusions: This preliminary analysis in hospitalized patients with T2D indicates that algorithm-driven BBT may lead to enhanced glycemic control and a higher rate of necessary therapy adjustments at discharge.

OP013 / #92

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

VIRTUAL ORAL PRESENTATIONS SESSION 1

PREDICTING THE RISK OF NOCTURNAL HYPOGLYCEMIA AT BEDTIME FOR INSULIN-TREATED PEOPLE WITH TYPE 2 DIABETES

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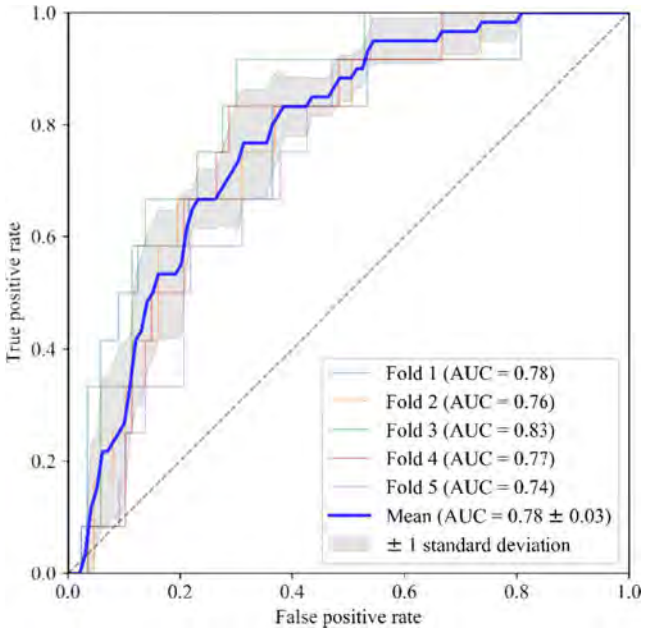
Background and Aims: Undetected nocturnal hypoglycemia is a problem in insulin-treated people with T2D that can lead to hypoglycemia unawareness and anxiety. The aim was to develop a prediction algorithm to warn people at risk at bedtime.

Methods: CGM data was collected from 67 insulin-treated people with T2D (NCT01819129). Data was structured into 24-hour periods and labelled as nocturnal hypoglycemia or not depending on whether fifteen consecutive minutes were spent below 3.0 mmol/L during the following night (00.01-05.59). The periods were divided into 'last night' (00.01-05.59), 'morning' (06.00-09.00), 'day' (06.00-00.00), and 'evening' (21.00-00.00) for predictor extraction. Periods were required below 20% missing data in each interval, and people without periods with nocturnal hypoglycemia were excluded. The minimum value, maximum value, range, slope (linear regression), glycemic variability percentage, standard deviation, variance, and mean were extracted for each interval as potential predictors. A relative variant for each predictor was calculated by subtracting the mean of previous periods, resulting in 64 potential predictors. Forward selection was used to select informative predictors, and a logistic



regression model was trained and validated using 5-fold cross-validation to predict 24-hour periods resulting in nocturnal hypoglycemia.

Results: Preprocessing identified 30 patients with 60/496 periods resulting in nocturnal hypoglycemia. Forward selection revealed that the optimal predictor combination was minimum value (evening), minimum value (day), mean (evening), and relative maximum value (day), which provided an averaged area under the receiver operating characteristics curve of 0.78 ($p < 0.001$) (Figure 1).

Conclusions: The algorithm was able to predict 24-hour periods resulting in nocturnal hypoglycemia and could prevent such cases.

OP014 / #379

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

VIRTUAL ORAL PRESENTATIONS SESSION 1

VALIDATION OF FEAR OF HYPOGLYCEMIA SCREENER: RESULTS FROM THE T1D EXCHANGE REGISTRY

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Background and Aims: To examine reliability and validity of a newly developed fear of hypoglycemia (FoH) screener as a practical and actionable tool for in-clinic use in adults with type 1 diabetes (T1D).

Methods: Adults with T1D recruited from T1D Exchange Registry completed draft screener online; screener items were developed from literature review, interviews with health care professionals (HCPs) and people with T1D. Psychometric analyses assessed reliability and validity of screener. Final FoH screener comprised 9-items assessing 2-domains – ''worry'' (6-items); ''behavior'' (3-items).

Results: 592 adults with T1D participated (age 43.1 ± 15.3years; T1D duration 24.1 ± 15years, 66.7% females, 91.6% White, 5.2% Hispanic, self-reported HbA1c 7.1% ± 1.2%). 30% participants reported severe hypoglycemia in the past 12-months; 33.4% reported impaired awareness of hypoglycemia. FoH screener showed internal consistency (Cronbach's $\alpha = 0.88$); reliability - highly correlated ($r = 0.71–0.75$) with Hypoglycemia Fear Survey (''worry'' and ''behavior'' subscales and total scores); construct validity - significant correlations with depression($r = 0.44$), anxiety($r = 0.47$), Diabetes Distress Subscales (powerlessness, management-distress, hypoglycemia-distress) ($r = 0.49–0.66$); Multivariable regression analysis showed higher FoH screener scores were significantly associated with higher HbA1c (regression coefficient, $\beta = 0.04$); with multi-morbidities ($\beta = 0.03$).

Conclusions: 9-item FoH screener demonstrated good reliability and validity. Further research is planned to assess clinical usability to help identify patients and assist effective HCP-patient conversations around FoH, in accordance with ADA's position on psychosocial care.

Acknowledgment: Authors thank Dr. Wendy Wolf (T1D Exchange,Boston,MA) for managerial support and oversight for this research, Ludi Fan (Eli Lilly and Company) for critical review of abstract and Uma Jyothi Kommoju (Eli Lilly and Company) for medical writing support of abstract.

OP015 / #357

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

VIRTUAL ORAL PRESENTATIONS SESSION 1

CLASSIFICATION OF DAILY CGM PROFILES AND ITS CLINICAL INTERPRETATION

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Background and Aims: We have demonstrated that the multitude of daily CGM profiles can be approximated by a fixed set of 483 ''archetype'' profiles called motifs. We continue this work by classifying all motifs into clinically-similar clusters (CSCs).

Methods: The motifs were hierarchically clustered into 33 CSCs such that motifs within each CSC have similar times below, within, and above the target range (TBR, TIR, TAR). The distinct motifs within each CSC define the ways a CGM trace can result in the same combination of TBR, TIR, and TAR. This two-step process (classify the daily CGM profile as a motif and identify the associated CSC) was applied to 180,794 daily CGM profiles generated by 2,180 subjects from 16 different studies.

Results: Clinical states, e.g. healthy, type 1 and type 2 diabetes (T1D, T2D), and treatment modalities of T1D (multiple daily injections [MDI], insulin pump, and closed-loop control

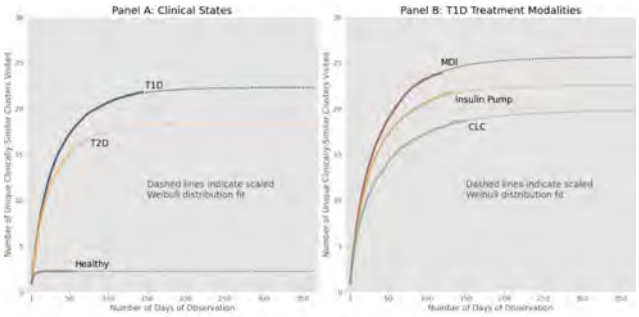
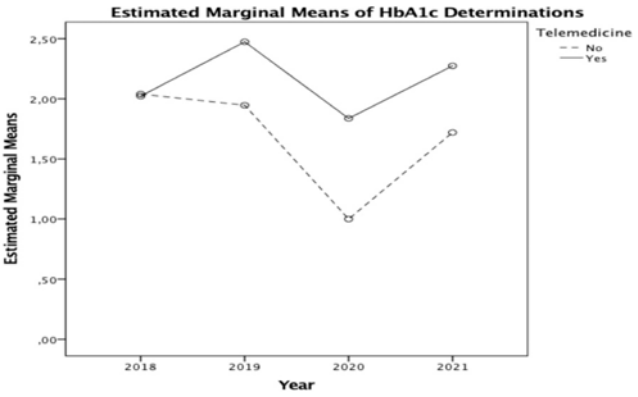


Figure 1: Panel A: Mean progression of CSCs visited over time in health, T2D, and T1D. Panel B: Mean progression of CSCs visited over time for different T1D treatment modalities: multiple daily injections (MDI), insulin pump, or closed-loop control (CLC). Higher number of visited CRCs indicates more volatile glycemic control.



[CLC]) were clearly differentiated by the progression of CSCs: Figure 1 presents the mean number of unique CSCs visited over time for different clinical states (Panel A) and different treatment modalities (Panel B). These progressions are closely approximated by scaled Weibull distributions, which has significant pattern-recognition implications.

Conclusions: A two-step procedure which first classifies a daily CGM profile as a motif (preserving the temporal structure of the data) and then identifies the associated CSC (representing glycemic control), clearly distinguishes CGM traces in health, T2D, T1D, and different treatments of T1D. We emphasize that both the motif and CSC sets are fixed, validated, and applicable to any data without modification.

OP016 / #720

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

VIRTUAL ORAL PRESENTATIONS SESSION 1

HBA1C DETERMINATIONS ACCORDING TO TELEMEDICINE ACCESS PRE AND POST LOCKDOWN IN LATIN AMERICAN CHILDREN WITH TYPE 1 DIABETES

V. Hirschler[1], C. Molinari[2], J. Pelicand[3], A. Figueroa Sobrero[4], P. Pinto Ibárcena[5], C. Del Aguila Villar[6], E. Scaiola[7], P. Bocco[8], D. Gonzalez[9], A. Mac[9], C. Ramirez Trillo[4], S. Lapertosa[10], C. Gonzalez[11]

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Background and Aims: To measure the changes in the number of hemoglobin A1c (HbA1c) determinations during 2020 lockdown compared with the previous two years (2018, 2019) and post-lockdown (2021) in Latin American children with T1DM with and without telemedicine access.

Methods: This is a multinational study of children with T1DM from three Latin American countries. The number of HbA1c determinations between 2018 and 2021 was extracted from patients' records.

Results: 217 children (60.4% F) aged 13.1 ± 3.2 years with a duration of 5.4 ± 2.7 years of T1DM in 2018 were evaluated. There was a higher prevalence of children with telemedicine access than those without (139(64.1%) vs. 78(35.9%); $p < 0.01$). Except for 2018, the number of HbA1c determinations was higher in children with telemedicine access than in those without (2.47 vs.1.95 in 2019, 1.84 vs. 1.00 in 2020, and 2.27 vs.1.72 in 2021, $p < 0.01$, respectively). The number of HbA1c determinations returned to similar values to 2018 during post-lockdown 2021 in children with telemedicine access (2.02 in 2018 vs.1.84 in 2020 vs. 2.27 in 2021) but did not return to previous values in those without access (2.04 in 2018 vs. 1.00 in 2020 vs.1.72 in 2021) (Figure).

Conclusions: During lockdown 2020, children with T1DM with telemedicine access had a significantly higher number of HbA1c determinations than those without access. Furthermore, the number of HbA1c determinations of Latin American children with T1DM during post-lockdown 2021 returned to similar values to 2018 in children with telemedicine access, but not in those without.

OP017 / #285

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

VIRTUAL ORAL PRESENTATIONS SESSION 1

EFFECTIVENESS OF MY DOSE COACH (MDC) USE DURING BASAL INSULIN (BI) TITRATION IN TYPE 2 DIABETES (T2D): REAL-WORLD DATA FROM ALGERIA, COLOMBIA, INDIA AND MEXICO

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[1]M.V. Hospital for Diabetes, Internal Medicine, Chennai, India, [2]Chellaram Diabetes Institute, Endocrinology, Pune, India, [3]Sanofi, Real World Evidence Generation, Digital Rwe,

Bridgewater, United States of America, [4]Sanofi, General Medicines, Bridgewater, United States of America, [5]Clinica Integral de Diabetes-CLID, Internal Medicine And Endocrinology, Medellín, Colombia, [6]Universidad Autonoma de Nuevo Leon, Endocrinology Division, Medical School And University Hospital, Nuevo Leon, Mexico, [7]Mustapha Pacha Hospital Algiers, Diabetes Department, Algiers, Algeria

Background and Aims: This retrospective cohort study evaluated the effectiveness of MDC, an FDA-approved BI dose titration app, use with BI on clinical outcomes.

Methods: People with T2D on BI therapy, who registered from 01/08/2018 through 30/09/2021 and recorded ≥2 fasting blood glucose (FBG) readings in the MDC app over a 2-week period were included in this analysis. FBG target achievement (≥3 consecutive measurements within the target range), change in FBG, and hypoglycemia (readings below HCP-defined cut-off per dose plan) were assessed.

Results: A total of 5,566 MDC users (Algeria, 881; Colombia, 505; India, 2,597; and Mexico, 1,583) with mean (SD) age 54.7 (13.8) years (∼50% female) were included. Overall, 3,097 (55.6%) achieved individualized FBG target and mean time to reach target was 15.6 days. The proportion of patients achieving FBG target was highest in Columbia (81.0%) and lowest in India (39.9%). Mean FBG decreased by 36.4 mg/dL (∼22%), and mean BI dose increased by 4 U (21.7%). The initial FBG value and FBG mean reduction were highest in India; whereas mean BI dose (U) increase was highest in Mexico. Hypoglycemia events were reported in 783 (14%) participants overall. Incidence of hypoglycemia was comparable across countries (**Table**).

Conclusions: More than 50% of the MDC users were able to successfully titrate their BI and achieve target FBG, demonstrating the potential application of MDC during insulin titration to improve diabetes management particularly in a resource-limited setting.

Table: Clinical outcome in MDC application users

	All Patients (N = 5,566)	Algeria (N = 881)	Colombia (N = 505)	India (N = 2,597)	Mexico (N = 1,583)
Reaching FBG Target					
Proportion reach Target, n (%)	3,097 (55.6)	612 (69.4)	409 (81.0)	1,036 (39.9)	1,040 (65.7)
Time to FBG Target (days), mean (SD)	15.6 (23.3)	14.3 (19.8)	10.3 (15.8)	19.4 (28.4)	14.6 (21.3)
FBG outcome (mg/dL)					
First FBG reading, mean (SD)	165.6 (71.1)	143.0 (53.4)	141.7 (55.0)	183.2 (75.2)	157.0 (70.2)
FBG change, mean (SD)	−36.4 (69.1)	−22.7 (54.5)	−24.4 (51.5)	−47.9 (75.8)	−29.1 (66.6)
Insulin dose outcome (U)					
Initial dose, mean (SD)	18.9 (9.5)	17.9 (9.9)	22.2 (11.3)	17.1 (7.5)	21.5 (10.8)
Dose change, mean (SD)	4.0 (14.5)	4.4 (17.0)	1.8 (6.4)	3.9 (16.5)	4.6 (11.1)
Hypoglycemia events					
Patients with ≥1 hypoglycemia, n (%)	783 (14.0)	205 (23.0)	72 (14.0)	379 (15.0)	127 (8.0)
Time to first hypoglycemia (days), mean (SD)	11.6 (17.9)	10.1 (15.6)	6.2 (8.0)	12.2 (16.9)	15.6 (25.6)
Number of hypoglycemia events/patient*, mean (SD)	2.5 (2.8)	2.8 (3.2)	2.7 (2.7)	2.5 (2.8)	2.0 (1.7)

*Number of hypoglycemia events/patient among those who experienced ≥1 hypoglycemia event.
FBG, fasting blood glucose; MDC, My Dose Coach; SD, standard deviation; U, units.

OP018 / #460

Topic: ***AS14-Human factor in the use of diabetes technology***

VIRTUAL ORAL PRESENTATIONS SESSION 1

DEFAULT HIGH AND LOW ALERT SETTINGS AND ACTIVATION FREQUENCIES AMONG NOVICE CGM USERS

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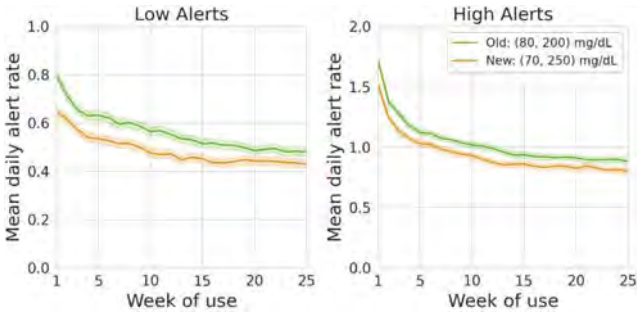
Background and Aims: Real-time CGM systems have configurable alerts for hypoglycemia and hyperglycemia. We examined alert activation frequencies and their associations with default settings for novice users of the Dexcom G6 CGM System.

Methods: A recent G6 software update changed the default (low, high) alert thresholds from (80, 200) to (70, 250) mg/dL, resulting in a wider range of non-alerting glucose levels for later adopters. The Dexcom customer database provided two anonymized cohorts of US-based users who installed the G6 app and began uploading data from iOS devices before or after the index date of 11-MAR-2020. Glycemia and frequency of alert activations were monitored for the first 180 days of use.

Results: The (80, 200) and (70, 250) cohorts (n = 10,306 and n = 9,154, respectively) were well-matched with respect to baseline attributes. Cohorts had similar TIR, TAR, TBR, and mean glucose levels ($p > 0.1$). Low alerts were less frequent than high alerts, both alert frequencies decreased with time, and the (80, 200) cohort experienced consistently more alerts than the (70, 250) cohort (Figure). Users in the (70, 250) cohort were less likely to adjust their settings than users in the (80, 200) cohort ($p < 0.001$).

Conclusions: Onboarding novice CGM users with the wider range of non-alerting glucose values implemented in the most recent software resulted in fewer alerts for hypoglycemia and hyperglycemia, with no detriment to glycemic control.



OP019 / #349

Topic: ***AS05-Glucose Sensors***

VIRTUAL ORAL PRESENTATIONS SESSION 2

SENSOR-DETECTED HYPOGLYCAEMIA IN SHORT-DURATION CGM DATA FROM MULTIPLE CLINICAL TRIALS IN DIABETES. PRELIMINARY RESULTS FROM THE HYPO-RESOLVE DATABASE.

P. Baumann[1], M. Cigler[1], D. Kuznetsov[2], M. Rosilio[3], D. Hochfellner[1], M. Ibberson[2], S. Amiel[4], S. Heller[5], M.-A. Gall[6], B. De Galan[7], T. Pieber[8], P. Choudhary[4,9], J. Mader[8]

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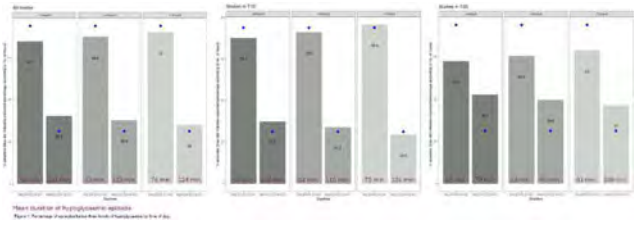
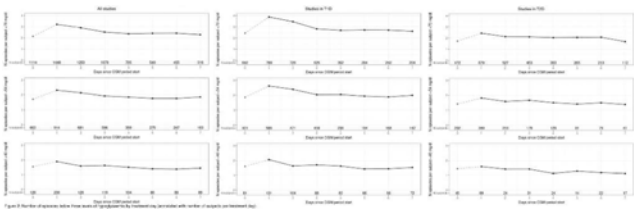
Background and Aims: Compared to time below range less is known about the frequency and temporal distribution of hypoglycaemic episodes in CGM data. Pooled analysis of multiple clinical trials from the Hypo-RESOLVE (Hypoglycaemia - REdefining SOLutions for better liVEs) database allows for large-scale exploration of sensor-detected hypoglycaemia (SDH).

Methods: We identified 15 studies (7 in T1D) with short-duration (<40 days) CGM (2165 participants, 45% with T1D). We explored frequency of SDH lasting ≥15 minutes on different levels (<70, <54, <40 mg/dl) by time of day and sensor runtime and glycaemic control by clock time.

Results: While nighttime accounts for 25% of hours in a day (0-6 am), we found 32% of SDH <40, 30% of SDH <54 and 28% of SDH <70 there (figure 1). This pattern was more pronounced in T2D (42, 40, 37%, respectively) than in T1D (30, 27, 24%, respectively). The number of daily SDH episodes <70 mg/dl and <54 mg/dl dropped after the first days and stabilized over sensor runtime while readings <40 mg/dl had less variability (figure 2). The drop was more pronounced in T1D while in T2D the curve over time was flatter for all SHD levels. Analysis by clock time showed tighter glycaemic control for T2D and a surplus of very low readings <40mg/dl for T1D (figure 3).

Conclusions: Further research will aim at explaining the detected patterns in SDH. This will provide people using CGM systems (including people living with diabetes, healthcare professionals as well as researchers and health authorities) with a benchmark of expectable patterns of hypoglycaemia in CGM data.





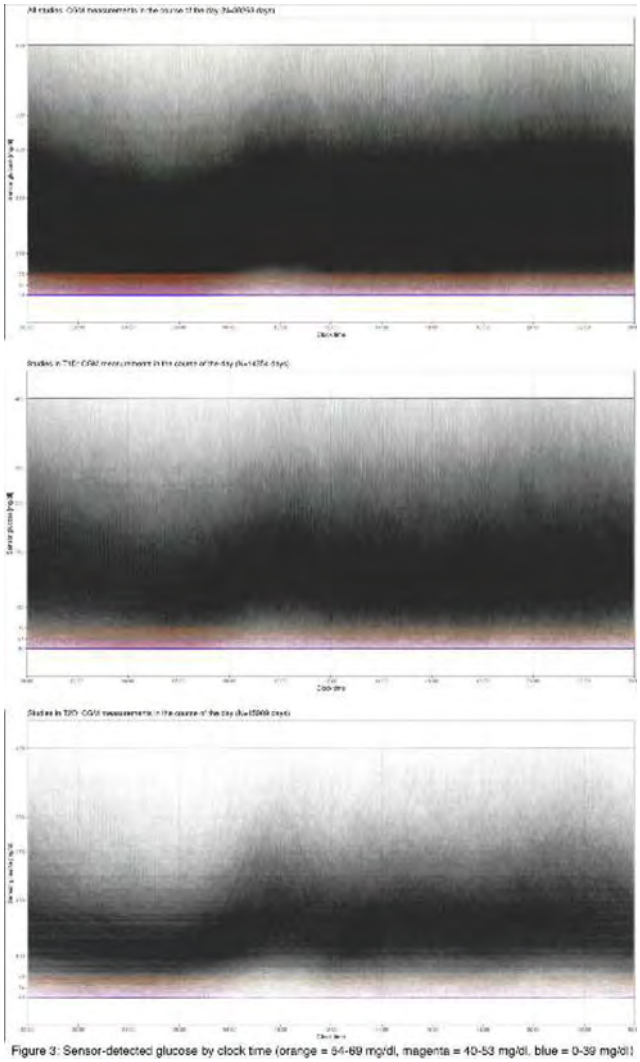


Figure 3: Sensor-detected glucose by clock time (orange = 54-69 mg/dl, magenta = 40-53 mg/dl, blue = 0-39 mg/dl)

OP020 / #766

Topic: ***AS05-Glucose Sensors***

VIRTUAL ORAL PRESENTATIONS SESSION 2

COST-EFFECTIVENESS OF A REAL-TIME CONTINUOUS GLUCOSE MONITORING SYSTEM VERSUS SELF-MONITORING OF BLOOD GLUCOSE IN TYPE 2 DIABETES PATIENTS ON INSULIN IN THE UNITED KINGDOM

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Background and Aims: A long-term health economic analysis was conducted to determine the cost-effectiveness of a real-time continuous glucose monitoring (rt-CGM) system versus

self-monitoring of blood glucose (SMBG) in Type 2 diabetes (T2D) patients treated with insulin.

Methods: The IQVIA CORE diabetes model was used for the analysis. Clinical data were sourced from a US retrospective cohort study of adult T2D patients on insulin and adapted to the UK. The baseline mean age (SD) of the cohort was 61 years (13.2) and proportion of female 51%. Mean baseline HbA1c for the cohort was 8.3% (67 mmol/mol). Patients using rt-CGM were assumed to have a reduction in HbA1c of -0.56% based on the mean difference between groups after 12-months follow-up. A quality-of-life (QoL) benefit associated with reduced finger-stick testing was applied. The analysis was conducted from the UK National Health Service payer perspective over a lifetime horizon.

Results: The rt-CGM system was associated with an incremental gain of 0.76 quality-adjusted life years (QALYs) compared with SMBG (mean [SD] 8.44 [2.26] versus 7.68 [2.10] QALYs). Total mean [SD] lifetime costs were GBP 2,551 higher with rt-CGM (GBP 78,801 [45,749] versus 76,250 [49,564]), resulting in an incremental cost-effectiveness ratio of GBP 3,348 per QALY gained. Sensitivity analyses demonstrated findings were sensitive to changes in QoL, HbA1c, and younger patient cohorts.

Conclusions: For T2D patients on insulin, rt-CGM was associated with significant clinical outcomes and is a cost-effective management option relative to SMBG based on a willingness-to-pay threshold of GBP 20,000 per QALY gained.

Table 1: Patient characteristics by CGM use status

	rtCGM N=13,376	isCGM N=1,006	SMBG N=7,543	P-value
Age, yrs Mean(SD)	19 (12)	15 (9)	18 (10)	<0.001
Age category,yrs - n(%)				<0.001
2-12	3707 (28)	351 (35)	1526 (20)	
12-26	7496 (56)	605 (60)	5438 (73)	
27-54	1752 (13)	34 (3)	385 (5)	
54-95	395 (3)	15 (2)	168 (2)	
Sex-n(%) Male	6733 (50)	522 (52)	4018 (53)	<0.001
Race-n(%)				<0.001
White	9704 (73)	831 (83)	5225 (69)	
Black	612 (4)	52 (5)	930 (12)	
Hispanic	1314 (10)	71 (7)	522 (7)	
Asian	1744 (13)	52 (5)	854 (11)	
Insurance-n(%)*				
Private	9393 (73)	880 (90)	2153 (51)	<0.001
Public	3107 (24)	37 (4)	1990 (47)	
A1c,%				<0.001
Median (IQR)	7.9 (2.1)	8.5 (2.2)	8.7 (2.9)	
Mean (SD)	8.2 (1.8)	8.8 (1.7)	9.1 (2.2)	
DKA-n(%)	262 (2)	50 (4)	707 (9)	<0.001
SH-n(%)	154 (1)	21 (2)	279 (4)	<0.001

OP021 / #143

Topic: ***AS05-Glucose Sensors***

VIRTUAL ORAL PRESENTATIONS SESSION 2

COMPARATIVE EFFICACY OF ISCGM, RTCGM, AND SMBG AMONG PATIENTS WITH TYPE 1 DIABETES: REAL-WORLD EVIDENCE FROM A MULTI-CENTER STUDY

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Background and Aims: Management of type 1 diabetes (T1D) involves consistent glucose monitoring to avoid acute complications. The use of real-time continuous glucose monitors (rtCGM) or intermittently scanning CGM (isCGM) relative to self-monitoring of blood glucose (SMBG) via fingerstick has aided in increasing the number of individuals with T1D reaching glycemic targets. This study aims to compare rtCGM, isCGM, and SMBG groups using real-world data from T1D patients in a large U.S.-based multi-center study.

Methods: Electronic health record data from the T1D Exchange Quality Improvement (T1DX-QI) Collaborative from 2017-2020 from # sites were analyzed. Patients with complete information on HbA1c, CGM status, and other covariates were included in this analysis. In addition, patients were classified as rtCGM, isCGM, or SMBG users based on their most recent clinic visit data.

Results: This analysis included 21,925 people living with T1D, 2-26 years old, of which 61% were rtCGM users, 5% were isCGM users, and 34% self-monitored blood glucose. Patients in the rtCGM and isCGM group were more likely to be privately insured (73% and 90%) and Non-Hispanic White (73% and 83%) compared to the SMBG group (51% and 69%)[$p < 0.001$ for both]. HbA1c levels and DKA events were lowest in the rtCGM group relative to isCGM and SMBG groups (Median A1c % (IQR): 7.9 (2.1) vs. 8.5(2.2) and 8.7 (2.9); $p < 0.001$, and DKA events (%): 2% vs. 4% and 9%; $p < 0.001$).

Conclusions: This real-world cross-sectional study demonstrates potential benefits of rtCGM relative to isCGM and SMBG in achieving better glycemic outcomes among people with T1D.

OP022 / #227

Topic: ***AS05-Glucose Sensors***

VIRTUAL ORAL PRESENTATIONS SESSION 2

INEQUITIES IN DIABETES DEVICE USE: T1D EXCHANGE BASELINE TREND ANALYSIS

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Background and Aims: Multiple cross-sectional studies have demonstrated lower use of Continuous Glucose Monitors (CGM) in Non-Hispanic Black (NHB) and Hispanic patients with Type 1 diabetes(T1D). This study is a multicenter trend analysis of ethnic and racial disparities in CGM use

Methods: The T1D Exchange Quality Improvement Collaborative (T1Dx-QI) identified four endocrinology centers from the learning network to pilot an equity-focused Quality Improvement study to address disparities in CGM use amongst NHB and Hispanic compared to Non-Hispanic White (NHW) patients. Retrospective aggregate data from the Electronic Medical Record was reported monthly to the coordinating center. The data were stratified by race and ethnicity. Median values were calculated using Lahey P run charts between Nov 2020 and June 2021. Data were analyzed and plotted on a trend chart

Results: The baseline data from participating clinics show a stable trend (p-value <0.001). The median CGM use was 58% amongst NHW patients, 49% among NHB patients, and 48% among Hispanic patients. The difference in the median between NHW and NHB patients is 9% and the difference between NHW and Hispanic patients is 10%

Conclusions: Baseline analysis of the participating sites in CGM use demonstrates fixed and persistent inequity in CGM use between NHW, NHB, and Hispanic patients. The inequities trend is projected to continue except systemic changes are employed. The T1Dx-QI developed a QI Equity Framework and she is using this with the participating centers to develop and scale interventions that address disparities for Non-Hispanic Black and Hispanic patients with T1D.

OP023 / #296

Topic: ***AS05-Glucose Sensors***

VIRTUAL ORAL PRESENTATIONS SESSION 2

A TOOL NOT A TREATMENT: THE EFFECT OF LONG-TERM CONTINUOUS/FLASH GLUCOSE MONITORING ON REAL-WORLD HYPOGLYCEMIA RATES (INPHORM STUDY)

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Background and Aims: Little is known about the effect of long-term continuous/flash glucose monitoring (C/FGM) on hypoglycemia rates in the real world.

Methods: Online baseline data were obtained from a real-world panel of Americans (≥18 years old) with T1DM or T2DM taking insulin and/or secretagogues. Multivariable negative binomial regression was conducted to isolate the total effect of ≥1 year C/FGM use on self-reported, past-month non-severe and past-year severe hypoglycemia (NSH, SH). Confounding variables were identified from a directed acyclic graph.

Results: A complete case analysis was performed on 1,412 baseline responders (T1DM: 18.27%, age: 49.48 (SD: 14.16) years, male: 48.30%). One in ten (T1DM: 27.13%; T2DM: 7.28%) reported using a C/FGM device for ≥1-year preceding baseline. Overall, the crude rate of NSH and SH was 4.41 (95% CI: 4.30-4.52) events per person-month (EPPM) and 2.68 (95% CI: 2.60-2.77) events per person-year (EPPY), respectively. Those who used a C/FGM device for ≥1 year experienced 9.05 (95% CI: 8.58-9.54) non-severe EPPM and 5.63 (95% CI: 5.26-6.02) severe EPPY. Controlling for confounding, ≥1-year CGM users, versus non-C/FGM users, reported twice the number of past-year SH (2.05 [95% CI: 1.38-3.05, $P < 0.001$]) and past-month NSH (2.02 [95% CI: 1.64-2.48, $P < 0.001$]). Similar effects were observed among <1-year C/FGM users versus non-C/FGM users.

Conclusions: C/FGM can be a valuable tool to help detect and manage hypoglycemia; but, in and of itself, it is not a preventative treatment. Ongoing, vigilant clinical care of C/FGM users is still required to achieve hypoglycemia reduction in the real world.

OP024 / #443

Topic: ***AS05-Glucose Sensors***

VIRTUAL ORAL PRESENTATIONS SESSION 2

NOVEL APPROACH OF DAY-1 PERFORMANCE IMPROVEMENT OF AN AMPEROMETRIC GLUCOSE SENSOR BY ACCELERATING SENSOR READINESS DURING WARM-UP PERIOD

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Background and Aims: WaveForm has commercialized the Cascade CGM, an electrochemical, trocar-less CGM system for people with diabetes. Accelerating sensor readiness during the initial warm-up phase and up to 48 hours has been recognized as important aspect of improving the performance of the amperometric sensor on day 1. The feasibility of using a specific voltage modulation pattern over the initial warm-up period was assessed in non-diabetic animal model (porcine) and humans.

Methods: Several sensors were inserted in anesthetized Yucatan-mini pigs. During the initial warm-up phase of 60 minutes the bias voltage was modulated. Then after a consistent current was obtained, the system was operated at s steady state bias potential. After about 3 hours the glucose level was elevated by infusion of saline containing 20% dextrose. Blood glucose samples by ear prick were taken every 10 min for a total of 4 hours. The current response of sensors with and without bias modulation was compared. Sensor accuracy was retrospectively assessed. Initial assessment of this approach was performed in a human study.

Results: In animals MARD was significantly improved during the initial 4 hours in sensors being conditioning by bias modulation (11.7%) over sensors treated with steady-bias voltage at 650 mV (19.5%, p<<0.05). Preliminary MARD of 12.5% observed in sensors with bias modulation worn by human subjects over 48 hours confirmed this result.

Conclusions: The feasibility of specific bias modulation during warm-up time of an amperometric sensor was demonstrated. We will report on the results from a currently ongoing clinical trial in humans with diabetes at the meeting.

OP025 / #564

Topic: ***AS05-Glucose Sensors***

VIRTUAL ORAL PRESENTATIONS SESSION 2

REAL WORLD TIME BELOW RANGE RELATED TO GLUCOSE VARIABILITY MEASURED BY EITHER TOTAL OR WITHIN-DAY COEFFICIENT OF VARIATION

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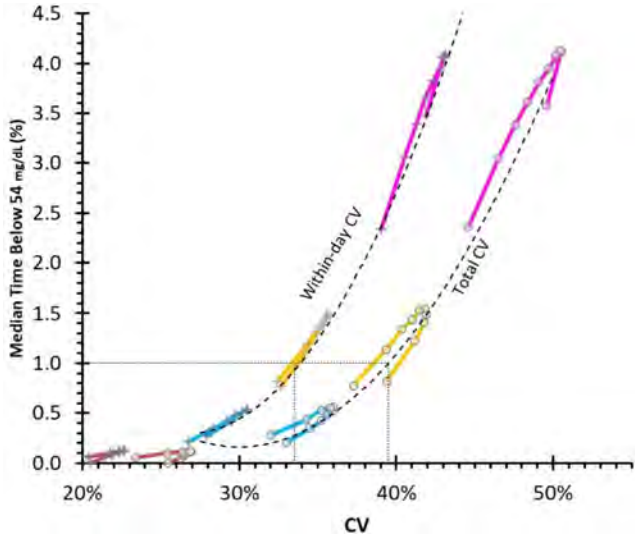
Background and Aims: To contrast the total and within-day coefficient of variation for glucose (CV) thresholds to guide clinical assessment of glucose variability and hypoglycemic exposure.

Methods: De-identified data provided glucose readings from 1,002,946 flash glucose monitor users. The total and within-day CV and daily scan rate for each reader were found. Readers were grouped by ten equal groups of scan rate, then quartile groups by t-CV and wd-CV were found, for 25,074 readers per group. The association of glucose variability and time below range (TBR) was examined by median time below 54 mg/dL and t-CV and wd-CV.

Results: The association of glucose variability and hypoglycemia was examined as shown in Figure 1. As expected, the wd-CV is always less than the t-CV at any given level of hypoglycemia exposure. Both wd-CV and t-CV were associated with time below 54 mg/dL. In order to achieve the consensus target of <1% time below 54 mg/dL, the associated wd-CV and t-CV values are 33.5% and 39.5%, respectively.



Conclusions: Health care professionals should be aware of the type of CV reported by the different CGM systems. To our knowledge, the CV calculated in the majority of CGM reports is the t-CV. Then, appropriate thresholds should be used to identify patients likely to meet TBR targets (t-CV <39.5% or wd-CV <33.5%). Figure 1: Association of glucose time below 54 mg/dL and glucose variability measured by t-CV and wd-CV. Quartile groups of wd-CV (cross signs) and Total CV (open circles, red = lowest, magenta = highest). N = 1,002,946 readers, each point is 25,074 readers.

OP026 / #321

Topic: ***AS15-Trials in progress***

VIRTUAL ORAL PRESENTATIONS SESSION 2

DEVELOPMENT OF A NOVEL VIRTUAL CGM INITIATION SERVICE TO ENHANCE CGM UPTAKE IN PRIMARY CARE PRACTICES

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Background and Aims: Primary Care (PC) performs diabetes management for approximately 50% of adult type 1 diabetes and 90% of type 2 diabetes in the United States, yet CGM uptake is significantly lower in PC than in endocrinology despite known glycemic and quality-of-life benefits. This project aims to increase CGM uptake in Colorado PC practices by developing a novel virtual CGM Initiation Service (virCIS) for PC practices.

Methods: The virCIS project partners with PC practices to identify candidates for CGM, perform CGM onboarding, and support transition of ongoing CGM management to the local PC practice. The program features a one-time, 45-minute CGM overview curriculum for practices, with instruction on how PC practices identify and enlist appropriate patients. virCIS will initiate CGM using a structured protocol implemented by clinical pharmacists, a diabetes care and education specialist, and a nutritionist, all with PC setting expertise. Program duration is three months, with routine updates to the referring practice, and concluding with a virtual "warm handoff" visit between virCIS, the PC practice, and the patient.

Results: Primary outcomes include change in HbA1c and changes in CGM glycemic metrics. Secondary outcomes include changes in BMI, diabetes distress, practice satisfaction, and patient satisfaction. Economic analysis will also be conducted, and a toolkit will be developed to empower other PC settings to develop their own CGM initiation services.

Conclusions: We anticipate that virCIS will increase PC practices' abilities to initiate and maintain CGM use while also improving glycemia, patient satisfaction, and practice satisfaction.

OP027 / #345

Topic: ***AS15-Trials in progress***

VIRTUAL ORAL PRESENTATIONS SESSION 2

IMPLEMENTING CGM IN PRIMARY CARE PRACTICES VIA THE AMERICAN ACADEMY OF FAMILY PHYSICIANS TIPS CGM MODULE WITH AND WITHOUT PRACTICE FACILITATION: A RANDOMIZED TRIAL

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Background and Aims: Primary care performs diabetes management for approximately 50% of adult patients with type 1 diabetes and 90% of those with type 2 diabetes in the United States, yet CGM uptake is significantly lower in primary care than in endocrinology despite known glycemic and quality-of-life benefits. This project aims to increase CGM uptake in primary care practices in Colorado, with a randomized trial comparing two CGM implementation strategies. The investigators, in conjunction with the American Academy of Family Physicians (AAFP), developed a Transformation in Practice Series (TIPS^{TM}) CGM implementation package for primary care practices. Practice facilitation is a strategy shown to enhance implementation efforts. This study will compare CGM implementation using AAFP TIPS^{TM} CGM with and without additional practice facilitation to assist in implementation.

Methods: 40 Colorado primary care practices will agree to use the AAFP TIPS^{TM} CGM package to implement CGM and will be randomized to receive (a) no additional support resources or (b) six professional practice facilitation sessions for CGM implementation.

Results: Primary outcome: CGM prescriptions initiated. Secondary outcomes: changes in HbA1c, CGM glycemic metrics, diabetes distress, practice satisfaction, and patient satisfaction. Economic analysis will also be conducted.

Conclusions: We anticipate that AAFP TIPS^{TM} CGM implementation will increase primary care practice CGM initiation, with practice facilitation adding incremental benefit. Relative costs vs. revenue will be determined and compared for the two groups.

OP028 / #316

Topic: ***AS07-Insulin Pumps***

VIRTUAL ORAL PRESENTATIONS SESSION 2

NIGHT-SHIFT WORK IS ASSOCIATED WITH POORER GLYCEMIC CONTROL IN PATIENTS WITH TYPE 1 DIABETES ON INSULIN PUMP THERAPY

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Background and Aims: Night shift-work is an example of severe circadian misalignment and is associated with increased risk of developing diabetes. In patients with established diabetes, shift-work may be associated with poor glycemic control, but the data are scarce. Our aim was to evaluate if among patients with type 1 diabetes (T1D) under continuous subcutaneous insulin infusion therapy (CSII), glycemic control is worse in night shift-workers (NSW) compared to daily-workers (DW).

Methods: Retrospective analysis of T1D patients under CSII followed at our department: 28 NSW and 28 randomly selected age and sex-matched controls (DW). We collected data from CGM from the last 90 days: time in range (TIR; 70-180 mg/dL), time above range (TAR), time below range (TBR), and glycemic variability (%CV). Patients treated with CSII plus SGLT2-I were not excluded.

Results: The groups were similar with respect to duration of diabetes, age and HbA1c before starting CSII, and treatment with SGLT2-I. A significantly lower TIR (53.5% (43.0-63.0) vs 65.5% (60.3-71.8), $p < 0.001$), higher TAR (39.0% (32.0-50.5) vs 27.5% (20.0-34.0), $p = 0.002$), and higher %CV (42.9% (37.6-47.5) vs 39.0% (35.9-41.3), $p = 0.003$) was observed in the NSW group (with no differences in TBR). Multivariate regression analysis showed that these results were independent of age, duration of diabetes, HbA1c before CSII, healthcare occupation and SGLT2-I treatment ($p < 0.05$).

Conclusions: Night shift-workers had significantly poorer glycemic control compared to daily-workers. Even with CSII therapy, alterations in dietary intake and sleep with circadian misalignment may represent a challenge to optimum control in this group of patients.

OP029 / #763

Topic: ***AS07-Insulin Pumps***

VIRTUAL ORAL PRESENTATIONS SESSION 2

CONTINUOUS GLUCOSE MONITORING IN CSII THERAPY IN DIFFERENT AGE GROUPS (0.5-

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Background and Aims: Insulin pump (CSII), continuous glucose monitoring (CGM) and sensor augmented pump (SAP) technology has evolved continuously over the last years. Aim of this study was to assess changes in use of these technologies over time and to identify potential issues regarding technology usage.

Methods: A large patient registry (Diabetes Prospective Follow-up Database, DPV) from Germany, Austria, Switzerland, and Luxembourg was used. The use of CSII, CGM, AID (automated insulin delivery) and SAP between 01/2018 and 06/2021 with T1D was analyzed depending on age, sex and region of care (see Table).

Use of	A: pre-pubertal (0.5–<8 years)	B: pre-pubertal (Tanner or w 6–11 years; m 6–12 years)	C: pubertal (Tanner or w >11–15 years; m >12–16 years)	D: post-pubertal (Tanner or w >15–25 years; m >16–25 years)
SAP 2018 (%,n)	40 (946/2,356)	35 (2,558/6,175)	29 (2,930/10,143)	21 (2,153/10,044)
SAP 2019 (%,n)	43 (1,071/2,507)	38 (3,165/8,269)	34 (3,544/10,381)	26 (2,696/10,352)
SAP 2020 (%,n)	42 (1,096/2,615)	37 (3,044/8,267)	34 (3,607/10,593)	29 (3,061/10,284)
SAP 2021 (%,n)	44 (1,057/2,416)	37 (2,865/7,749)	33 (3,297/9,838)	29 (2,576/8,783)
AID 2018 (%,n)	12 (272/2,356)	4 (365/6,175)	3 (275/10,143)	2 (155/10,044)
AID 2019 (%,n)	17 (425/2,507)	8 (664/8,269)	5 (503/10,381)	3 (323/10,352)
AID 2020 (%,n)	24 (631/2,615)	14 (1,181/8,267)	10 (1,061/10,591)	7(736/10,284)
AID 2021 (%,n)	18 (443/2,416)	13 (995/7,749)	9 (929/9,838)	8 (682/8,783)

Results: 43,835 patients with T1D treated in 416 diabetes centres between 2018 and 2021 met the inclusion criteria. In group C, 56% of female patients used CSII and 36% SAP, whereas 47% of male patients used CSII and 29% SAP (both $p < 0.001$).In group D, 53% female patients used CSII, 31% SAP and 69% CGM. Whereas 41% of the male patients used CSII, 23% SAP and 65% CGM (all $p < 0.001$).There was a significant difference in the use of CSII, CGM and AID between the old and new federal states of Germany (CSII 55% versus 52%, CGM 76% versus 71%, AID 12% versus 8%; (all $p < 0.001$)).

Conclusions: There has been an increase in the overall use of SAP and AID with the highest use in the younger age groups. A significant difference in the use of SAP between female and male patients could be demonstrated during puberty and in young adults. The new technologies are used more often in the old federal states of Germany.

Primary and Secondary Endpoints[a]	TZP 5 mg (N=71)	TZP 10 mg (N=79)	TZP 15 mg (N=72)	IDeg (N=74)
LFC (%)				
Baseline	14.86 (1.108)	14.78 (1.039)	16.65 (1.092)	16.58 (1.053)
Week 52[b]	10.11 (0.795)*	8.16 (0.792)**	8.59 (0.768)**	13.18 (0.791)
Relative change from baseline at Week 52[c]	-29.78 (5.607)*	-47.11 (5.582)**	-39.59 (5.417)**	-11.17 (5.579)
LFC targets: % participants with				
LFC ≤10% at baseline	32.6 (5.813)	38.0 (5.643)	19.9 (4.873)	29.5 (5.372)
LFC ≤10% at Week 52[b]	60.4 (7.979)*	77.9 (6.409)**	73.9 (6.694)**	34.8 (7.865)
≥30% relative decrease in LFC at Week 52[b]	66.9 (7.394)*	81.4 (5.623)**	78.8 (5.970)**	32.1 (7.190)
Visceral adipose tissue volume (L)				
Baseline	6.87 (0.240)	6.21 (0.232)	6.81 (0.238)	6.34 (0.230)
Week 52[b]	5.42 (0.187)**	5.00 (0.178)**	4.88 (0.181)**	6.90 (0.182)
Abdominal SC adipose tissue volume (L)				
Baseline	10.93 (0.506)	10.21 (0.491)	10.34 (0.502)	10.04 (0.485)
Week 52[b]	9.07 (0.747)**	8.52 (0.736)**	8.42 (0.774)**	11.10 (0.240)
Body weight (kg)				
Baseline	98.0 (1.93)	93.4 (1.85)	95.6 (1.92)	91.3 (1.92)
Week 52	86.9 (0.85)**	84.9 (0.83)**	83.5 (0.85)**	97.2 (0.86)
HbA_{1c} (mmol/mol)				
Baseline	66.8 (1.19)	68.4 (1.14)	65.6 (1.18)	65.6 (1.18)
Week 52	44.7 (1.34)**	43.3 (1.32)**	41.2 (1.33)**	53.4 (1.36)
HbA_{1c} (%)				
Baseline	8.27 (0.109)	8.41 (0.104)	8.15 (0.108)	8.15 (0.108)
Week 52	6.24 (0.122)**	6.12 (0.121)**	5.92 (0.122)**	7.04 (0.124)
Liver enzymes concentration (U/L)				
ALT at baseline	28.0 (1.71)	25.8 (1.54)	26.1 (1.59)	24.7 (1.53)
ALT at Week 52[c,d]	21.8 (1.12)	19.1 (0.97)*	17.8 (0.89)**	22.8 (1.20)
AST at baseline	20.7 (0.97)	19.6 (0.90)	20.6 (0.96)	20.0 (0.95)
AST at Week 52[c,d]	18.3 (0.76)	17.8 (0.74)*	16.5 (0.67)**	20.4 (0.87)

Data are estimates (SE), unless otherwise noted. *p<0.05 and **p<0.001 are both vs IDeg.

TZP doses were achieved through stepwise 2.5-mg dose escalation every 4 weeks. IDeg starting dose was 10 U/day and it was titrated to a FSG <5 mmol/l following a treat-to-target algorithm. Mean IDeg dose at Week 52 was 58.8 U/day

[a]mITT-Efficacy Analysis Set, unless otherwise noted: on treatment data prior to initiating rescue therapy from mITT population excluding patients with baseline and postbaseline data not obtained or not valid. N values vary across primary and secondary endpoints at Week 52.

[b]Missing values at Week 52 were imputed with LOCF using mITT efficacy analysis set (if early termination or unscheduled visit with MRI scan available).

[c]mITT-Safety Analysis Set: all available data from mITT population including safety follow-up regardless of adherence to study drug or use of rescue therapy including patients with non-missing baseline and at least one non-missing post-baseline record.

[d]Statistical significance based on percent change from baseline vs IDeg.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; FSG = fasting serum glucose; HbA_{1c} = haemoglobin A_{1c}; IDeg = insulin degludec; LFC = liver fat content; LOCF = last observation carried forward; mITT = modified intent-to-treat (all randomised patients who took at least one dose of study drug); N = number of patients in specified dataset; SC = subcutaneous; SE = standard error; TZP = Tirzepatide.

OP030 / #82

Topic: ***AS08-New Medications for Treatment of Diabetes***

ORAL PRESENTATIONS SESSION 2

EFFECT OF TIRZEPATIDE VERSUS INSULIN DEGLUDEC ON LIVER FAT CONTENT AND ABDOMINAL ADIPOSE TISSUE IN PATIENTS WITH TYPE 2 DIABETES (SURPASS-3 MRI)

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Background and Aims: The effect of tirzepatide, a novel dual GIP/GLP-1 receptor agonist, vs insulin degludec (IDeg) on liver fat content (LFC) and visceral and abdominal subcutaneous adipose tissue (VAT and ASAT) was assessed with MRI techniques in a subpopulation of participants in the SURPASS-3 trial.

Methods: Insulin-naive participants with type 2 diabetes and Fatty Liver Index ≥60 had an MRI scan performed before randomisation (1:1:1:1) to once-weekly tirzepatide (5, 10, 15 mg) or once-daily IDeg as add-on to metformin with/without sodium-glucose co-transporter-2 inhibitors (SGLT-2i). The primary outcome was the change from baseline in LFC at Week 52 using pooled data from tirzepatide 10/15-mg arms vs IDeg. Secondary outcomes compared the individual tirzepatide doses vs IDeg at Week 52 for LFC, VAT and ASAT volumes; proportions of participants achieving LFC targets.

Results: A total of 296 participants had evaluable MRI data during the study (mean baseline age, 56.2 years; diabetes duration, 8.3 years; HbA_{1c}, 8.2%; weight, 94.4 kg; BMI, 33.5 kg/m^2; 30% on SGLT-2i). The reduction from baseline in LFC at Week 52 was significantly greater for the pooled tirzepatide 10/15-mg arms vs IDeg arm and for all individual tirzepatide doses vs IDeg. The proportions of participants achieving LFC targets were significantly greater in each tirzepatide arm vs IDeg arm. All tirzepatide doses reduced VAT and ASAT volumes at Week 52 while IDeg increased both. The results were similar regardless of the concomitant use of SGLT-2i.

Conclusions: Tirzepatide demonstrated clinically meaningful reductions in LFC and VAT and ASAT volumes compared to IDeg in this SURPASS-3 substudy.

OP031 / #185

Topic: ***AS08-New Medications for Treatment of Diabetes***

ORAL PRESENTATIONS SESSION 2

EFFECT OF TIRZEPATIDE VERSUS INSULIN DEGLUDEC ON GLYCEMIC CONTROL CAPTURED WITH CONTINUOUS GLUCOSE MONITORING IN PATIENTS WITH TYPE 2 DIABETES (SURPASS-3 CGM)

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Background and Aims: To evaluate the effects of tirzepatide, a dual GIP/GLP-1 receptor agonist, vs insulin degludec (IDeg) on glycaemic control captured with continuous glucose

monitoring (CGM) over 24 hours in a subpopulation of participants in the SURPASS-3 trial.

Methods: Insulin-naive participants with type 2 diabetes treated with metformin with/without sodium-glucose cotransporter-2 inhibitors (SGLT-2i) were randomized (1:1:1:1) to once-weekly tirzepatide (5, 10, 15 mg) or once-daily IDeg. Interstitial glucose values were collected by CGM at 5-minute intervals for 7-10 days at baseline, week 24 (Wk24) and week 52 (Wk52). Primary outcome was percentage of time in tight range (TITR) (3.9-7.8 mmol/L) during a 24-hour period for pooled tirzepatide 10mg/15mg compared to IDeg at Wk52. Secondary outcomes included comparing tirzepatide vs IDeg for the percentage of time in range (TIR), time below range (TBR) $\leq$3.9 mmol/L, and coefficient of variation (CV) at Wk52.

Results: In the tirzepatide (5 mg N = 64, 10 mg N = 51, 15 mg N = 73) and IDeg (N = 55) groups, overall mean baseline HbA1c was 8.14% and fasting serum glucose was 9.40 mmol/L. Pooled tirzepatide 10 mg/15 mg spent significantly more TITR than IDeg at Wk52 (72.60 ± 2.45% vs 48.04 ± 3.74% p < 0.001). The percentage of TBR ≤3.9 mmol/L at Wk52 was significantly lower for all doses of tirzepatide vs IDeg. Tirzepatide significantly reduced the Within-day CV vs IDeg at Wk52. No significant differences were observed based on SGLT-2i utilization.

Conclusions: Tirzepatide demonstrated superior glycaemic control and decreased glycaemic variability measured using CGM with lower risk of hypoglycaemia in comparison to insulin degludec.

	Tirzepatide 5 mg	Tirzepatide 10 mg	Tirzepatide 15 mg	IDeg
Percent TITR 3.9-7.8 mmol/L				
Baseline	22.7 (2.97)	25.5 (3.42)	21.1 (2.77)	22.2 (3.22)
Week 24	59.9 (3.48)	70.8 (4.07)**	72.7 (3.33)**	51.6 (3.91)
Week 52	59.6 (3.59)*	72.4 (3.97)**	72.6 (3.50)**	48.0 (4.01)
Percent TIR 3.9-10.0 mmol/L				
Baseline	51.9 (3.88)	60.7 (4.47)	49.4 (3.62)	53.9 (4.20)
Week 52	84.9 (2.54)*	91.0 (2.78)**	91.2 (2.49)**	75.0 (2.84)
Percentage of TAR >10.0 mmol/L at Week 52	14.9 (2.60)	8.2 (2.85)**	8.5 (2.54)**	22.5 (2.90)
Percentage of TBR ≤3.9 mmol/L at Week 52	0.6 (0.18)**	1.0 (0.25)*	0.8 (0.20)**	2.4 (0.42)
Within-day CV at Week 52	18.6 (0.55)**	16.2 (0.60)**	16.1 (0.54)**	24.4 (0.61)

Unless otherwise stated, a constrained longitudinal data analysis model (cLDA) was used. Baseline and post-baseline CGM measures were considered as dependent variables, in conjunction with the constraint of a common baseline mean across the treatment groups.
Percentage of time ≤3.9 mmol/L at 52 weeks used a constrained tobit mixed-effects model. Values are over a 24-hour period.
Data are least square mean (SE) values, unless otherwise stated.
Tirzepatide doses were achieved through stepwise 2.5-mg dose escalation every 4 weeks. IDeg was titrated to a FSG <5 mmol/L following a treat-to-target algorithm. Mean IDeg dose at 52 weeks was 0.6 U/kg/day.
*p<0.05 and **p<0.001 vs insulin degludec.
Subjects were included in the analysis of actual values if they had at least one non-missing value at either baseline or post-baseline.
Percent TIR was calculated as the number of observations within the specified range divided by the total number of observations in the time interval.
CV= coefficient of variation; FSG = fasting serum glucose; IDeg = insulin degludec; N = number of patients; TITR = time in tight range; TIR = time in range; TAR= time above range; TBR= time below range.

OP032 / #235

Topic: ***AS08-New Medications for Treatment of Diabetes***

ORAL PRESENTATIONS SESSION 2

AUTOMATED INSULIN DELIVERY (AID)-ENHANCED WITH SGLT2I AS COMBINED THERAPY IN TYPE 1 DIABETES

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Background and Aims: Use of sodium-glucose cotransporter 2 inhibitors (SGLT2i) as adjunct therapy to insulin in type 1 diabetes (T1D) has been previously studied. Here we present data from the first free-living trial combining low-dose SGLT2i with commercial automated insulin delivery (AID) or predictive low glucose suspend (PLGS) systems.

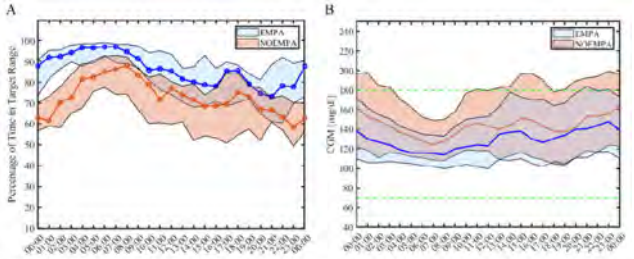

Figure. Detailed CIQ-EMPA vs CIQ-NOEMPA contrast with respect to TIR and CGM for each hour of the day. (A) An envelope plot of the percent time in the target range according to the time of day. (B) Post-randomization hourly median sensor glucose with interquartile envelope. Green lines represent the 70 and 180 mg/dL glycemic levels. Data points (thick lines) denote the hourly median values, and the lower and upper boundary of each shaded region the 25th and 75th percentiles, respectively.

Methods: In an eight-week, randomized, controlled, crossover trial, adults with T1D received 5 mg/day empagliflozin (EMPA) or no drug (NOEMPA) as adjunct to insulin therapy. Participants were also randomized to sequential orders of AID (Control-IQ) and PLGS (Basal-IQ) systems for four and two weeks, respectively. The primary endpoint was percent time-in-range (TIR) 3 · 9-10mmol/L during daytime (7:00-23:00h) while on AID (NCT04201496).

Results: 39 subjects were enrolled, 35 were randomized, 34 (EMPA; n = 18 and NOEMPA n = 16) were analyzed with intention-to-treat intention (IIT), 32 (EMPA; n = 16 and NOEMPA n = 16) completed the trial. On AID, EMPA vs. NOEMPA had higher daytime TIR 81% vs. 71% with a mean estimated difference of +9 · 9% [95%CI 0.6 to 19.1];p = 0.04. On PLGS, the EMPA vs NOEMPA daytime TIR was 80% vs. 63%, mean estimated difference of +16.5%[95% CI 7.3, 25.7];p<0.001. One subject on SGLT2i and AID had mild diabetic ketoacidosis that was precipitated by non-functioning insulin pump infusion site blockage.

Conclusions: In an eight-week outpatient study, the addition of 5 mg daily empagliflozin to commercially available AID or PLGS systems significantly improved daytime glucose control in individuals with T1D, without increased hypoglycemia risk. These promising results warrant further evaluation in large-scale clinical trials.

OP033 / #255

Topic: ***AS08-New Medications for Treatment of Diabetes***

ORAL PRESENTATIONS SESSION 2

ACHIEVEMENT OF HBA1C LESS THAN 5.7% WITHOUT WEIGHT GAIN AND HYPOGLYCEMIA IN PEOPLE WITH T2D TREATED WITH TIRZEPATIDE ACROSS THE PHASE 3 SURPASS PROGRAM

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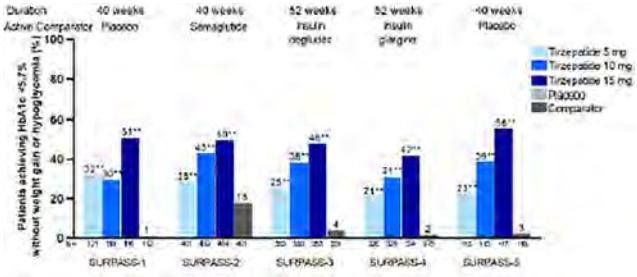
Background and Aims: Tirzepatide, a novel dual GIP/GLP-1 receptor agonist developed for type 2 diabetes treatment, provided greater HbA1c and body weight reductions compared with placebo and active comparators with 23% to 62% of tirzepatide-treated participants achieving a HbA1c <5.7% in the phase 3

SURPASS studies. This post-hoc analysis evaluated the proportion of participants who achieved a HbA1c <5.7% without weight gain and hypoglycemia in these studies.

Methods: We compared the proportion of participants achieving the triple endpoint between the tirzepatide (5, 10, or 15 mg) and respective comparator groups using the efficacy analysis dataset without rescue medication. End of treatment HbA1c and weight were evaluated at week 40 (SURPASS-1, 2, 5) and week 52 (SURPASS-3, 4). Hypoglycemia included blood glucose level <54 mg/dL with symptoms of hypoglycemia or severe hypoglycemia.

Results: More participants treated with any dose of tirzepatide achieved the triple endpoint compared to placebo or active comparators in SURPASS 1-5 (Figure). Tirzepatide 15mg led to 51%, 50%, 48%, 42%, 56% (in SURPASS 1-5, respectively) of participants reaching the triple endpoint, compared to 1% with placebo (SURPASS 1), 18% with semaglutide 1mg (SURPASS 2), 4% with degludec (SURPASS 3), 2% with glargine U100 (SURPASS 4), and 3% with placebo (SURPASS 5).

Conclusions: Significantly more participants treated with tirzepatide achieved normoglycemia without weight gain and hypoglycemia compared to placebo, semaglutide 1 mg, or basal insulin. Up to 56% of the participants treated with tirzepatide 15 mg achieved this triple endpoint.



Percentage of patients aching the composite endpoint of HbA1c < 5.7% without weight gain and hypoglycaemia in the SURPASS-1, 2, 3, 4, and 5 studies. Weight gain was defined as a change from baseline in weight <0.1 kg. Missing data was imputed based on observed data in the same treatment arm from subjects who had their efficacy measure at the endpoint visit assessed after early discontinuation of study drug. A logistic regression model using imputed data with baseline HbA1c value, baseline weight, pooled country, and treatment as factors was used in each study to compare treatment arms. Prior use of oral antihyperglycemic medication (OAM) (Yes, No), baseline OAM use (Met, Met plus SGLT-i), baseline SGLT-2i use (yes/no), and baseline metformin use (yes/no) were used as additional covariates in SURPASS-1, SURPASS-3, SURPASS-4, and SURPASS-5, respectively. Active comparators are semaglutide 1 mg for SURPASS-2, insulin degludec for SURPASS-3, and insulin glargine U100 for SURPASS-4. N = number of subjects in imputed data. Between treatment p-value ** <0.001

OP034 / #311

Topic: ***AS08-New Medications for Treatment of Diabetes***

ORAL PRESENTATIONS SESSION 2

T1DM REMISSION AND B-CELL REGENERATION, INDUCED BY ORAL ADMINISTRATION OF TRIPLE-DRUG COMBINATION OF DPP-4 INHIBITOR, PPI, AND GABA IN NOD MICE. A PROOF-OF-CONCEPT

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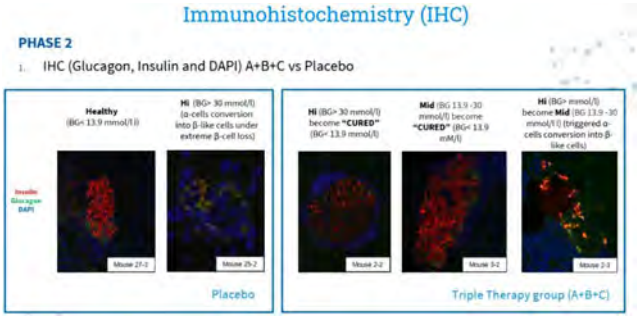
Background and Aims: Our concept views T1DM as an immune-triggered neurodegenerative disorder of the endocrine



pancreas. Our previous pilot studies in adults have shown that with triple therapy (TT) insulin demands were reduced by 59%, in parallel with a significant reduction of HBA1C and without weight loss. 31.6% of participants entered a long-term remission and became insulin-free.

Methods: We studied 150 NOD mice for a total of 268 days, including the observation period, two main experiments which lasted 70 days and included the treatment arm, prevention arm and crossover. After 99 days (supervision), 51 animals became diabetic and were randomly assigned to five groups: ABC; AB; AC; BC, and Placebo (A - GABA; B – Sitagliptin; C – Omeprazole).

Results: The ABC group demonstrated the best effect compared to other combinations. On day 71 the ABC vs Placebo groups showed: Blood Glucose (BG) 15.7 ± 7.7 and 27.3 ± 10.2 nmol/l ($p = 0.036$); C-peptide 0.96 ± 0.54 and 0.42 ± 0.77 nmol/l ($p = 0.022$); insulin 7.09 ± 2.72 and 3.20 ± 3.27 nmol/l ($p = 0.018$); Insulin/Glucagon ratio 0.19 ± 0.07 and 0.09 ± 0.09 ($p = 0.021$); exogenous insulin demands 0.3 ± 0.9 and 1.8 ± 1.4 units/mice ($p = 0.009$) respectively. Immunohistochemistry analysis demonstrated the elevated number of insulin – producing cells in ABC group when compared to Placebo.

Conclusions: TT has resulted in significant improvement in the clinical, laboratory, and morphological parameters in NOD mice. 55% of animals in the ABC group have entered remission. All-in-all this study is proof of concept and efficacy of the new T1DM treatment approach.

OP035 / #405

Topic: ***AS08-New Medications for Treatment of Diabetes***

ORAL PRESENTATIONS SESSION 2

AT278 (U500) – PK/PD AND SAFETY OF RAPID-ACTING CONCENTRATED INSULIN ASPART

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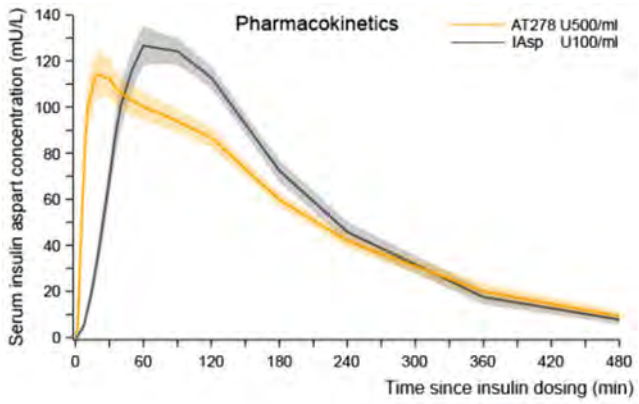
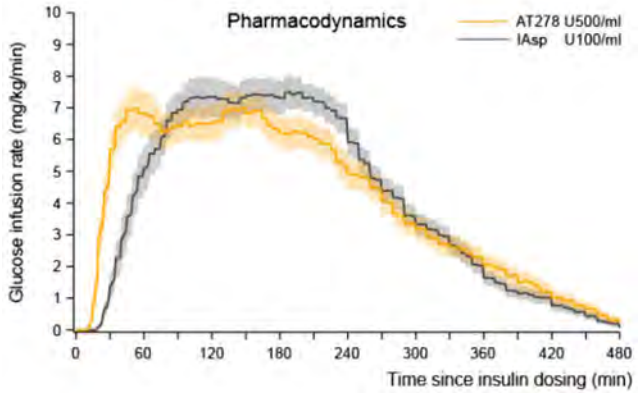
Background and Aims: Concentrated insulins allow administration of high insulin doses in a smaller volume. This enables a reduction in the number of injections for people with diabetes with high insulin needs and supports miniaturisation of insulin delivery devices. PK/PD and safety of a new concentrated insulin aspart formulation (AT278 U500/ml) were evaluated and compared with that of standard insulin aspart (IAsp U100/ml).





Methods: Serum insulin aspart and plasma glucose were measured in 38 adult male subjects with type 1 diabetes following a single s.c. dose (0.3 U/kg) of insulins in a randomised, double-blind, crossover, euglycaemic clamp study.

Results: AT278 showed a faster onset of insulin exposure compared with IAsp, as demonstrated by an earlier onset of appearance (-6.5 min, $P < 0.0001$), earlier tEarly50%Cmax (-23.0 min, $P < 0.0001$), and 4.0 times higher AUCInsulin,0-30min (95% CI: 3.29; 4.90). AT278 showed a more rapid onset of glucose-lowering effect compared with IAsp, as demonstrated by an earlier onset of action (-9.5 min, $P < 0.0001$) and earlier tEarly50%GIRmax (-20.0 min, $P < 0.0001$). Overall insulin exposure and glucose-lowering effect were comparable between both insulins (AUCInsulin,0-8h treatment ratio 0.98 [95% CI: 0.92; 1.00]; AUCGIR,0-8h treatment ratio 1.02 [95% CI: 0.95; 1.09]). All reported adverse events were mild in intensity and no safety signals were detected.

Conclusions: Concentrated insulin aspart AT278 maintains the rapid-acting characteristics in a reduced dose volume. It has the potential to improve blood glucose management and convenience for people on high-dose insulin therapy and to match the demands of next generation insulin delivery devices with smaller reservoirs.

OP036 / #428

Topic: *AS08-New Medications for Treatment of Diabetes*

ORAL PRESENTATIONS SESSION 2

PREVENTION OF T1DM, INDUCED BY ORAL ADMINISTRATION OF TRIPLE-DRUG COMBINATION OF DPP-4 INHIBITOR, PPI, AND GABA IN NOD MICE. A PROOF-OF-CONCEPT

S. Levit[1], *A. Nedorubov*[2]

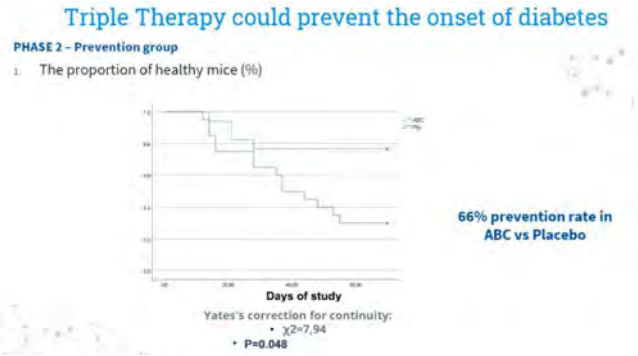
[1]*Institute of Endocrinology and Metabolism, Ramat Ha Hayal, Tel Aviv, Israel,* [2]*Sechenov University, Center Of Preclinical Studies, Moscow, Russian Federation*

Background and Aims: T1DM prevention remains the challenge. Studies dedicated to this issue are almost exclusively aimed at the immune system; the results are mainly disappointing or insufficient to draw definite conclusions. Our concept views T1DM as an immune-triggered neurodegenerative disorder of the endocrine pancreas. Our previous studies in NOD mice and humans have shown the effectiveness of triple therapy (TT) in β-cell preservation and regeneration.

Methods: We studied 150 NOD mice for a total of 268 days. After 99 days of the supervision period, the 94 animals who remained healthy were randomly assigned to five groups: ABC; AB; AC; BC, and Placebo (A - GABA; B – Sitagliptin; C – Omeprazole). The duration of the study was 70 days

Results: The ABC group demonstrated the best effect compared to other combinations. On day 71, the average metrics of ABC vs Placebo groups showed: Number of mice who remained healthy:17 vs. 9 ($p = 0.004$); Blood Glucose (BG) 9.9 ± 6.2 vs. 19.0 ± 7.8 mmol/l ($p = 0.001$); C-peptide 1.8 ± 0.3 vs. 0.8 ± 0.7 nmol/l; Glucose/insulin ratio 1.2 ± 1.6 vs. 5.5 ± 5.5 ($p = 0.001$); Glucose/C-peptide ratio 6.3 ± 7.7 vs. 112.1 ± 193.3 respectively ($p = 0.001$); The prevention rate of the onset of T1DM was 66% in ABC group compared to placebo ($p = 0.0048$).

Conclusions: TT can effectively prevent T1DM in NOD mice. All in all, this is a proof-of-concept of our method.



OP037 / #689

Topic: *AS03-Artificial Pancreas*

ORAL PRESENTATIONS SESSION 2

IP-IP PADOVA SIMULATOR: INTRAPERITONEAL INSULIN DELIVERY AND GLUCOSE SENSING

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Background and Aims: Intraperitoneal (IP) route for insulin delivery represents a more physiologic route for type 1 diabetes (T1D) treatment as compared to the subcutaneous (SC) infusion. To develop new IP implantable systems for closed-loop treatment, new insulin kinetics models are mandatory to design robust IP controllers. In order to provide a reliable simulation environment for testing new IP controllers, both IP delivering and sensing (IP-IP) models have to be considered. A new IP-IP simulator is needed.

To this aim, an IP extended version of the FDA accepted SC simulator (IP-T1DS) has been developed.

Methods: A new IP insulin kinetics model has been implemented with IP delivery entering the liver compartment in addition to a new IP glucose sensing model. As an example, a simulated system response of 1-day closed-loop IP and intravenous (IV) insulin delivery in an average patient is depicted in Figure 1.

Results: The new IP-T1DS has generated 100 in silico individuals with T1D incorporating intra- and inter-day variability of insulin sensitivity.

Conclusions: The availability of an IP-T1DS has allowed us to design and test a new control algorithm for IP insulin delivery and glucose sensing closed-loop therapy. The work was supported by H2020-FETPROACT Project FORGETDIABETS, n. 951933.

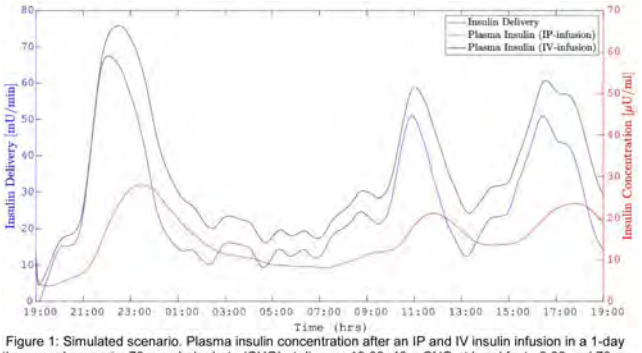

Figure 1: Simulated scenario. Plasma insulin concentration after an IP and IV insulin infusion in a 1-day three meal scenario: 70 g-carbohydrate (CHO) at dinner ~19:00, 40 g-CHO at breakfast ~8:00 and 70 g-CHO at lunch ~13:00.

OP038 / #415

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

ORAL PRESENTATIONS SESSION 2

THE ASSOCIATION BETWEEN TIME IN RANGE %, MEASURED BY CONTINUOUS GLUCOSE MONITORING (GCM) AND PHYSICAL & FUNCTIONAL INDICES AMONGST OLDER PEOPLE WITH TYPE 2 DIABETES

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Background and Aims: People with diabetes have an increased risk for mobility disability and a more rapid decline in muscle mass (sarcopenia) compared to those without diabetes. Studies have demonstrated an association between A1C and Sarcopenia. Less is known regarding the relationship with Time In Range (TIR). **Aims:**To assess among older people with type 2 diabetes, the cross sectional association between: TIR and aerobic capacity, gait speed, strength, balance and frailty indices.

Methods: A cross sectional study, conducted amongst people with diabetes over the age of 60. Participants were provided with a blinded CGM system- (iPro™ professional CGM, Medtronic) for 1 week and underwent elaborate physical-functional assessment in the beginning and at the end of that week.

Results: This analysis pertains to 144 men and women. After adjustment for age and gender, a 1% higher TIR (70-180) was associated with a 0.169 higher score on the 6-minute walk score, a measure of aerobic capacity and endurance (P-value = 0.023), 0.119 higher score on the Grip test, a measure of muscle force on the upper limb (P-value = 0.039), 0.164 lower score on the 360-turn test, a measure of dynamic balance (P-value = 0.039) and 0.165 lower score on the Timed Up & Go(TUG), a measure of fall risk and balance (P-value = 0.037).

Conclusions: Higher % TIR is associated with better scores on indices of muscle force, aerobic capacity and a measure of balance and predicting falls. Future studies are needed in order to elucidated if glucose levels are merely a marker of disease severity, or if there is possibly a causal relationship.

OP039 / #538

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

ORAL PRESENTATIONS SESSION 2

COMPARING THE BENEFITS OF A PAINLESS LANCING DEVICE IN PEOPLE WITH DIABETES IN IMPROVING SELF-MONITORING FREQUENCY AND HBA1C

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Background and Aims: Pricking of fingertips has always been an impediment in periodic blood glucose monitoring. We compared the benefits of Genteel, a vacuum-based lancing device, in PWD in improving the self-monitoring frequency and HbA1c.

Methods: An open-label, 24-week cross over trial where PWD were matched using propensity score and randomly allocated to GC or CG arm (G- Genteel; C- Conventional). GC exclusively used Genteel for 12 weeks, and then switched to the conventional method of SMBG for additional 12 weeks, and vice versa for CG. A total of 110 patients, including 58 T1D and 52 T2D, were recruited. Both arms were provided with the same glucometer. CG arm used the lancet and lancing device which they were using prior to randomization and GC used Butterfly lancets during the first 3 months. Reduction in HbA1c, %SMBG adherence over 24-weeks and subjective assessment of pain were assessed.

Table 1

		Genteel	Conventional	P-value
HbA1c reduction (Percentage change)	T1D (58)	-4.87	-0.85	0.026*
	T2D (52)	-7.27	-4.34	0.015*
% SMBG adherence [Mean (SD)]	T1D (58)	83.10 (10.72)	77.82 (13.45)	0.0513
	T2D (52)	78.44 (14.10)	48.96 (18.43)	<0.0001*
% Pain reduction [Mean (SD)]	T1D (58)	-66.38(10.58)	-34.77 (5.66)	<0.0001*
	T2D (52)	-65.38 (11.83)	-35.26 (8.51)	<0.0001*
% Probability of using Genteel ® device in future [Mean (SD)]	T1D (58)	-66.90 (16.14)	-36.21 (15.20)	<0.0001*
	T2D (52)	-63.46 (17.59)	-39.62 (17.49)	<0.0001*

Note - p value are based on paired t-test.

Results: Data from 110 patients (58 T1D and 52 T2D) showed a significant reduction in HbA1c ($p < 0.05$), improved SMBG adherence in T2D ($P < 0.05$) and reported reduction in pain ($P < 0.05$) after using Genteel. A significant number of patients ($p < 0.05$) also reported that they will continue to use Genteel lancing device in the future [Table1].

Conclusions: This advanced lancing device has helped manage the limitations of conventional lancing devices. T2D showed significant increase in SMBG adherence and HbA1c reduction using genteel than conventional device compared to T1D. Percentage reduction of pain and probability of using genteel in both T1D and T2D was approximately same while probability of using conventional device was comparatively less.

OP040 / #790

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

ORAL PRESENTATIONS SESSION 2

PERIOPERATIVE CLOSED-LOOP INSULIN DELIVERY VERSUS STANDARD INSULIN THERAPY - A RANDOMISED CONTROLLED PARALLEL CLINICAL TRIAL IN ADULTS WITH TYPE 2 DIABETES

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Background and Aims: Given the increasing prevalence and clinical relevance of perioperative hyperglycaemia, there is an ongoing interest in development of novel approaches to optimize glycaemic control in the surgical population. We evaluated the efficacy and safety of fully automated closed-loop (CL) compared with standard insulin therapy in adults with type 2 diabetes (T2D) undergoing elective surgery.

Methods: In an open-label, single-centre, randomised, parallel study, 45 adults with T2D (15 females, mean ± SD: age 68 ± 12years, HbA1c 7.5 ± 1.8%) undergoing elective surgery (55.6% abdominal, 22.2% cardiovascular, 2.2% thoracic, 6.7% neurosurgerical, 11.1% orthopaedic) were randomized to either receive fully CL glucose control (CamAPS HX) using Fiasp or standard insulin therapy (control). The primary outcome was the %time from hospital admission to discharge with glucose levels within the target range (5.6 to 10.0mmol/L), as measured by continuous glucose monitoring. Trial registration NCT04361799.

Results: Twenty-three were assigned to CL, and 22 to the control group. The %time in target glucose range (5.6 to 10.0mmol/L) was 74.8 ± 10.3% with CL vs. 53.9 ± 20.6% with control; mean difference 20.9% [95%CI 10.9 to 30.9%]; $P < 0.001$). Mean glucose was lower with CL than control (8.0 ± 0.7 vs. 9.4 ± 2.5mmol/L; $P = 0.026$). Time in hypoglycaemia did not differ between groups (<3.0mmol/L; median[IQR] 0.0 [0.0;0.02%] vs. 0.0[0.0;0.2%]; $P = 0.92$. No between-group difference was observed for total daily insulin requirements ($P = 0.72$) and length of surgery ($P = 0.52$). No study-related serious adverse events occurred in either group.

Conclusions: Fully CL improved glucose control without increasing the risk of hypoglycaemia compared to standard insulin therapy in adults with T2D undergoing elective surgery.

	Closed-loop (n=23)	Control (n=22)	p-value
Primary outcome			
Time in target [5.6-10.0mmol/L] (%)	74.8±10.3	53.9±20.6	<0.001
Secondary outcomes			
Percent of time with sensor glucose level			
< 5.6 mmol/L (%)	6.8 [4.5; 9.5]	6.4 [1.6; 15.0]	0.657
< 3.9 mmol/L (%)	0.2 [0.0; 0.6]	0.0 [0.0; 0.6]	0.336
< 3.0 mmol/L (%)	0.0 [0.0; 0.02]	0.0 [0.0; 0.0]	0.915
>10.0mmol/L (%)	16.1±8.9	34.2±26.4	0.005
> 20.0 mmol/L (%)	0.0 [0.0; 0.0]	0.0 [0.0, 0.3]	0.166
Mean sensor glucose levels (mmol/L)	8.0±0.7	9.4±2.5	0.026
Sensor glucose SD (mmol/L)	2.1±0.4	2.6±0.8	0.014
Sensor glucose CV (%)	26.3±3.8	28.6±7.3	0.194
Total daily insulin dose (Units)	15.2 [11.7; 27.8]	15.4 [6.8; 24.2]	0.723
Surgery duration (min)	249.0±128.9	272.2.0±111.4	0.528

Data are mean±SD or median [IQR]

Funding: Swiss Helmut Horten Foundation, Swiss Foundation for Anaesthesiology and Intensive Care, product support by Dexcom Inc

OP041 / #220

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ORAL PRESENTATIONS SESSION 3

STENOPOOL: A SYSTEM FOR MANAGING ALL DIABETES DEVICE DATA

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Background and Aims: Insulin pumps, CGMs and glucose meters are now an integrated part of diabetes management. Most devices have their own software, and clinicians must switch between these during consultations. Our aim was to develop one platform for all diabetes device data independent of manufacturers.

Methods: Using the open source cloud-based diabetes management software from Tidepool.org we developed a stand-alone solution for all diabetes devices used at Steno Diabetes Center Copenhagen, providing service to more than 11.000 people with diabetes. The solution had to be customized to comply with GDPR regulations, hosted on an authorized server, have single sign-on and user administration using Microsoft Active Directory, detailed logging of users and allow home-based access and upload using the national login-system available for all citizens in Denmark.

Results: As of November 2021, we started using the solution in the clinic, and continue further developments including closer integration with our electronic healthcare record (Epic, USA). People using different devices are now able to upload and access their own data in the same program, which also enables closer patient-provider interaction as well as telemedicine consultations. Also, we are now able to collect continuous quality data, do clinical and real-world evidence studies and start the development of more advanced use of diabetes data such as treatment guidance and alerts using AI technology.

Conclusions: By using open-source software, it was feasible to create a single diabetes management platform for all diabetes devices data for benefit of people with diabetes, quality improvement.

OP042 / #448

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ORAL PRESENTATIONS SESSION 3

REDUCTION IN DIABETES-RELATED HOSPITALIZATION RATES AFTER REAL-TIME CONTINUOUS GLUCOSE MONITOR (RTCGM) INITIATION

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Background and Aims: Inadequate glycemic control in patients with diabetes can result in diabetes-related hospitalizations. RtCGM helps with glycemic management by providing current glucose level and glucose trends. This study evaluated change in diabetes-related hospitalizations before and after rtCGM initiation.

Methods: A retrospective analysis of administrative claims data from the Optum Clinformatics® Database was conducted. CGM naïve patients with type 1 (T1D) and type 2 diabetes (T2D) initiated rtCGM (Dexcom G6) between 8/1/2018 and 3/31/2020 (index date = earliest observed pharmacy claim). Continuous health plan enrollment of 12-months pre, and 12-months post index date and ≥1 sensor pharmacy claim after index was required for study inclusion. Individuals with evidence of pregnancy were excluded. Diabetes-related ER and inpatient visits were assessed during the 12-months pre- and 12-months post-index periods and expressed as changes in number of visits and days of hospital stay.

Results: A total of 806 T1D (average age = 38.8 (sd = 14.2) years, 45% female) and 337 T2D (average age = 52.6(sd = 10.5) years, 46% female) rtCGM users on intensive insulin therapy met inclusion criteria. Statistically significant reductions were observed after rtCGM initiation in diabetes-related inpatient stays (T1D = -54%, $p < 0.001$; T2D = -48%, $p < 0.001$). RtCGM initiation resulted in reduced average length of stay (T1D = -0.39 days, $p = 0.01$; T2D = -0.88 days, $p = 0.02$). However, reductions in diabetes-related ER visits did not reach statistical significance (T1D = -29%, $p = 0.07$; T2D = -15%, $p = 0.52$).

Conclusions: These findings provide real-world evidence rtCGM was associated with reduced diabetes-related hospitalizations. Improved access to rtCGM may help more T1D and T2D patients avoid serious glycemic excursions that result in hospitalizations.

OP043 / #466

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ORAL PRESENTATIONS SESSION 3

PRINCIPAL DIMENSIONS OF GLYCEMIC VARIABILITY AND QUALITY OF GLYCEMIC CONTROL IN DIABETES

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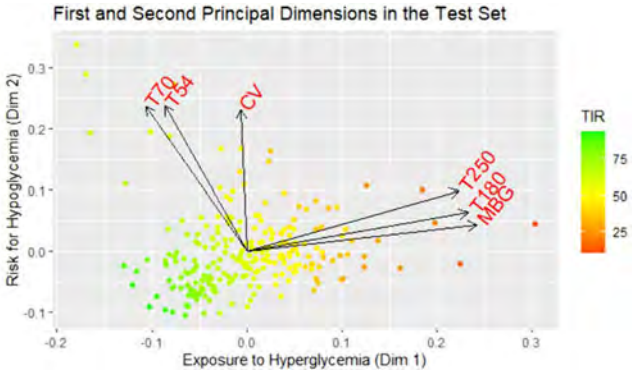
Background and Aims: Many of the available metrics to quantify glycemic variability (GV) and quality of glycemic control (QGC) derived from continuous glucose monitoring (CGM) data, are highly correlated. The aim of this work is to identify the principal uncorrelated dimensions of GV and QGC, to be considered in the assessment of diabetes management.

Methods: Six widely-used metrics were evaluated on CGM traces generated by 782 participants in 6 studies in type 1 and type 2 diabetes (T1D, T2D): mean blood glucose (MBG); percent time >180 mg/dL (T180), >250 mg/dL (T250), <70 mg/dL (T70), <54 mg/dL (T54); coefficient of variation (CV). Principal component analysis (PCA) was used to identify two principal uncorrelated dimensions of GV and QGC. These principal dimensions were first identified in a training set (550 subjects) and then fixed and validated in an independent test set (232 subjects).



Results: PCA identified two principal dimensions explaining >90% of the original variance in the testing data, irrespective of treatment modality, age range, and diabetes type. These dimensions represent exposure to hyperglycemia, or therapy efficacy, as indicated by a combination of MBG, T180, and T250 (Dimension 1), and risk for hypoglycemia, or therapy safety, as indicated by T70, T54, and CV (Dimension 2). A graphical representation of the two dimensions is shown in the figure.

Conclusions: Two uncorrelated dimensions are sufficient to characterize GV and QGC in diabetes, and to explain over 90% of the variance carried by common metrics. Thus, quantitatively, treatment optimization is reduced to a 2-dimensional problem.

OP044 / #814

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ORAL PRESENTATIONS SESSION 3

ACTIVE & PASSIVE SHARING OF DIABETES DEVICE DATA TO CLINICS IS ASSOCIATED WITH REDUCED A1C AND DECREASED DKA RATES

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Background and Aims: Reviewing device data is an integral part of routine diabetes care. Streaming or uploading this data prior to in-person or telehealth clinic visits may indicate increased engagement in self-management behaviors. This study aimed to evaluate if having streaming/uploaded data at the start of a clinic visit was associated with improvements in diabetes outcomes.

Methods: Individuals with T1D, aged <23 years, who received care from a single network of pediatric diabetes clinics in the Midwest USA from 3/2020 to 11/2021 were included. Uploading prior to the start of a clinic visit or having streaming data from at least one diabetes device defined the ''connected'' group. Sharing classification was recorded by CDE as part of routine visit documentation.

Results: Observations from 2116 unique individuals living with T1D were included in the analysis. Of which, 1063 had shared data at the time of their visit (50.2%). Mean A1c was statistically lower in those who were actively or passive sharing data (8.3% vs 9.3%, $p < 0.001$). Mean episodes of DKA were also lower (0.16 episodes/patient vs 0.05 episodes/patient, $p < 0.05$).

Conclusions: Passively or actively sharing data for clinic visits may be considered an adjunct measure of engagement in self-management. Our data suggest that an association exists between sharing data and decreased HbA1c and decreased incidence of DKA events. As technologies continue to advance, efforts to passively connect these data to diabetes clinics will become increasingly important.

OP045 / #717

Topic: ***AS15-Trials in progress***

ORAL PRESENTATIONS SESSION 3

ALPHA-MELANOCYTE STIMULATORY HORMONE: A NOVEL PLAYER IN POST-PRANDIAL GLUCOSE DISPOSAL IN SKELETAL MUSCLE IN HUMANS

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Background and Aims: Studies in rodents demonstrate that increases in circulating pituitary-derived alpha-melanocyte stimulatory hormone (α-MSH) contribute to post-prandial glycaemic control. Moreover, intravenous administration of exogenous α-MSH lowers glucose excursions during oral glucose tolerance testing (OGTT) in mice. We set out to interrogate whether this action translated to human physiology both *in vivo* and *in vitro*

Methods: Using a randomized double-blinded cross-over design, fifteen healthy volunteers received infusions of physiological saline, 15, 150 and 1500 ng/kg/hr α-MSH initiated 30 minutes prior to the administration of a standard OGTT. Plasma glucose and insulin was measured during the OGTT. To assess the effect of α-MSH on glucose disposal into skeletal muscle disposal, 15 subjects underwent sequential hyperinsulinaemic-euglycaemic clamp, concomitant to either saline or 150ng/kg/hr α-MSH infusion. In a separate cohort of healthy volunteers ($n = 6$), *vastus lateralis* muscle biopsies were obtained and used to establish cultures of primary human myotubes. Tritiated 2-deoxy-D-glucose was used to monitor glucose uptake in response to α-MSH.

Results: Infusion of α-MSH (1500ng/kg/hr) reduced the incremental area under the curve (iAUC) for plasma glucose ($p = 0.02$), and plasma insulin ($p = 0.006$) by approximately 20%. At high steady state insulin concentrations in clamp studies, α-MSH increased glucose requirements for the maintenance of euglycaemia. Primary human myotube cultures expressed melanocortin receptor subtypes (MC1R>MC3R ≈ MC4R) and both 10nM and 100nM α-MSH increased glucose uptake by two-fold versus vehicle ($p = 0.001$).

Conclusions: These findings substantiate a role for peripheral α-MSH as a hitherto undescribed component of the endocrine control of glycaemia in human physiology.

OP046 / #505

Topic: ***AS15-Trials in progress***

ORAL PRESENTATIONS SESSION 3

RATES OF SENSOR DETECTED HYPOGLYCAEMIA AND PATIENT REPORTED HYPOGLYCAEMIA; PRELIMINARY DATA FROM THE HYPO-METRICS TRIAL

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Background and Aims: Many hypoglycaemic episodes detected by continuous glucose monitoring (CGM) are asymptomatic. The HypoMETRICS study aims to understand the impact of symptomatic and asymptomatic sensor-detected hypoglycaemia (SDH). We report preliminary study data on rates of SDH and patient-reported hypoglycaemia (PRH).

Methods: We recruited people with insulin-treated diabetes who had experienced ≥1 hypoglycaemic episode in the last month and were hypoglycaemia aware by Gold score. Participants continued their usual method of glucose monitoring, with blinded CGM and recorded episodes of PRH in real-time through a purpose-built smartphone app for 10 weeks. PRH was defined as symptomatic episodes that resolved on carbohydrate ingestion, or a self-measured glucose <4 mmol/l (72mg/dl).

Results: The present analysis includes 105 participants (81 type 1 diabetes, 24 type 2 diabetes), mean (SD) age 49.1(15.9) years, diabetes duration 20.8(13.3) years, 63 using Flash and 4 using CGM. Mean time in range was 60(14.4) %, with time below 3.9mmol (70mg/dl) 4.7(3.9) %; time below 3mmol(54mg/dl) at 1.1(1.5) %. There were 7132 and 1931 level 1 and level 2 hypoglycaemic episodes with a mean rate 6.8(4.1) and 1.8(1.8) episodes/week respectively. Prolonged hypoglycaemia (below 3mmol for >2hours) accounted for 8% of level 2 hypoglycaemia, with 0.2 (0.4) episodes/week. Participants recorded 3,967 PRHs at 3.8(3.1) episodes/week.

Conclusions: As rates of SDH at 3.9mmol were 80% higher than PRH, this would suggest significant asymptomtic hypoglycaemia, even in people with hypoawareness intact. Using sensor data alone to judge awareness should be done with caution.

OP047 / #438

Topic: ***AS16-COVID-19 and Diabetes***

ORAL PRESENTATIONS SESSION 3

TYPE 2 DIABETES IMPAIRS ANTIVIRAL IMMUNITY BY PREVENTING THE INDUCTION OF FASTING METABOLISM

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Background and Aims: Type 2 diabetes (T2D) is a major risk factor for developing severe infectious disease, such as COVID-19. The endocrine and immune system closely interact following viral infection, which is deregulated in T2D. Previously, we showed in humans and mice that viral infection causes transient insulin resistance, which can lead to permanent loss of glycemic control in subjects with pre-diabetes. How changes in systemic glycemia benefit the antiviral response, and how this derails in T2D is mostly unknown.

Methods: Mice were infected with virulent strains of cytomegalovirus or lymphocytic choriomeningitis virus. Glucose-, insulin- and pyruvate-tolerance tests and hyperinsulinemic euglycemic clamping were used to determine the metabolic state of animals. Conditional knock-out models were used to measure the impact of cytokines on metabolism of specific organs. Diet-induced obesity models were used to determine the impact of hyperglycemia on the antiviral response.

Results: Severe viral infection causes pancreatic β-cell hyperfunctionality following their stimulation with the cytokine IFNγ by local T cells. Virus-induced hyperinsulinemia impaired glucose release by the liver and promoted induction of fasting metabolism, because of reduced hepatic glycogenolysis, causing relative, transient hypoglycemia (RHG). RHG was beneficial to the antiviral response by promoting the release of antiviral cytokines by endothelial cells, which impaired viral replication. Obese mice failed to induce fastng metabolsim, resulting in lower antiviral cytokines, higher viral titers and increased pathology.

Conclusions: Metabolic adaptations following infection are of major importance for optimal control of viral replication. In context of T2D, these changes cannot be accomplished, thus leading to more frequent and severe infections.

OP048 / #365

Topic: ***AS01-Closed-loop System and Algorithm***

VIRTUAL ORAL PRESENTATIONS SESSION 3

IN SILICO DESIGN AND ASSESSMENT OF A TIME-VARYING PID CONTROLLER FOR AN INTRAPERITONEAL ARTIFICIAL PANCREAS

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Background and Aims: The Proportional Integral Derivative controller (PID) is adopted in several applications including the artificial pancreas (AP). An advantage of PID is that only three parameters are needed and is normally subject-tailored with one personalization parameter, the Total Daily Insulin (TDI). No predictive models like in MPC are needed. The slow dynamics of the subcutaneous (SC) route limits PID effectiveness requiring the need of meal announcement. The faster dynamics of intraperitoneal (IP) delivery open the possibility of avoiding meal announcement. In this work, we propose a time-varying PID, test it in silico on the novel IP-Padova simulator (IP-T1DS) which incorporates intra- and inter-day variability of insulin sensitivity.

Methods: We identify the average IP insulin-glucose transfer function starting from data collected on the IP-T1DS, an extended version of the SC FDA accepted simulator. We consider the Insulin-to-Carbohydrate Ratio (CR) as personalization parameter as an alternative to TDI. From the CRs associated to the different portions of the day, we design a time-varying PID. We test the two PIDs simulating a 12-week protocol.

Results: Both controllers are effective without meal announcement, but the time-varying PID is less sensitive to the different day portions.

Conclusions: We propose a time-varying PID for a fully implantable IP AP. IP-PIDs are effective without meals announcement thanks to the faster dynamics of IP sensing and delivery. Personalization through CR faces insulin sensitivity variations, increasing control performance w.r.t. TDI-based personalization. The work was supported by H2020-FETPROACT Project FORGETDIABETS, n. 951933.

OP049 / #141

Topic: ***AS01-Closed-loop System and Algorithm***

VIRTUAL ORAL PRESENTATIONS SESSION 3

COMPARATIVE EFFICACY OF HYBRID CLOSED-LOOP INSULIN DELIVERY SYSTEMS (HCLS) AND SENSOR AUGMENTED PUMPS (SAP) AMONG PEOPLE WITH TYPE 1 DIABETES: A U.S. BASED MULTI-CENTER STUDY

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Background and Aims: Evidence from clinical trials have demonstrated the glycemic benefits of hybrid closed-loop insulin delivery systems (HCLS) in children and adults. The primary objective of this study was to provide real-world data on glycemic outcomes and population characteristics in those using HCLS compared to other treatment modalities.

Methods: Electronic health record data (2019-2021) from the T1D Exchange Quality Improvement (T1DX-QI) Collaborative were analyzed for 15,091 people with T1D. Patients with data on insulin delivery mode [HCLS, sensor augmented pump therapy (SAP), pump only, or multiple daily injections (MDI)], A1c at their most recent clinic visit, and other demographic covariates were included in this analysis. Individuals were classified across insulin delivery groups based on information documented by a healthcare provider at their most recent clinic visit.

Results: In this study population, 744 (5%) were HCLS users, 2,326 (15%) were SAP users, 3,879 (26%) used pump only, and 8,142 (54%) were MDI users. Median (IQR) A1c in the HCLS group was 7.3% (IQR: 6.7,8.0%) compared to 8.0% (IQR: 7.2,9.1%) in the SAP group, 8.3% (IQR: 7.2,10.0%) in the pump only group and 8.7% (IQR: 7.4,10.5%) in the MDI group. Linear mixed models showed HbA1c to be 0.7% lower in the HCLS group compared to SAP, adjusting for age, gender, race/ethnicity and insurance status [Estimated Marginal Mean (95% CI): 7.8% (IQR: 7.3,8.4%) vs 8.7% (IQR: 8.2,9.0%)].

Table 1: Patient characteristics by insulin delivery modality (N=15,091)

	HCLS N=744	SAP N=2326	Pump only N=3879	MDI N=8,142	p-value
Age, yrs - mean(SD)	20 (13)	17 (9)	19 (12)	20 (12)	<0.001
Sex-n(%) Male	333 (45)	1099 (47)	2044 (53)	4479 (55)	<0.001
Race-n(%) White	388 (52)	592 (25)	2325 (60)	4204 (52)	<0.001
Black	22 (3)	198 (9)	475 (12)	988 (12)	
Hispanic	38 (5)	39 (2)	262 (7)	881 (11)	
other/unknown	296 (40)	1496 (64)	817 (21)	2068 (25)	
Insurance-n(%)					<0.001
Private	552 (79)	1371 (73)	1973 (59)	3843 (59)	
Public	132 (19)	467 (25)	1325 (40)	2400 (37)	
HbA1c%, Median (IQR)	7.3 (6.7,8.0)	8.0 (7.2,9.0)	8.3(7.2,10.0)	8.7 (7.4,10.5)	<0.001
Individuals with Diabetic Ketoacidosis event (%)	54 (7)	216 (9)	486 (13)	1371 (17)	<0.001
Individuals with Hypoglycemia event n,(%)	10 (2)	73 (12)	206 (11)	725 (16)	<0.001

Conclusions: This is a large multi-site real-world study demonstrating significant clinical benefits of HCLS use relative to other insulin treatment options.

OP050 / #588

Topic: ***AS01-Closed-loop System and Algorithm***

VIRTUAL ORAL PRESENTATIONS SESSION 3

DIABELOOP IN LONG STANDING TYPE 1 DIABETES WITH DEMENTIA

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Background and Aims: CASE-REPORT DIABELOOP IN LONG STANDING TYPE 1 DIABETES WITH DEMENTIA Menzen M[1], Ostrowski-Krause M[1], Otten F[2], Mohr S[1] 1 Gemeinschaftskrankenhaus Bonn, Department of Endocrinology 2 Gemeinschaftskrankenhaus Bonn, Department of Geriatrics 85 years old woman with type 1 diabetes, diagnosed 1946. Now treated with multiple dose injection of insulin lispro to mealtime 1IU at morning, 0,5 IU at lunch and dinner per 10g carbohydrate

and 6 Units of detemir once daily. HbA1c 60 mmol/mol, stimulated c-Peptid: 0,046ng/ml. Concomitant diseases: Heart failure with preserved ejection fraction, pulmonary arterial hypertension. Frailty with severe sarcopenia (Frailty Share FI 75), incipient dementia (MMST 23/30) with dominant deficits in visuoconstructive skills. 2021 she suffered from two severe hypoglycemia stage III with falls and fracture of os pubis and cranial brain trauma. Both situations caused by unintentional double injection of bolus insulin. Even CGMS with Dexcom G6 supervised by social worker was not able to prevent the rapide drop of blood sugar.

Methods: We decided to switch therapy to automated insulin delivery with AccuChek insight, Dexcom G6 combined with Diabeloop DBLG1 with insulin aspart. No meal annoncement was done. She ate 40g of carbohydrates to each meal.

Results: Tissue glucose in mean was ~180mg/dl with no hypoglycemia and rise after meal up to a maximum of 284 mg/dl for a few minutes with rapid drop to upper range targets. Beta-hydroxybutrate measured in this situations has been in normal ranges.

Conclusions: This is the first case report of AID use in long standing type 1 diabetes with dementia to our knowledge.

OP051 / #170

Topic: ***AS01-Closed-loop System and Algorithm***

VIRTUAL ORAL PRESENTATIONS SESSION 3

IMPROVED GLYCEMIA AND QUALITY OF LIFE AMONG LOOP USERS - A RETROSPECTIVE ANALYSIS OF REAL-WORLD DATA FROM A SINGLE CENTRE.

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Background and Aims: Despite being an off-label method of insulin delivery, increasing numbers of people with type1 diabetes (T1D) worldwide choose Loop, a form of Do-it-yourself Automated Insulin Delivery. We sought to collect data in an Edmonton cohort of known Loop users, to assess glycemic outcomes, safety and the perceived impact on quality of life (QOL).

Methods: A retrospective observational study of adults with T1D using Loop. Glycemic control (HbA1c andtime in range (TIR)) and safety outcomes (hospital admissions and time below range (TBR)) were assessed pre and post Loop use. QOL outcomes were explored using INSPIRE, Diabetes Impact and Device Satisfaction (DIDS) measures, and semi-structured interviews. Data are presented as mean ±SD.

Results: 24 adults; 66.7% female, mean age 37.0 ±13.0 years, duration of diabetes 24.6 ±11.8 years and 19.6 ±11.5 months of Loop use. Glycemic control significantly improved with Loop; HbA1c 7.2 ±1.0% vs. 7.9 ±0.8%, p = 0.002, and TIR (3.9-10.0mmol/L) 70.9 ±15.6 % vs 57.7 ±10.0%, p = 0.004. There was a non-significant reduction in TBR (<3.9mmol/L) with Loop, 2.2 ±1.3% vs pre-Loop 2.6 ±1.8%, p = 0.161. Two episodes of DKA (one associated with concurrent sodium glucose transporter-2 inhibitor use) and no severe hypoglycaemia occurred in a total of 470 months Loop. Positive QOL impact was explored in qualitative analysis and indicated through INSPIRE 84.0 ±17.9, Diabetes Impact 2.9 ±0.9 and Device Satisfaction 8.9 ±0.8 scores.

Conclusions: This local cohort who have chosen and continue to use Loop, demonstrate a beneficial impact on glycemic control and QOL, with no significant increase in hypoglycaemia or safety concerns highlighted.

OP052 / #458

Topic: ***AS01-Closed-loop System and Algorithm***

VIRTUAL ORAL PRESENTATIONS SESSION 3

COMPARING GLUCOSE CONTROL DURING MODERATE-INTENSITY, HIGH-INTENSITY AND RESISTANCE EXERCISE WITH CLOSED-LOOP INSULIN DELIVERY WHILE PROFILING POTENTIAL ADDITIONAL SIGNALS IN ADULTS WITH TYPE 1 DIABETES

B. Paldus[1,2], D. Morrison[2], D. Zaharieva[3], M. Lee[1,2], H. Jones[1,2], V. Obeyesekere[1], J. Lu[1,2], S. Vogrin[2], A. La Gerche[4,5], S. Mcauley[1,2], R. Macisaac[1,2], A. Jenkins[2,6], G. Ward[1,2], P. Colman[7], C. Smart[8], R. Seckold[8], B. King[8], M. Riddell[9], D. O'Neal[1,2]

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Background and Aims: To compare glucose control with hybrid closed loop (HCL) when challenged by moderate-intensity exercise (MIE), high-intensity intermittent exercise (HIE) and resistance exercise (RE) while profiling counter-regulatory hormones, lactate, ketones, and kinetic data in adults with type 1 diabetes.

Methods: Open-label multisite randomized crossover trial. Adults with type 1 diabetes undertook 40-min of HIE, MIE, and RE in random order while using HCL (Medtronic 670G) with hypoglycaemia preventative measures including use of a temporary target and supplemental carbohydrates. Primary outcome was median (IQR) continuous glucose monitoring (CGM) time-in-range (TIR, 70-180 mg/dL) for 14-hours post-exercise commencement. Accelerometer data and venous glucose, ketones, lactate, and counter-regulatory hormones were measured for 280-min post-exercise commencement.

Results: Median TIR was 81% [67, 93]%, 91% [80, 94]%, and 80% [73, 89]% for 0-14 hours post-exercise commencement for HIE, MIE and RE, respectively (n = 30), with no difference between exercise types (MIE v HIE; p = 0.11, MIE v RE p = 0.11, HIE v RE p = 0.90). Time-below-range was 0% for all exercise bouts. For HIE and RE compared with MIE, there were greater increases respectively in noradrenaline (p = 0.01, p = 0.004), cortisol (p < 0.001, p = 0.001), lactate (p < 0.001, p < 0.001) and heart rate (p = 0.007, p = 0.015). During HIE compared with MIE, there were greater increases in growth hormone (p = 0.024).

Conclusions: Under controlled conditions, HCL provided satisfactory glucose control with no difference between exercise type. Lactate, counter-regulatory hormones, and kinetic data, differentiate type and intensity of exercise, and their measurement may help inform insulin needs during exercise. However, their potential utility as insulin dosing modulators will be limited by subcutaneous insulin pharmacokinetics.

OP053 / #315

Topic: ***AS01-Closed-loop System and Algorithm***

VIRTUAL ORAL PRESENTATIONS SESSION 3

SAFETY AND GLYCEMIC CONTROL DURING THE MEDTRONIC ADVANCED HYBRID CLOSED-LOOP (AHCL) PIVOTAL TRIAL IN YOUTH AGED 7-17 YEARS WITH TYPE 1 DIABETES (T1D)

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Background and Aims: Early evaluation of the Medtronic AHCL pivotal trial in youth demonstrated improved time in target range (TIR, 70-180mg/dL) and reduced time at >180mg/dL, compared with baseline.[1] The present study reports results on the complete pediatric cohort.

Methods: Participants (N = 160, aged 7-17 years) with T1D underwent baseline run-in (~2 weeks) with HCL, SAP, PLGM or CSII therapy followed by a three-month AHCL-enabled study period where the 100mg/dL and the 120mg/dL target setpoints were used (~45 days for each). Analyses compared mean HbA1c, sensor glucose (SG), coefficient of variation of SG, time spent at SG ranges and insulin delivery between run-in and study (Wilcoxon signed-rank test or t-test). Safety data were also summarized.

Results: Outcomes from baseline to study end, and by glucose target, are shown (Table). With AHCL, those achieving the target TIR of >70% and HbA1c of <7.0% increased from 15% (N = 24/160) to 51% (N = 82/160) and 16% (N = 25/160) to 26% (N = 35/136), respectively. There was one severe hypoglycemic event (Baseline) and no diabetic ketoacidosis events.

Table. Glycemic outcomes of participants aged 7-17 years with type 1 diabetes during the MiniMed™ advanced hybrid closed-loop system pivotal trial.

	Study Participants (Aged 11.3 ± 2.5 years)				
	Baseline[a]	Study[b]	P	Glucose Target	
				100 mg/dL (N=152)[c]	120 mg/dL (N=159)[c]
Time in AHCL, %	--	93.5 ± 6.1	--	93.0 ± 7.5	94.2 ±5.9
HbA1c, %	7.9 ± 0.9	7.4 ± 0.7[f]	<.001[e]	--	--
SG, mg/dL	168.8 ± 19.9	152.7 ± 10.6	<.001[e]	149.6 ± 12.0	155.2 ± 10.7
CV of SG, %	37.3 ± 4.3	37.7 ± 4.2	.212	38.7 ± 4.3	36.2 ± 4.4
Percentage of time spent at sensor glucose range (mg/dL)					
<54	0.7 ± 0.7	0.6 ± 0.5	.619[e]	0.7 ± 0.7	0.6 ± 0.5
<70	2.7 ± 2.0	2.7 ± 1.6	.427[e]	3.2 ± 2.0	2.3 ± 1.5
70-180	59.4 ± 11.8	70.3 ± 6.5	<.001[e]	70.7 ± 7.1	70.1 ± 6.9
>180	38.0 ± 12.4	27.0 ± 6.7	<.001[e]	26.1 ± 7.3	27.6 ± 7.1
>250	12.1 ± 7.5	7.1 ± 3.8	<.001[e]	6.9 ± 4.0	7.2 ± 3.9
TDD, units	42.3 ± 19.5	44.9 ± 20.5	<.001[e]	45.5 ± 20.6	44.0 ± 20.0
Total basal, units	17.0 ± 8.2	17.4 ± 8.2	.113[e]	18.5 ± 8.6	16.2 ± 7.7
Total bolus, units	25.2 ± 12.6	27.5 ± 12.9	<.001[e]	27.0 ± 12.6	27.8 ± 13.0
Automated bolus, %[d]	0.2 ± 1.3	25.2 ± 8.3	<.001	24.6 ± 8.5	25.8 ± 8.7
User-initiated bolus, %[d]	99.8 ± 1.3	74.8 ± 8.3	<.001	75.4 ± 8.5	74.2 ± 8.7
Carb ratio	11.9 ± 4.8	11.2 ± 4.6	<.001[e]	11.2 ± 4.6	11.2 ± 4.6
Carb/day, g	187.4 ± 70.6	185.2 ± 60.0	.737[e]	183.1 ± 60.2	187.0 ± 62.1

Data are shown as means±SD.
[a]Sensor-integrated pump, HCL, or predictive low glucose management feature used. Automated bolus was inadvertently delivered on 7 systems.
[b]Combined 100mg/dL and 120mg/dL glucose targets.
[c]Some participants withdrew early before glucose target change or may have used only one target per investigator discretion or other concern.
[d]Percentage of total bolus.
[e]Wilcoxon signed-rank test.
[f]N=136 participants.
SG=Sensor glucose, CV=Coefficient of variation, TDD=Total daily insulin dose.
[1]Shin et al., *Diabetes Technol Ther*. 2021;23(SUPPL 2):A25-A26.

Conclusions: Findings demonstrate increased TIR (by ~11%, ~2.6hrs/day) and reduced HbA1c (by -0.5%) with unchanged time in hypoglycemia, versus baseline therapy, in youth with T1D using the Medtronic AHCL system.

OP054 / #485

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

VIRTUAL ORAL PRESENTATIONS SESSION 4

YOUTH WITH TYPE 1 DIABETES BENEFIT FROM EARLY CONTINUOUS GLUCOSE MONITORING INITATION IRRESPECTIVE OF DIABETIC KETOACIDOSIS AT DIAGNOSIS: 4T PILOT STUDY RESULTS

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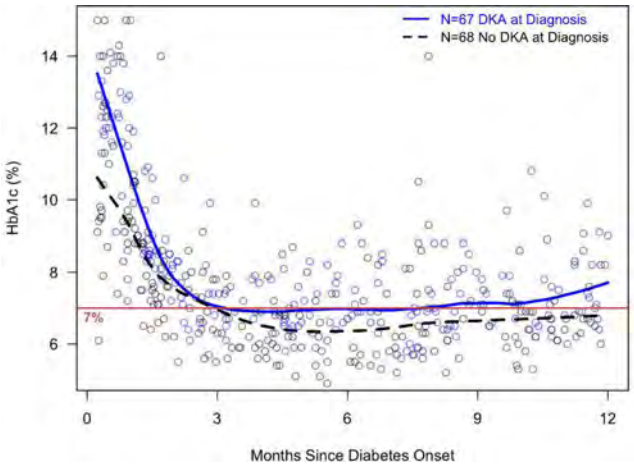
Background and Aims: The 4T pilot study offered continuous glucose monitoring (CGM) to youth with type 1 diabetes (T1D) within 1 month of diagnosis. Diabetic ketoacidosis (DKA) at diagnosis is associated with short- and long-term complications. Our aim was to determine the impact of the 4T pilot study on hemoglobin A1c (HbA1c) levels in youth who presented in DKA versus without DKA across 12 months.

Methods: In the 4T pilot study (n = 135), HbA1c levels were compared in youth that presented in DKA (n = 67) at T1D diagnosis versus youth without DKA (n = 68) at diagnosis. HbA1c levels were evaluated using a locally estimated scatter plot smoothing (LOESS).

Results: Youth with DKA at diagnosis had a higher starting HbA1c at diagnosis (12.6 ± 2.0%) compared to youth without



DKA (11.9 ± 2.2%) at diagnosis (Figure 1). Youth with DKA at diagnosis also had an earlier and higher HbA1c (nadir 6.9% at 4 months) than the group with no DKA at diagnosis (nadir 6.3% at 5 months). Although HbA1c levels had a slight drift upward in the group with DKA at diagnosis at 12-months, the overall HbA1c trajectory remained steady across 12 months post-diagnosis in both groups.

Conclusions: In the 4T program, we observed an improvement in HbA1c trajectories for youth, irrespective of DKA presentation at diagnosis. However, these data highlight the potential need for additional support for youth that present in DKA at diagnosis to achieve recommended clinical HbA1c targets and programs to diagnose T1D before DKA develops.

OP055 / #422

Topic: ***AS08-New Medications for Treatment of Diabetes***

VIRTUAL ORAL PRESENTATIONS SESSION 4

INTRALYMPHATIC GAD-ALUM (DIAMYD®) IMPROVES GLYCEMIC CONTROL IN TYPE 1 DIABETES PATIENTS CARRYING HLA DR3-DQ2

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Background and Aims: Residual beta cell function is crucial for prevention of complications. Most immune interventions have failed with minimal efficacy and/or unacceptable risks. GAD-alum (Diamyd®) in combination with Vitamin D has shown promising results in Type 1 diabetes (T1D) patients carrying HLA DR3-DQ2. We aimed to further explore the efficacy of intralymphatic GAD-alum (Diamyd®) therapy combined with vitamin D on blood glucose recorded by continuous glucose monitoring (CGM) in individuals with recent-onset T1D carrying HLA DR3-DQ2.

Methods: DIAGNODE-2 (NCT03345004) was a multicenter, randomized, placebo-controlled, double-blind trial of 109 recent-onset T1D patients aged 12–24 years with GAD65 antibodies and fasting C-peptide >0.12 nmol/L, which randomized patients to either three intralymphatic injections of 4 μg GAD-alum and oral vitamin D, or placebo. 14-day CGM recording at Month 0, 6 and 15 were obtained. Treatment arms were compared by mixed-effects models for repeated measures adjusting for baseline values.

Results: We included 98 patients with CGM recordings of sufficient quality (27 Diamyd-treated and 15 placebo-treated DR3-DQ2-positive patients) with a median (mean) recording length of 14 (13) days. In DR3-DQ2-positive patients, % time in range (3.9-10 mmol/L; 70-180 mg/dL) declined less between baseline and Month 15 in Diamyd-treated compared to placebo-treated patients (-5.1% and -16.7%, respectively, $P = .0075$), with reduced time ($P = .0036$) and number of excursions ($P = .0072$) above 13.9 mmol/L (250 mg/dL), and better glucose management indicator (GMI, $P = .0025$). GMI correlated strongly with HbA1c after 6 months.

Conclusions: Intralymphatic GAD-alum (Diamyd®) improves glycemic control in recently diagnosed T1D patients carrying HLA DR3-DQ2.

OP056 / #358

Topic: ***AS08-New Medications for Treatment of Diabetes***

VIRTUAL ORAL PRESENTATIONS SESSION 4

INDIRECT TREATMENT COMPARISON OF READY-TO-USE GLUCAGON RESCUE TREATMENTS FOR SEVERE HYPOGLYCEMIA: NASAL GLUCAGON VERSUS LIQUID STABLE GLUCAGON

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Background and Aims: An indirect treatment comparison (ITC) evaluated the efficacy and safety differences between 2 ready-to-use severe hypoglycemia rescue treatments, nasal glucagon (NG, Eli Lilly and Company) and liquid stable glucagon rescue pen (GRP, Xeris Pharmaceuticals), in adults with type 1 or type 2 diabetes.

Methods: Systematic literature reviews identified 3 randomized clinical trials assessing the efficacy and safety of NG versus reconstituted injectable glucagon (IG), and 3 trials of GRP versus IG. No head-to-head trials of NG versus GRP were identified. The Bayesian fixed-effect network meta-analysis was used to perform the ITC. Endpoints included the proportion of participants achieving treatment success (defined as increase in blood glucose to ≥70mg/dL or an increase of ≥20mg/dL from nadir blood glucose within 30mins), maximum blood glucose, and treatment-emergent adverse events (TEAE). Participants with a nadir blood glucose value of ≤54mg/dL were analyzed.

Results: A similar proportion of GRP (98.9%[279/282]) and NG participants (99.4%[155/156]) achieved treatment success (Wald method p = 0.63). The mean max blood glucose values were 220mg/dL for GRP and 168mg/dL for NG, with a significant treatment difference between GRP and NG, while adjusting IG as a comparator (17.32mg/dL, 95% credible interval: [3.94, 30.97]). Proportions of participants experiencing ≥1 TEAE were 48.8% for GRP and 38.5% for NG (odds ratio: 1.31[0.67, 2.31]). Subgroup analyses showed consistent results.

Conclusions: NG and GRP had comparable efficacy in reversing insulin-induced hypoglycemia in adults with diabetes.

NG had a mean max blood glucose below 180mg/dL, which may have implications on the re-establishment of euglycemia after severe hypoglycemia rescue.

OP057 / #484

Topic: ***AS10-Devices Focused on Diabetic Preventions***

VIRTUAL ORAL PRESENTATIONS SESSION 4

TRANSDERMAL CAPILLARY BLOOD COLLECTION FOR C-PEPTIDE IS A PRACTICAL, ACCEPTABLE AND RELIABLE ALTERNATIVE TO VENOUS SAMPLING IN CHILDREN AND ADULTS WITH TYPE 1 DIABETES

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Background and Aims: C-peptide (CP) is a useful measure in type 1 diabetes (T1D) to assess interventions to preserve beta cell function, risk progression in pre-clinical T1D and diabetes etiology. Venous sampling is limited due to practical considerations, including invasive sampling, limited access to phlebotomy, shielding patients, and remote consultations. We assessed plasma CP collected from a transdermal capillary blood (TCB) device as a practical alternative.

Methods: 71 children and adults with T1D (median age 14.8y(IQR 9.1-17.7), diabetes duration 4.0y(1.5-7.7)) and 20 controls (age 42.2y(IQR:38.0-52.1) had a concomitant venous and TCB sample collected for measurement of plasma CP. Acceptability was assessed by age-appropriate questionnaires.

Results: Venous plasma CP was assessed across a wide range of values (median = 45.5pmol/L, IQR(<3.3, 626), range (<3pmol/L, 2792). Median TCB plasma volume was 50uL(IQR 40, 50). TCB plasma CP was highly correlated to venous plasma CP (correlation coefficient = 0.996). TCB CP had 100% sensitivity and 98% specificity to detect venous CP >200pmol/L. Children and adults with T1D self-reported higher pain scores for venous compared to TCB sampling (<16y: 2/10 venous vs 1.1/10 TCB, 0 = no pain, 10 = very painful); >16y: 2.9/7 vs 1.2/7, 1 = no pain, 7 = very painful). T1D participants preferred TCB over venous sampling (63% (44/70) vs 7% (5/70)); 30% (21/70) were undecided.

Conclusions: Transdermal collection for C-peptide is a highly sensitive and specific method for detecting endogenous insulin production and is a preferred method in children, young people and adults with type 1 diabetes compared to venous sampling. TCB may be a practical alternative to venous sampling for C-peptide, avoiding the need to access a healthcare professional for traditional venepuncture.

OP058 / #542

Topic: ***AS14-Human factor in the use of diabetes technology***

VIRTUAL ORAL PRESENTATIONS SESSION 4

FAMILY SHARING OF DIABETES RESPONSIBILITIES FOR CONTINUOUS GLUCOSE MONITORING (CGM) USE: AN UPDATE OF THE DIABETES FAMILY RESPONSIBILITY QUESTIONNAIRE (DFRQ)

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Background and Aims: The DFRQ is a widely-used measure of parent involvement in diabetes management, created >30 years ago. With increased use of diabetes technologies, it is timely to update the DFRQ regarding CGM use. We evaluated the psychometric properties of an updated DFRQ.

Methods: Youth with T1D participating in a CGM study and their parents completed the DFRQ survey with four additional CGM-specific items (i.e., responding to CGM alerts/alarms). Higher scores indicate more parent involvement. Item-to-total correlations and Cronbach's α assessed internal consistency; correlations determined concurrent and predictive validity.

Results: Participants (N = 119, 49% female) were (mean±SD) aged 13.2 ± 2.7yrs, with T1D for 6.6 ± 3.5yrs. The revised survey had 14 items after removal of items with little variability, low item-to-total correlation, or outdated features. Cronbach's α for the updated DFRQ was 0.88 for youth and 0.93 for parents. Youth and parent DFRQ scores were highly correlated ($r = 0.81$, $p < 0.0001$). Youth and parent scores were inversely correlated with youth age ($r = -0.76$, $r = -0.81$, respectively, both $p < 0.0001$) and T1D duration ($r = -0.23$, $p = 0.01$; $r = -0.33$, $p = 0.0004$). Higher youth and parent scores were also correlated with higher parent reports of youth diabetes treatment adherence ($r = 0.43$, $r = 0.49$, respectively, both $p < 0.0001$). For youth aged <13yrs, higher parent DFRQ scores were positively associated with youth CGM percent time-in-range (TIR) (70-180mg/dL) 3 months later ($r = 0.36$, $p = 0.02$).

Conclusions: The updated DFRQ youth and parent surveys demonstrated strong psychometric properties and predictive validity for percent TIR for youth aged <13yrs. These surveys can help assess family responsibility-sharing for CGM use in clinical and research settings.

OP059 / #181

Topic: ***AS14-Human factor in the use of diabetes technology***

VIRTUAL ORAL PRESENTATIONS SESSION 4

FOUNDATIONAL USER EXPERIENCE NEEDS FOR NEWLY-DIAGNOSED PEOPLE WITH T2 DIABETES

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Background and Aims: Initiating onto an injectable diabetes treatment can be met with resistance, concerns, and misconceptions by end users (2009, Rubin et al., 2014, Brod et al.). Without addressing these issues, patients may reject or discontinue their treatment (Atvur, 2021).

Methods: We performed thematic analysis of qualitative and quantitative research regarding the lived experiences of people on injectable therapies for T2 diabetes. We synthesized findings relating to end user concerns, desires, and expectations in order to form a list of ''jobs-to-be-done'' for a successful solution (2016, Chistensen et al.)

Results: This analysis uncovered >70 jobs-to-be-done, constraints, and outcome expectations people initiating on injectable therapy may experience. These findings were organized into 5 UX criteria which can be used for improving system design decisions for T2 treatment solutions.

Conclusions: The resulting 5 UX criteria can be used to inform foundational design and systems development activities towards a more user-centred T2 treatment solution.

OP060 / #452

Topic: ***AS15-Trials in progress***

VIRTUAL ORAL PRESENTATIONS SESSION 4

EFFICACY, DURABILITY, AND SAFETY OF FARICIMAB IN DIABETIC MACULAR EDEMA (DME): 1-YEAR RESULTS FROM THE PHASE 3 YOSEMITE AND RHINE TRIALS

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Background and Aims: DME is a serious, vision-threatening complication of diabetic retinopathy. Intravitreal anti-VEGF therapy is the standard of care for DME; however, optimal vision outcomes often require frequent injections that are burdensome for patients, caregivers, and health care systems. Dual inhibition of VEGF-A and angiopoietin-2 may promote vascular stability and durable efficacy beyond anti-VEGF therapies. YOSEMITE (NCT03622580) and RHINE (NCT03622593) evaluated dual VEGF-A/angiopoietin-2 inhibition with faricimab, the first bispecific antibody designed for intraocular use.

Methods: Patients with DME were randomized 1:1:1 to faricimab every 8 weeks (Q8W), faricimab per personalized treatment interval (PTI), or aflibercept Q8W. Dosing intervals in the PTI arms were adjusted (Q4W up to Q16W) based on prespecified vision and anatomic criteria. The primary endpoint was mean best-corrected visual acuity change at 1 year, averaged over weeks 48, 52, and 56. Other efficacy and safety endpoints were assessed Q4W through week 100.

Results: In total, 1891 patients were enrolled in YOSEMITE (N = 940) and RHINE (N = 951). Both trials met their primary endpoint: mean 1-year vision gains with faricimab Q8W or PTI were noninferior to aflibercept Q8W. Anatomic outcomes (including change in central subfield thickness, absence of DME, and absence of intraretinal fluid over time) consistently favored faricimab over aflibercept. At week 52, > 50% and >70% of the faricimab PTI arms achieved Q16W and ≥ Q12W dosing, respectively. Faricimab was well tolerated, with no new safety signals identified.

Conclusions: At 1 year, faricimab Q8W or PTI offered durable vision gains and anatomic improvements with up to Q16W dosing.

OP061 / #341

Topic: ***AS15-Trials in progress***

VIRTUAL ORAL PRESENTATIONS SESSION 4

A COGNITIVE BEHAVIORAL THERAPY INTERVENTION (FREE)TO REDUCE FEAR OF HYPOGLYCEMIA IN YOUNG ADULTS WITH TYPE 1 DIABETES (T1D): A RANDOMIZED CONTROLLED TRIAL

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Background and Aims: Hypoglycemia is life-threatening and can lead to serious physical and psychological sequelae resulting in fear of hypoglycemia (FOH). FOH can impact diabetes self-management, glycemic control and reduce quality of life. The aim of this study was to determine the impact of a cognitive-behavioral therapy intervention (Fear Reduction Efficacy Evaluation [FREE]) compared to a diabetes education attention control on the primary outcome of FOH and secondary outcomes of self-management, glycemic control and variability.

Methods: This clinical trial of 51 young adults (18-35 years) with T1D ≥ 1 year who experienced FOH were randomized to 8 weeks of either the FREE program or a diabetes education attention control group. Real-time continuous glucose monitors (CGM) were worn by all participants. Measures of FOH, A1C, CGM-derived glucose parameters and diabetes self-management were obtained at: baseline (week 0) and post-program (weeks 8 and 12).

Results: FOH was reduced and self-management improved at the end of the FREE program compared to the attention control. FREE was associated with an improvement in glycemic parameters: time-in-range (TIR; +6.4% vs. -0.7% p = .011) and reduced time in hyperglycemia (-5.4% vs. +0.6%, p = .028) respectively, compared to the attention control group. FREE had direct and indirect effects on self-management behavior and TIR.

Conclusions: A cognitive behavioral therapy-based intervention demonstrated promise in reducing FOH and improving glucose indices by improving self-management behavior.

OP062 / #353

Topic: ***AS15-Trials in progress***

VIRTUAL ORAL PRESENTATIONS SESSION 4

GAS-PHASE BIOSENSOR FOR EXHALED ACETONE AS AN EARLY DIAGNOSTIC MARKER FOR DIABETES

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Background and Aims: Acetone in exhaled breath has the potential to be a biomarker for non-invasive monitoring of the

progress of diabetes. From this point of view, an acetone biosniffer (gas-phase biosensor) for the assessment of acetone in exhaled breath for early diagnosis of diabetes mellitus was developed and applied to the breath acetone analysis.

Methods: NADH-dependent secondary alcohol dehydrogenase (S-ADH) can reduce acetone to be isopropanol with the oxidation of NADH to NAD+. Therefore, the decreasing of NADH fluorescence intensity with the S-ADH reaction can be utilized to determinate acetone concentration. The acetone biosniffer was composed of an NADH fluorescence measurement unit, a flow-cell attached to the optical fiber probe, and an enzyme-immobilized membrane. When bio-sniffer contacted the gaseous acetone, the change of fluorescence intensity caused by S-ADH would be detected by the photo detector.

Results: This acetone bio-sniffer showed high sensitivity to acetone vapor. The dynamic range of the sensor was from 20 to 5300 ppb acetone. Then, we applied the bio-sniffer to measure breath acetone concentration. The mean concentration of breath acetone in all healthy subjects was 750.0 ppb. However, the mean exhaled acetone in diabetic patients was 1207.7 ppb, which was much higher than that in healthy subjects and showed a significant difference.

Conclusions: The breath acetone level for diabetic patients was higher than that of healthy subjects. This finding is worthwhile in the study of breath biomarkers for diabetes mellitus diagnosis. This bio-sniffer provides a new kind of analytical tool for the non-invasive early diagnosis of diabetes mellitus in the near future.

OP063 / #188

Topic: ***AS14-Human factor in the use of diabetes technology***

VIRTUAL ORAL PRESENTATIONS SESSION 4

DIABETES PROVIDER BIAS TO RECOMMENDING DIABETES TECHNOLOGY FOR PATIENTS ON PUBLIC INSURANCE IN THE UNITED STATES

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Background and Aims: Despite documented benefits of Continuous Glucose Monitors and insulin pumps in managing type 1 diabetes, inequities in the use of devices persist with lower use among Non-Hispanic Blacks and Hispanic patients compared to Non-Hispanic White patients. We aimed to examine the role of insurance mediated provider implicit bias in recommending diabetes technology

Methods: One hundred and nine adult and pediatric diabetes providers across seven US endocrinology centers completed an implicit bias assessment using a revised D-PIB tool. Providers were randomized and assigned case vignettes with different insurance statuses and patient names to proxy racial identity. Bias was tagged as providers recommending more technology for patients with private insurance or ranking insurance as one of the top 3 factors considered in recommending diabetes technology. Analysis was done using descriptive statistics and multivariate logistic regression.

Results: Implicit bias against public insurance was common (n = 66, 61%). When compared to those who had a bias, providers who did not have bias had fewer practice years (5.3 ± 5.3 years vs 9.3 ± 9 years, p = 0.006). The difference in mean age between the group with bias (42.2 ± 11 years) versus the group without bias (38.3 ± 9.3 years) trended towards significance, p = 0.05. The provider's sex, race/ethnicity, personal diagnosis of T1D, roles, workplace characteristics, or perception of bias did not differ in the groups

Conclusions: Insurance mediated implicit bias was observed in our cohort. Addressing implicit bias will involve an approach rooted in racial justice, economic equity, and equitable access to health care and education. Public insurers need to increase equitable coverage to reduce inequities

OP064 / #374

Topic: ***AS02-New Insulin Analogues***

VIRTUAL ORAL PRESENTATIONS SESSION 4

GLYCEMIC CONTROL WITH ONCE WEEKLY BASAL INSULIN FC IN PERSONS WITH TYPE 2 DIABETES MELLITUS USING CONTINUOUS GLUCOSE MONITORING IN A PHASE 2 STUDY

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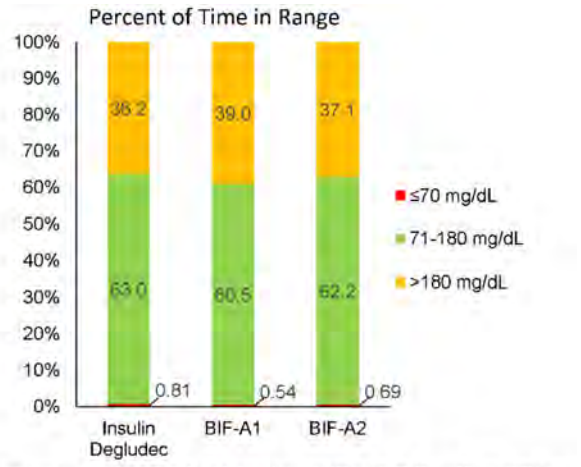
Background and Aims: Basal insulin Fc (BIF; LY3209590) is a novel, once-weekly, long-acting IgG Fc-fusion protein assessed for the treatment of diabetes mellitus. A 32-week study evaluating the safety and efficacy of BIF vs degludec in persons with type 2 diabetes mellitus (T2DM) previously treated with a basal insulin showed HbA1c non-inferiority of BIF vs degludec



Data presented are the mean percentage of a 24-hour period spent ≤70 mg/dL, 71-180 mg/dL, and >180 mg/dL.

Abbreviations: BIF, basal insulin Fc; BIF-A1, BIF dosing algorithm with different fasting glucose targets of ≤140 mg/dL; BIF-A2, BIF dosing algorithm with different fasting glucose targets of ≤120 mg/dL.

with significantly fewer hypoglycemic events (≤70 mg/dL). Here we present continuous glucose monitoring (CGM) data derived by Dexcom G6, allowing a more detailed assessment of glycemic control of BIF vs degludec.

Methods: The study included 2 dosing algorithms for BIF with different fasting glucose (FG) targets: ≤140 mg/dL (BIF-A1) and ≤120 mg/dL (BIF-A2). Degludec was titrated to FG ≤100 mg/dL. Subjects were randomized to 1 of the 3 arms.

Results: Subject (N = 399) mean age was 60.2 yrs and baseline HbA1c was 8.1%. For the entire 32 weeks, the percent of 24 hrs in range, hyperglycemia and hypoglycemia was similar for the 3 arms (Figure). At Week 32, total duration of hypoglycemia was similar across 7 days post-injection for BIF-A1 and A2, showing that duration of hypoglycemia is independent of day post-injection.

Conclusions: CGM data confirm that BIF showed similar glycemic control vs degludec despite higher FG targets and numerically lower time in hypoglycemia. The flat pharmacokinetic profile enables near peakless insulin concentrations without an increase in hypoglycemia risk at highest exposure.

OP065 / #90

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

IMPROVED GLYCEMIC CONTROL WITH HYBRID CLOSED-LOOP (HCL) VERSUS CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) THERAPY: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL (RCT)

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Background and Aims: This study investigated safety and effectiveness outcomes after HCL versus CSII use for six months.

Methods: Participants (n = 302, aged 2-80 years) with T1D were randomized to MiniMed™ 670G system HCL or control (CSII without CGM) for six months, after completing a baseline run-in period (∼2 weeks). Effectiveness endpoints included difference in A1C, time spent below target range (TBR <70mg/dL), time spent in target range (TIR, 70-180mg/dL) over 24 hours and nighttime, and coefficient of variation (CV). Endpoints were evaluated by baseline HbA1c >8% (Group 1) and baseline HbA1c ≤8% (Group 2) first, then by combined groups (Group 1 and 2). A one-way ANOVA was used to compare HCL and CSII outcomes. Safety endpoints included severe hypoglycemic, diabetic ketoacidosis (DKA) and serious device-related adverse events (AEs).

Results: For each group, HbA1c and TBR <70mg/dL were lower with HCL versus CSII ($p < 0.001$ for both, Table). For the overall group, the nighttime and 24-hour TIR, in addition to CV, were also improved with HCL ($p < 0.001$ for all). Throughout the study period, there was 1 serious device-related AE (HCL), 4 severe hypoglycemic (HCL:0, Control:4) events, and no DKA events.

Conclusions: This large RCT demonstrated significant improvement in glycemic control with HCL therapy over CSII therapy irrespective of baseline HbA1c.This large RCT demonstrated significant improvement in glycemic control with HCL therapy over CSII therapy irrespective of baseline HbA1c.

Table. Change in HbA1c, TBR<70 mg/dL, TIR, and CV based on baseline HbA1c in individuals with T1D randomized to HCL versus CSII therapy

	HCL (Aged 39.5 ± 15.6 years)				CSII (Aged 35.7 ± 16.4 years)				Difference (HCL – CSII)	P
	N	Baseline	Study End	Change	N	Baseline	Study End	Change		
Primary endpoints										
HbA1c, % (Group 1 (Baseline HbA1c >8%))	76	9.2 ± 1.2	7.7 ± 0.9	-1.6 ± 1.3	77	9.0 ± 0.9	8.2 ± 0.9	-0.8 ± 0.9	-0.8 [-1.1, -0.4]	<.0001*
TBR<70mg/dL, % (Group 2 (Baseline HbA1c ≤8%))	73	2.2 ± 5.0	2.4 ± 1.9	NA	74	1.7 ± 6.0	7.3 ± 5.3	NA	4.9 [-6.3, -3.6]	<.0001†
Secondary endpoints										
TBR<70 mg/dL, % (Group 1)	76	4.4 ± 4.4	2.3 ± 2.3	NA	77	4.5 ± 4.9	4.6 ± 5.2	NA	-2.2 [-3.6, -0.9]	<.0001†
HbA1c, % (Group 2)	73	7.3 ± 0.6	7.0 ± 0.6	-0.4 ± 0.5	74	7.2 ± 0.5	7.2 ± 0.7	-0.0 ± 0.9	-0.3 [-0.5, -0.1]	<.0001*
TIR, % Nighttime (Group 1 + Group 2)	151	53.6 ± 28.7	73.8 ± 14.3	NA	151	51.9 ± 17.5	55.6 ± 20.8	NA	18.8 [14.5, 23.1]	<.0001†
TIR, % (Group 1 + Group 2)	151	52.5 ± 16.1	67.4 ± 10.8	NA	151	51.8 ± 13.1	55.4 ± 15.0	NA	12.0 [9.0, 15.1]	<.0001†
HbA1c, % (Group 1 + Group 2)	151	8.3 ± 1.4	7.3 ± 0.8	-1.0 ± 1.2	151	8.1 ± 1.1	7.7 ± 1.0	-0.4 ± 0.9	-0.6 [-0.8, -0.3]	<.0001*
Other endpoints										
CV, % (Group 1 + Group 2)	151	40.7 ± 6.9	35.0 ± 5.5	NA	151	41.6 ± 6.9	40.3 ± 7.8	NA	-5.3 [-7.0, -3.7]	<.0001†

Data are presented as mean ± SD or mean (95% CI)
*Comparison of change in HbA1c between HCL and CSII
†Comparison of end of study TBR, TIR, or CV between HCL and CSII
N=Randomized participants; TBR=Time below range; TIR=Time-in-target range; CV=Coefficient of variation of serious glucose; NA=Not applicable

OP066 / #105

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

PERFORMANCE OF OMNIPOD® 5 AUTOMATED INSULIN DELIVERY SYSTEM AT SPECIFIC GLUCOSE TARGETS FROM 110-150MG/DL OVER THREE MONTHS IN VERY YOUNG CHILDREN WITH TYPE 1 DIABETES

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Background and Aims: Insulin therapy should be individualized for users' unique treatment goals. The Omnipod 5 System provides automated insulin delivery (AID) with customizable glucose targets from 110-150mg/dL (6.1-8.3mmol/L). This analysis assessed system performance at specific glucose targets during the 3-month pivotal study in very young children (aged 2-5.9y) with type 1 diabetes (T1D).

Methods: Participants with A1C<10% (86mmol/mol) used the AID system for 3 months at home after a 14-day standard therapy (ST) phase. Glucose targets from 110-150mg/dL (6.1-8.3mmol/L) in 10mg/dL (0.55mmol/L) increments were programmable by time of day. Primary safety and efficacy endpoints, respectively, were occurrence of severe hypoglycemia (SH) and diabetic ketoacidosis (DKA), and sensor glucose percent time in target range (TIR) (70-180mg/dL, 3.9-10.0mmol/L) during AID at each glucose target compared with ST.

Table. Glycemic Outcomes for Very Young Children during the Standard Therapy (ST) and Automated Insulin Delivery (AID) Phases at Each Glucose Target

Glycemic Outcomes	Standard Therapy Phase[b]	AID target 110mg/dL (6.1 mmol/L)	AID target 120mg/dL (6.7 mmol/L)	AID target 130mg/dL (7.2 mmol/L)	AID target 140mg/dL (7.8 mmol/L)	AID target 150mg/dL (8.3 mmol/L)†
Sample size, n[a]	**80**	**47**	**61**	**47**	**20**	**16**
Mean glucose, mg/dL (mmol/L)	171 ± 31 (9.5 ± 1.7)	153 ± 18*[c] (8.5 ± 1.0)	157 ± 21*[c] (8.7 ± 1.2)	161 ± 25*[b] (8.9 ± 1.4)	169 ± 18*[b] (9.4 ± 1.0)	169 ± 20*[b] (9.4 ± 1.1)
Percent time in range, %						
<54 mg/dL (<3.0 mmol/L)	0.2 (0.1, 0.8)	0.3 (0.2, 0.7)	0.2 (0.1, 0.5)	0.2 (0.1, 0.7)	0.2 (0.0, 0.5)	0.1 (0.0, 0.2)
<70 mg/dL (<3.9 mmol/L)	2.2 (0.9, 4.7)	2.4 (1.5, 3.9)	1.6 (1.1, 2.7)*[c]	1.4 (0.6, 2.9)*[c]	1.4 (0.4, 2.7)*[c]	0.8 (0.1, 2.0)*[c]
70-180 mg/dL (3.9-10.0 mmol/L)	57.2 ± 15.3	69.3 ± 9.5*[c]	68.3 ± 11.3*[c]	67.3 ± 14.6*[b]	63.0 ± 11.9*[b]	65.0 ± 15.0*[b]
>180 mg/dL (>10.0 mmol/L)	39.4 ± 16.7	27.6 ± 10.5*[b]	29.3 ± 12.1*[c]	30.4 ± 15.4*[b]	35.4 ± 12.2*[b]	33.9 ± 15.0*[b]
≥250 mg/dL (≥13.9 mmol/L)	14.8 ± 12.1	7.7 ± 5.9*[c]	8.9 ± 6.2*[c]	10.6 ± 9.4*[c]	12.6 ± 6.2*[c]	11.4 ± 7.2*[b]
Number of days per person per target	-	55.7 (25.9, 80.5)	50.3 (28.4, 74.4)	16.3 (7.8, 32.1)	17.9 (3.0, 30.8)	14.9 (6.1, 22.4)
Cumulative number of person-days (% of total days)	1120	2438 (33%)	3084 (42%)	1067 (15%)	404 (5.5%)	237 (3.2%)

Data are mean ± SD or median (IQR)

†Does not include use of 150mg/dL target in combination with the HypoProtect feature, now called Activity feature. In the study, the HypoProtect feature could be enabled by the user in times of increased risk of hypoglycemia, such as exercise, which automatically increased the target to 150mg/dL (8.3mmol/L) and reduced insulin delivery. This feature was used for 113 (1.5%) cumulative person-days.

[a]Includes any participant who used the specified target for a minimum of 288 nonconsecutive data points. Results are calculated only for times when a participant was using that target.

[b]Statistical analyses between standard therapy phase and each AID target were paired with the same participants analyzed. Results during standard therapy for each subset of participants are not shown.

*[b]Significant difference from standard therapy phase with p-value <0.05 using two-sided paired t-test.

*[c]Significant difference from standard therapy phase with p-value <0.05 using two-sided Wilcoxon signed rank test.

Results: Participants (N = 80), aged (mean±SD) 4.7 ± 1.0y with T1D duration 2.3 ± 1.1y, had a total daily dose (TDD) of 13.7 ± 4.4units (range 5.3-27.1units) and baseline A1C of 7.4 ± 1.0% (57 ± 10.9mmol/mol) (range 5.4-10.2%, 36-88mmol/mol). TIR improved during the AID phase with all targets, while time <70mg/dL (<3.9mmol/L) remained low at the 110mg/dL (6.1mmol/L) target and decreased with all other targets (Table). There was no correlation between time-weighted average target and age (r = -0.02) or TDD (r = 0.05), (both p > 0.05). There were no SH or DKA episodes.

Conclusions: The Omnipod 5 System was safely used by a large cohort of very young children with T1D at glucose targets from 110-150mg/dL (6.1-8.3mmol/L). The 110mg/dL (6.1mmol/L) and 120mg/dL (6.7mmol/L) targets were used most often, at a combined 75% of the time.

OP067 / #135

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

HYBRID CLOSED-LOOP GLUCOSE CONTROL COMPARED WITH SENSOR AUGMENTED PUMP THERAPY IN OLDER ADULTS WITH TYPE 1 DIABETES: A MULTICENTRE, MULTINATIONAL, RANDOMISED, CROSSOVER STUDY

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Background and Aims: Older adults with type 1 diabetes (T1D) have distinct characteristics that can make optimising glycaemic control challenging. We hypothesised that hybrid closed-loop is safe and more effective than sensor-augmented pump (SAP) therapy in older adults with T1D.

Methods: In a multicentre, multinational (UK and Austria), randomised, crossover study, adults aged 60 years and over with T1D using insulin pump therapy underwent two 16-week periods comparing hybrid closed-loop (CamAPS FX) and SAP therapy in random order. The primary endpoint was the proportion of time sensor glucose was in target range between 3.9 and 10.0mmol/L. ClinicalTrials.gov NCT04025762.

Results: Thirty-seven participants (mean±SD age 67 ± 5 years, baseline HbA1c 7.4 ± 0.9% [57 ± 10mmol/mol]) were randomised between 4 September 2019 and 2 October 2020. The proportion of time glucose was between 3.9 and 10.0mmol/L was 8.6 percentage points (95% CI 6.2 to 11.0) higher during closed-loop compared to SAP (p < 0.001). Time with glucose >10.0mmol/L was 8.4 percentage points lower (95% CI -11.0 to -6.0; p < 0.001), mean glucose was 0.7mmol/L lower (95% CI -0.9 to -0.5; p < 0.001), and glycated haemoglobin was 0.2% lower

(95% CI -0.4 to -0.1; p < 0.001) with closed-loop than with SAP. Time in hypoglycaemia (<3.9mmol/L) was similar between periods (p = 0.54). Two severe hypoglycaemia events occurred during the SAP period. There were no other treatment related serious adverse events.

Conclusions: Hybrid closed-loop insulin delivery is safe and achieves superior glycaemic control than SAP therapy without increasing the risk of hypoglycaemia in older adults with T1D.
Funding: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

OP068 / #137

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

A COMPARISON OF TWO HYBRID CLOSED-LOOP SYSTEMS IN ITALIAN CHILDREN AND ADULTS WITH TYPE 1 DIABETES

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Background and Aims: The aim of this study was to compare the efficacy of the currently available Advanced Hybrid Closed Loop (AHCL) technologies, *Tandem Control-IQ* and *Minimed780G*, on glycemic control in pediatric and adult patients with Type 1 Diabetes (T1D).

Methods: Continuous glucose monitoring (CGM) data from 90 patients, who upgraded to *Minimed780G* or *Tandem Control-IQ*system and have completed 1-month observation period, were retrospectively analyzed. The two groups were matched and reduced to 32 patients each to minimize the imbalances among basic characteristics. Additionally, an adjustment for baseline HbA1c levels was required.

Results: All 64 matched patients showed a statistically significant improvement of time in range (TIR) (+9.1%, p = 0.001), time above range (TAR) >250 mg/dl (-9.9%, P = <0.001), standard deviation (SD) (-12.8%, P = 0.001) and average glycemia (-22.8%, P = <0.001). *Tandem Control-IQ* system significantly reduced the frequency of hypoglycemia 70-54 mg/dl, while *Minimed 780G* increased it (-0.77% vs +0.44% p = 0.018).

Conclusions: The use of ACHL systems led to a significant improvement of glycemic control. *Minimed 780G* appears to be more effective in managing hyperglycemia, while *Tandem Control-IQ* seems to be more effective in reducing time in hypoglycemia. Understanding the strengths and weaknesses of these devices could be useful to define a customized insulin therapy.

OP069 / #150

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

ACCURACY OF BGL PREDICTION FROM A PERSONALIZABLE PHYSIOLOGICAL MODEL OF BLOOD GLUCOSE DYNAMICS USING REAL-WORLD DATA

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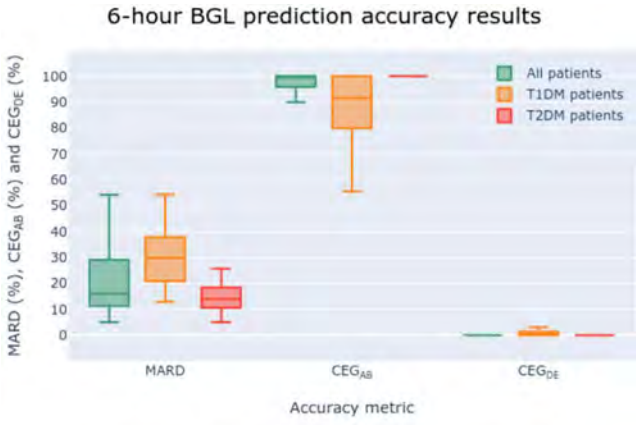
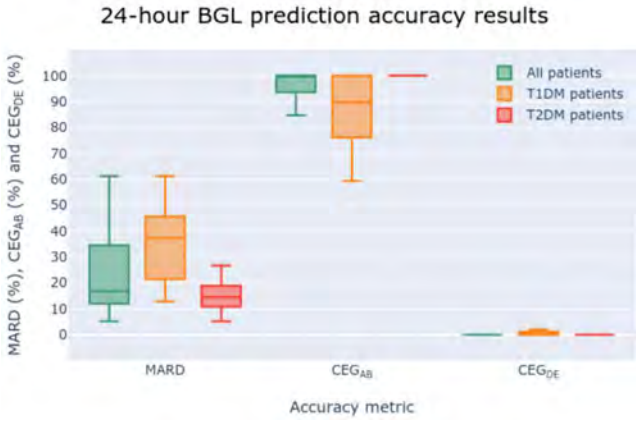
Background and Aims: Glycemic control is challenging due to the complex blood glucose (BGL) regulation dynamics. A system generating personalized models to mimic the individual BGL regulation physiology was developed, enabling BGL predictions up to 24 hours and personalized insulin dose optimization.

Methods: 96 subjects (30 T1DM and 66 T2DM, 53 female, age 47.9 ± 15.5 years, BMI of 29.1 ± 5.0 kg/m2) included in a clinical study carried out in partnership with Grupo Fleury and Medtronic were monitored during 144 hours with CGM (required 2 or more calibrations/day), activity tracker and our own mobile app to collect BGL, meal, insulin and physical activity data. The model was individually trained using 96-hour data, and tested using 24-hour data by calculating 6-hour and 24-hour BGL prediction curves that were evaluated using MARD and Consensus Error Grid (CEG).

Results: The median MARD for all, T1DM and T2DM patients for 6-hour BGL predictions was 16.0%, 29.8% and 13.9% respectively, and for 24-hour was 16.8%, 37.1% and 14.5% respectively. The median CEG points in zones AB (CEG_{AB}) for 6-hour and 24-hour BGL predictions for all and T2DM patients was 100%, while T1DM patients showed 91.6% and 89.7% respectively. The median CEG points in zones DE (CEG_{DE}) was 0% for all groups and prediction horizons.





Conclusions: Our model accurately predicted BGL up to 24-hour ahead, showing potential on BGL excursion risk identification, insulin dose optimization, preventive actions recommendation, among others. We thank Grupo Fleury for clinical, financial, protocol design, structure, and follow-up support, and Medtronic for providing the iPro2 CGMs and protocol design support.

OP070 / #182

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

DOES PARENTAL SLEEP QUALITY IMPROVE AFTER HIBRID CLOSE-LOOP SYSTEM MEDTRONIC 780G INSTAURATION?

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Background and Aims: Type 1 diabetes (T1D) requires intensive management in order to achieve a good metabolic control. Parents assume a huge responsibility in the medical care of their children, including night attention and may lead to the loss of the sleep quality. New hybrid closed-loop insulin therapy systems (HCLS), combine automated insulin delivery through an algorithm and self-delivered mealtime boluses. This reduces the decision-making required. This study aims to see if these systems improve sleep quality in parents of children with T1D by reducing their intervention along the night.

Methods: We performed a longitudinal study to assess sleep quality in caregivers of T1D children and adolescents, before and 3-months after HCLS initiation (Medtronic 780G system) using a validated sleep-quality survey (Pittsburgh Sleep Quality Index-PSQI). Paired t-Student and Chi-Square were used to analyze differences. Significance if p-value <0.05.

Results: 39 patients/caregivers were recruited, 23 (59%) patients were female, mean age 12.5(±2.64), 21(50%) were in pubertal tanner 5 and mean diabetes duration was 5.4(±3.6) years. 24(61.5%) had MDI modality. Caregivers (survey respondents) were mainly women, 34(87.2%), mean age in years 44.1(±5.3). After HCLS instauration, the global PSQI score improved considerably along with better subjective sleep, reduction on latency sleep and reduced waking-up events [table 1]. Secondarily, we observed higher rate of patients meeting glucose control goals, with a reduction in mean Hb1Ac% (from 7.54(±0.97), to 7.07(±0.74); $p < 0.001$), increased TIR (from 55.4(±15.5) to 72.5(±9.7); $p < 0.001$).

Conclusions: We observed an improvement in parental sleep quality, together with an improvement in glycemic control after HCLS instauration.

Table 1.- Comparative sleep quality before and after HCLS therapy

	Before HCLS	After HCLS	p-value
Time interval (months)	4.7 (1.3)		
Parental Sleep Quality			
Global PSQI Score	9.7 (4.2)	4.2 (2.5)	< 0.001
Subjective sleep quality score	2.05 (0.60)	0.84 (0.53)	< 0.001
Very good	0 (0)	9 (23.1)	< 0.001
Fairly good	6 (15.4)	27 (69.2)	
Fairly bad	25 (64.1)	3 (7.7)	
Very bad	8 (20.5)	0 (0)	
Sleep latency score	1.53 (1.25)	0.82 (0.94)	< 0.001
Minutes to fall asleep	30.3 (4.03)	21 (3.4)	< 0.001
< 15 minutes	13 (33.3)	19 (51.4)	0.030
16-30 minutes	14 (35.9)	15 (35.9)	
31-60 minutes	11 (28.2)	2 (5.4)	
> 60 minutes	1 (2.6)	1 (2.7)	
Cannot get to sleep < 30 minutes			
Not during last month	17 (43.6)	23 (59)	0.003
Less than once a week	0 (0)	7 (17.9)	
Once or twice a week	4 (10.3)	3 (7.7)	
Three or more a week	18 (46.2)	6 (15.4)	
Sleep duration Score	1.79 (0.95)	0.56 (0.64)	0.356
Sleep duration (Hours)	5.58 (1.29)	7.06 (1.00)	0.065
Sleep efficiency score	1.23 (0.20)	0.38 (0.12)	0.030
Sleep disturbance score	1.10 (0.38)	0.82 (0.50)	0.036
Wake up in the middle of the night			
Not during last month	2 (5.2)	15 (38.5)	<0.001
Less than once a week	0 (0)	9 (23.1)	
Once or twice a week	4 (10.3)	9 (23.1)	
Three or more a week	33 (84.6)	6 (15.4)	
Have to get up to use the bathroom			
Not during last month	24 (64.1)	26 (66.7)	0.304
Less than once a week	1 (2.6)	4 (10.3)	
Once or twice a week	3 (7.7)	4 (10.3)	
Three or more a week	10 (25.6)	5 (12.8)	

OP071 / #213

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

COMPARISON OF NOCTURNAL GLUCOSE MANAGEMENT AFTER EXERCISE AMONG DUAL-HORMONE, SINGLE-HORMONE AUTOMATED INSULIN DELIVERY SYSTEM AND USUAL CARE IN TYPE 1 DIABETES: A POOLED ANALYSIS

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Background and Aims: Only two studies have compared the efficacy of dual-hormone (DH) automated insulin delivery (AID) systems, single-hormone (SH) AID and usual care (UC) on post-exercise overnight glucose management in people living with type 1 diabetes (PWT1D); their conclusions differ. By pooling data from these two studies, we aim to draw stronger conclusions.

Table 1: Comparison of dual-hormone automated insulin delivery system, single-hormone automated insulin delivery system and usual care for nocturnal glucose management after exercise (Adults)

	UC	SH	DH	SH minus UC	DH minus UC	DH minus SH
TIR (3.9–10.0 mmol/L) (%) [a]	65.1±37.0	83.1±20.5	94.0±11.9	18.0±40.8**	28.8±38.1***	10.8±20.1*
Mean glucose value (mmol/L)	6.4±2.9	6.4±1.6	6.3±1.3	0±3.0	-0.1±2.9	-0.1±1.2
TIT (3.9–7.8 mmol/L) (%) [b]	48.6 (18.1, 88.2)	70.8 (50.0, 97.2)	84.7 (57.6, 99.3)	26.4 (-17.4, 54.9)*	29.2 (-1.4, 58.2)**	2.3 (-8.3, 33.3)
	50.0±37.0	69.0±27.9	79.2±23.6	19.0±44.4	29.2±41.8	10.2±27.1
% CGM time <3.9 mmol/L [b]	0 (0, 57.6)	0 (0, 20.1)	0 (0, 0)	0 (-38.2, 0)***	0 (-54.2, 0)***	0 (-9.0, 0)***
	24.2±35.6	9.6±16.6	2.7±8.6	-14.6±34.8	-21.5±35.4	-6.9±16.3
% CGM time <3.0 mmol/L [b,c]	0 (0, 3.5)	0 (0, 0)	0 (0, 0)	0 (-3.5, 0)	0 (-2.1, 0)	0 (0, 0)
	11.7±25.9	2.7±9.3	0.3±1.4	-9.0±24.9	-11.4±26.0	-2.4±9.5
% CGM time >7.8 mmol/L [b]	1.4 (0, 47.9)	5.6 (0, 41.0)	8.3 (0, 34.0)	0 (-26.4, 29.2)***	0 (-27.1, 11.1)***	0 (-10.3, 7.6)**
	25.8±35.5	21.4±27.9	18.1±23.9	-4.4±44.3	-7.7±37.6	-3.3±22.1
% CGM time >10.0 mmol/L [b]	0 (0, 6.9)	0 (0, 1.4)	0 (0, 1.7)	0 (0, 0)***	0 (0, 0)***	0 (-0.7, 0)***
	10.7±25.2	7.3±15.6	3.3±9.2	-3.4±27.8	-7.3±25.7	-4.0±13.0
% CGM time >13.9 mmol/L [b,c]	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
	3.0±13.7	0.5±2.1	0.1±0.7	-2.6±14.0	-2.9±13.8	-0.4±1.8
SD (mmol/L)	1.1±0.8	1.3±0.7	1.1±0.6	0.2±1.1	0±0.8	-0.2±0.7
CV (%)	18.3±10.9	20.5±10.1	17.5±7.7	2.2±15.8	-0.8±12.8	-3.0±10.6

Data are the median (IQR) or mean ±SD.

[a] Primary outcome

[b] For non-normally distributed data, both median (IQR) and mean ± SD are shown

[c] Statistical analyses were not performed due to the low variation within groups, where the majority of values were zero.

Abbreviations: CGM = continuous glucose monitoring; CV = coefficient of variation; DH = dual-hormone automated insulin delivery system; SD = standard deviation; SH = single-hormone automated insulin delivery system; TIR = time in range; TIT = time in target; UC = usual care

*: P < 0.05; **: P < 0.01; ***: P < 0.001.

Methods: Data were pooled from two open-label, randomized, controlled, crossover studies. Forty-one adults PWT1D [median (Q1-Q3) age: 34.0 years (29.5, 51.0), mean ± SD hbA1c: 7.5 ± 0.2%] and 17 adolescents PWT1D [age: 14.0 (13.0, 16.0), hbA1c: 7.8 ± 0.2%] underwent DH-AID, SH-AID and UC (pump+capillary blood glucose). Each intervention contained an evening, 60-minute, moderate aerobic exercise session. The primary outcome was time in range% (TIR%) overnight (00:00-06:00) post-exercise based on continuous glucose monitoring. The three groups were compared using linear mixed effect model or generalized linear mixed model.

Results: Among adults, TIR% (mean ± SD) was 94.0% ± 11.9%, 83.1% ± 20.5% and 65.1% ± 37.0% during DH-AID, SH-AID and UC intervention, respectively ($P < 0.05$ for all between-group comparisons) (Table 1). DH-AID was superior to SH-AID and UC, and SH-AID was superior to UC regarding hypo- and hyperglycemia prevention but not glycemic variability. Among adolescents, DH-AID and SH-AID were both superior to UC regarding hypo- and hyperglycemia prevention but not glycemic variability (Table 2). Glycemic outcomes were similar between DH-AID and SH-AID ($P > 0.05$).

Conclusions: Regarding post-exercise nocturnal glucose management, AIDs were both better than UC for both adult and adolescent PWT1D; DH-AID was better than SH-AID among adult but not adolescent PWT1D.

Table 2: Comparison of dual-hormone automated insulin delivery system, single-hormone automated insulin delivery system and usual care for nocturnal glucose management after exercise (Adolescents)

	UC	SH	DH	SH minus UC	DH minus UC	DH minus SH
TIR (3.9–10.0 mmol/L) (%) [a]	78.6±27.2	91.6±14.0	83.2±25.8	13.0±31.5	4.6±34.3	-8.4±26.9
Mean glucose value (mmol/L) [b]	6.8±2.0	6.6±1.6	7.0±3.1	-0.2±2.2	0.2±3.2	0.4±2.8
TIT (3.9–7.8 mmol/L) (%) [b]	65.3 (34.0, 94.4)	73.6 (54.2, 98.6)	76.4 (54.2, 100)	8.3 (-27.1, 51.4)	2.8 (-14.6, 47.9)	0 (-20.8, 25)
	61.7±32.5	72.3±25.8	72.3±30.2	10.6±45.9	10.6±35.7	0±29.9
% CGM time <3.9 mmol/L [b]	0 (0, 13.9)	0 (0, 0)	0 (0, 6.3)	0 (-11.7, 0)***	0 (-9.0, 2.8)**	0 (0, 6.3)
	7.3±11.5	2.9±7.2	4.0±7.2	-4.4±13.6	-3.3±13.8	1.1±8.9
% CGM time <3.0 mmol/L [b,c]	0 (0, 1.4)	0 (0, 0)	0 (0, 0)	0 (-1.4, 0)	0 (-1.4, 0)	0 (0, 0)
	4.5±10.0	0±0	1.0±2.8	-4.5±10.0	-3.5±10.8	1.0±2.8
% CGM time >7.8 mmol/L [b]	29.2 (0, 56.3)	20.8 (0, 44.4)	13.9 (0, 44.4)	0 (-49.3, 25.7)**	-2.8 (-27.1, 9.7)***	0 (-22.2, 14.6)
	31.0±33.2	24.8±26.9	23.7±30.6	-6.2±43.2	-7.3±33.6	-1.1±30.0
% CGM time >10.0 mmol/L [b,c]	0 (0, 23.6)	0 (0, 2.1)	0 (0, 19.5)	0 (-20.1, 0)	0 (-11.8, 3.6)	0 (0, 3.6)
	14.1±26.3	5.6±13.4	12.8±25.2	-8.6±27.6	-1.3±31.8	7.3±26.0
% CGM time >13.9 mmol/L [b,c]	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
	0.9±3.7	2.3±7.3	6.5±20.4	1.4±4.0	5.6±19.6	4.2±19.8
SD (mmol/L)	1.5±1.1	1.4±1.1	1.6±1.4	-0.1±1.2	0.1±1.4	0.2±1.2
CV (%)	22.7±15.3	19.9±10.2	21.0±13.3	-2.8±16.7	-1.8±19.7	1.0±11.5

Data are the median (IQR) or mean ±SD.

[a] Primary outcome

[b] For non-normally distributed data, both median (IQR) and mean ± SD are shown

[c] Statistical analyses were not performed due to the low variation within groups, where the majority of values were zero.

Abbreviations: CGM = continuous glucose monitoring; CV = coefficient of variation; DH = dual-hormone automated insulin delivery system; SD = standard deviation; SH = single-hormone automated insulin delivery system; TIR = time in range; TIT = time in target; UC = usual care

*: P < 0.05; **: P < 0.01; ***: P < 0.001.

OP072 / #280

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

GLYCAEMIC AND SAFETY OUTCOMES ASSOCIATED WITH DO-IT-YOURSELF ARTIFICIAL PANCREAS SYSTEMS (DIYAPS): INITIAL INSIGHTS FROM THE ASSOCIATION OF BRITISH CLINICAL DIABETOLOGIST'S (ABCD) DIYAPS AUDIT PROGRAMME

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Background and Aims: The use of DIYAPS is increasing with several thousand of users worldwide. Given their unapproved and unlicensed status, objective glycaemic and safety data is needed. The ABCD DIYAPS audit programme was launched in 2020 with the aim of providing clinically validated data. We present our most up-to-date data from the audit.

Methods: Data were extracted from the ABCD DIYAPS audit tool. Those with baseline and available follow-up data were included. Main outcomes of interest were related to glucose control (e.g. HbA1c, time-in-range) and safety (e.g. adverse events, hospital admissions) outcomes. Analyses were performed using Stata 16.

Results: Data were included for 101 individuals, 55% male, mean ± SD baseline HbA1c 54 ± 16 mmol/mol and weight 84.1 ± 26.0kg, median diabetes duration 25.5 years (IQR 17.0-33.5). After mean ± SD follow-up of 1.6 ± 1.1years HbA1c decreased significantly by -6.4mmol/mol (95% CI -3.4–9.5, $p < 0.001$). Mean time-in-range (3.9-10mmol/L) at follow-up was 79% (SD ±11.5) and time-below-range 3.1% (SD ±2.2). Two adverse events related to DIYAPS use were reported – insulin over-delivery due to third-party app interference. One user continued to experience severe hypoglycaemia. Three admissions were noted (2 hypoglycaemia, 1 hyperglycaemia) but there was no significant change in the number of hospital admissions (baseline 7 events) or paramedic callouts following DIYAPS commencement (no events at baseline or follow-up).

Conclusions: Our data suggest that DIYAPS use is associated with clinically significant improvements in HbA1c, with most achieving optimal time-in-range and time-below-range. Ongoing vigilance for adverse events will be needed and comparison with commercially available alternatives will be vital moving forwards.

OP073 / #773

Topic: ***AS15-Trials in progress***

ORAL PRESENTATIONS SESSION 4

SPOTLIGHT-AQ PRECISION DIABETES MANAGEMENT: EFFICACY AND COST-EFFECTIVENESS FOR USE IN ROUTINE CARE WITH PEOPLE WITH TYPE 1, TYPE 2 DIABETES OR PRE-DIABETES

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Background and Aims: Background: Existing therapeutic interventions to treat diabetes are well known, yet the majority of people with diabetes do not consistently achieve blood glucose targets (even individual therapy targets) for optimal health, despite the large range of treatment options available. Such outcomes have remained stubbornly poor for decades with <25% adults with diabetes achieving glycaemic targets. The medical healthcare model is not ideally suited to supporting effective diabetes management. In routine clinical care, patient-identified priority concerns may be missed by the care team. Aim: To determine clinical and cost effectiveness of the Spotlight-AQ Pre-clinic assessment and mapped care planning intervention in a multi-centre RCT

Methods: Participants: Adults with type 1, type 2 or pre-diabetes attending routine care outpatient appointments. **Design:** Multi-centre, parallel group, individually randomised trial comparing consultation duration in adults with type 1, type 2 or pre-diabetes using the Spotlight Consultations pre-clinic assessment compared to usual care in the Spotlight-AQ study. **Intervention**: An outpatient pre-clinic intervention delivered within one week prior to scheduled routine outpatient appointment. **Sample size**: 200 recruited

Results: Primary outcome measure: Duration of routine outpatient consultation. **Secondary outcome measures:** Functional health status Diabetes distress Depression Treatment satisfaction Impact on self-care behaviours HCP burnout HCP treatment satisfaction and burden Hypoglycaemia (time less than 70mg/dL) Hyperglycaemia (time above 180 mg/dL) Change in weight Change in HbA_{1c} Cost effectiveness of intervention **Trial Registration**: ISRCTN15511689

Conclusions: Preliminary results will be presented with implications for routine care delivery in terms of reducing healthcare professional burnout whilst improving physical and mental health outcomes for people with diabetes

OP074 / #511

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

DIABETIC KETOACIDOSIS AFTER INITIATION OF SGLT-INHIBITION UNDER HYBRID CLOSED-LOOP THERAPY IN TYPE 1 DIABETES

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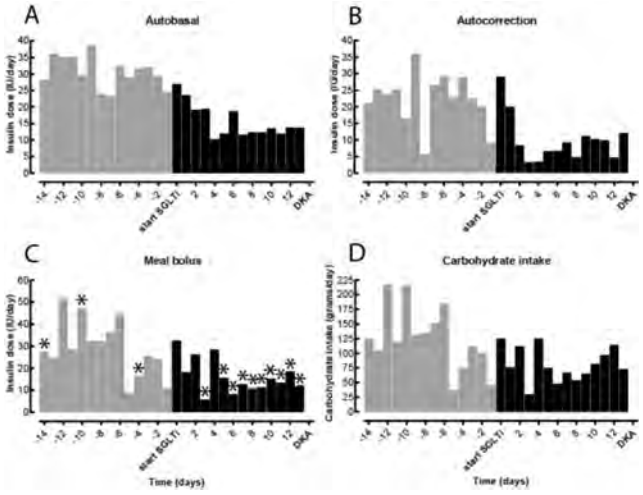
Background and Aims: Despite clinical benefits and regulatory approval in Europe, there is reluctance to sodium-glucose cotransporter inhibitor (SGLTi) use in type 1 diabetes (T1D), due to increased risk of developing diabetic ketoacidosis (DKA). Not much is known about the possible risks or benefits when combining SGLTi with hybrid closed-loop (HCL) systems.

Methods: Detailed description of changes in daily insulin dosing by a Medtronic MiniMed™ 780G algorithm in a 23-year-old woman with T1D after SGLTi initiation leading to DKA.

Results: Within a few days after start of SGLTi, the HCL control algorithm reduced the autobasal and autocorrection doses (panel A and B in Figure). Meal bolus insulin doses were already reduced in the week prior to initiation of SGLTi (panel C), as a result of a lower carbohydrate intake by our patient (panel D). After start of SGLTi, meal bolus insulin doses remained at a lower level, not only due to lower carbohydrate intake, but also due to frequent activation of the 'safe meal bolus' (* in panel C). Taken together, there was a significant 49% reduction in total daily insulin dose in the 2 weeks after start of SGLTi, leading to development of DKA due to insulin doses below the minimum needed to prevent ketone formation.

Conclusions: We recommend caution with SGLTi use in people with T1D and concomitant Medtronic MiniMed™ 780G use, until more is known about the influence of SGLTi on HCL control algorithm functioning, in order to avoid an even greater risk of DKA.



OP075 / #816

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 4

SIGNIFICANCE AND FUTURE TRENDS OF AID-SYSTEMS FROM THE PERSPECTIVE OF PHYSICIANS

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Background and Aims: How do physicians assess AID-Systems in terms of their current and future importance for diabetes care?

Methods: In 2021 305 diabetologists in Germany (48% female, average age 53.7 years) were asked via online surveys about their current and future assessment of AID-Systems.The results were compared with the 2019 survey, in which 337 diabetologists (43% female, mean age 53.2 years) participated.

Results: Currently, 58.6% (2020: 51.4%) of diabetologists consider AID-Systems to be important for diabetes care, in 5 years 89.3% (2020: 86.4%). Diabetologists estimate that in approx. 9 years one in two PwD TD1 in Germany will be a user of an AID-System, and in approx. 17 years 90% will use an AID-System. Currently, they estimate that 57.6% of all PwD-TD1 are suitable for an AID-System. Diabetologists see the clearest impact of AID-Systems in an increased need for diabetes self-mangement education (78.9%), but also in PwD becoming much more autonomous and empowered (62.8%). Regarding possible negative effects of AID-Systems, diabetologists see only few risks: 20% fear that PWD will have less contact with the diabetes team, 16.9% are concerned that PWD will not be able to cope with the technological change. Only 7.9% fear that PWD will become riskier with AID-Systems, only 1.7% have fears that the diabetes team will become superfluous.

Conclusions: Overall, diabetologists assess AID-Systems as a important innovation for diabetes care and that this will soon become the standard therapy for T1D. The effort for Diabetes self-management education and support is estimated to be relatively high, possible disadvantages relatively low.

OP076 / #123

Topic: *AS05-Glucose Sensors*

ORAL PRESENTATIONS SESSION 5

THE RELATIONSHIP BETWEEN CHRONIC COMPLICATIONS AND TIME IN RANGE IN PEOPLE WITH TYPE 1 DIABETES: A RETROSPECTIVE CROSS-SECTIONAL REAL-WORLD STUDY

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Background and Aims: Time in range (TIR; glucose of 70-180 mg/dL) overcomes some of the limitations of HbA1c in the individual assessment of glycemic control. This study evaluates whether TIR is associated with the presence of chronic complications in a real-world population of people with type 1 diabetes (T1D).

Methods: Sensor-measured TIR and the occurrence of microvascular (diabetic retinopathy [DR], diabetic nephropathy [DN], diabetic peripheral neuropathy [DPN]) and macrovascular complications in 812 people with T1D were analyzed cross-sectionally. Binary logistic regression was used to evaluate the contribution of TIR to the presence of chronic complications, after correction for sex, age, diabetes duration, BMI, blood pressure, lipid profile, smoking, lipid lowering and antihypertensive therapy.

Results: Mean TIR was 52.7 ± 15.2%. Overall, 46.1% had at least one microvascular complication (34.5% DR, 23.9% DN, 16% DPN) and 16.6% suffered from any macrovascular complication. The prevalence of at least one microvascular complication (p for trend <0.001), DR (p for trend <0.001) and DN (p for trend = 0.036) decreased with increasing TIR quartiles (figure 1). The odds ratio of having at least one microvascular complication, DR, DN, DPN or any macrovascular complication per 1% increase in TIR was 0.969 (95%CI: 0.957-0.982, p < 0.001), 0.959 (95%CI: 0.945-0.974, p < 0.001), 0.981 (95%CI: 0.967-0.995, p = 0.008), 0.980 (95%CI: 0.964-0.997, p = 0.019) and 0.975 (95%CI: 0.958-0.992, p = 0.005) respectively.

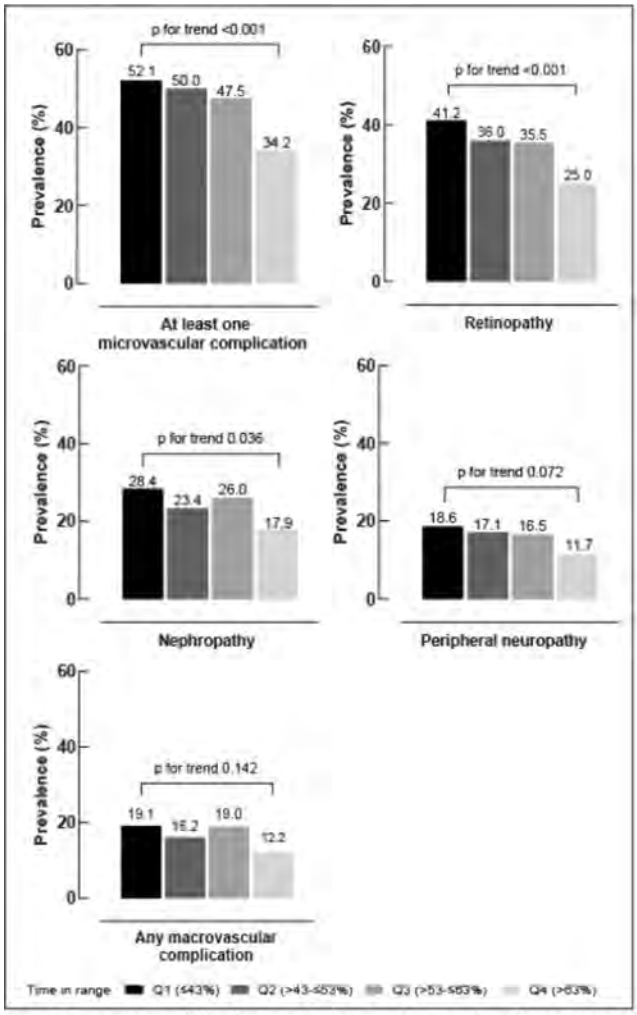

Figure 1: The prevalence of at least one microvascular complication, retinopathy, nephropathy, peripheral neuropathy and any macrovascular complication according to time in range quartiles.

Conclusions: TIR is inversely associated with the presence of chronic diabetes complications. These data add validity to the use of TIR as key measure of glycemic control and endpoint of clinical trials, in addition to HbA1c.

OP077 / #194

Topic: *AS05-Glucose Sensors*

ORAL PRESENTATIONS SESSION 5

IMPAIRED AWARENESS OF HYPOGLYCAEMIA; PREVALENCE AND ASSOCIATED FACTORS BEFORE AND AFTER FREESTYLE LIBRE USE IN THE ASSOCIATION OF BRITISH CLINICAL DIABETOLOGISTS (ABCD) AUDIT

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Background and Aims: Impaired awareness of hypoglycaemia (IAH) causes significant morbidity and mortality in people living with diabetes. This analysis of audit data was performed to ascertain the prevalence of IAH before and after FreeStyle Libre (FSL) use, factors associated with IAH and improvement in awareness of hypoglycaemia following initiation of FSL.

Methods: Data of adults living with diabetes in the UK using FSL, collected from the ABCD audit were analysed. The Gold score was used to assess awareness of hypoglycaemia; a score of ≥4 indicated IAH, a score of 7 indicated complete unawareness of hypoglycaemia. Paired data was used to investigate prevalence and logistic regression analyses were performed to explore factors associated with IAH.

Results: There were 14248 adults living with diabetes (96.4% had Type 1 diabetes) and 6383 people had follow-up data, mean follow-up time 7.6 months. The baseline prevalence of IAH, complete unawareness of hypoglycaemia and severe hypoglycaemia (in previous 12 months) in this population was 28.1%, 3.7% and 14.4% respectively. With the use of FSL, the prevalence of IAH, complete unawareness of hypoglycaemia and severe hypoglycaemia reduced to 18.1%, 3.2% and 4.7% respectively. Improved awareness of hypoglycaemia with the use of FSL was associated with a shorter duration of diabetes($P = 0.001$) and a higher percentage time in range($P = 0.004$).

Conclusions: This national audit shows the significant prevalence of IAH in people living with diabetes. We identified that Freestyle Libre use is associated with a reduction of IAH, complete unawareness of hypoglycaemia and severe hypoglycaemia in people with Type 1 diabetes.

OP078 / #266

Topic: ***AS05-Glucose Sensors***

ORAL PRESENTATIONS SESSION 5

BEYOND TIME-IN-RANGE: IDENTIFYING TIME-OF-DAY WITH HYPOGLYCEMIA RISK

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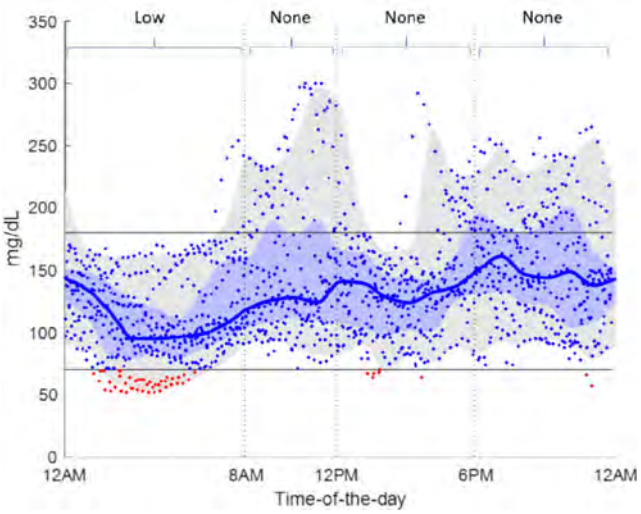
Background and Aims: Hypoglycemia during specific times of the day may warrant treatment adjustment. Glucose pattern analysis can help identify worrisome patterns to potentially prevent hypoglycemia. No study has assessed the risk for hypoglycemia in persons who achieve goals for time in range (TIR, glucose 70 – 180 mg/dL) and time below range (TBR, glucose <70 mg/dL and <54 mg/dL). We use pattern analysis to identify hypoglycemia risk in persons achieving these CGM targets.

Methods: De-identified glucose data from the first sensor of each reader of the FreeStyle Libre flash glucose monitoring system were analyzed to calculate TIR and TBR. Hypoglycemia risk was assessed using glucose pattern analysis in users meeting the CGM metrics targets (>70% TIR, and <4% and <1% TBR). Glucose patterns are indicators of hypo- (low-pattern) or hyperglycemia (high-pattern) risk based on the Likelihood-of-Low-Glucose algorithm.

Results: We identified 60446 FreeStyle Libre users who met the CGM targets. Glucose pattern analysis indicated high hypoglycemia risk in 18% of these users. Below is an example of glucose data with TIR = 81.6%, time <70 = 3.7%, time <54 = 0.5%, and a low-pattern during the overnight TOD. While the patient meets the TIR targets, pattern analysis indicates overnight hypoglycemia risk.

Conclusions: Even though TIR guidelines are a good target to achieve, patients could still have hypoglycemia localized in a specific TOD period not captured by the TIR targets. Pattern analysis of glucose data can be effective in pinpointing such areas of concern and help in identifying the potential root cause.



OP079 / #351

Topic: ***AS05-Glucose Sensors***

ORAL PRESENTATIONS SESSION 5

REDUCING DISPARITIES IN HEMOGLOBIN A1C DURING THE FIRST YEAR OF DIABETES DIAGNOSIS: ACCOMPLISHMENTS AND AREAS FOR IMPROVEMENT IN THE 4T STUDY

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Background and Aims: Continuous glucose monitoring (CGM) is associated with significant improvements in hemoglobin A1c (HbA1c) in youth with type 1 diabetes (T1D). Youth

Figure 1a: Scatter plot of HbA1c values over the first 12 months of the study, with locally estimated scatter plot smoothing for youth with public versus private insurance. The solid lines represent the 4T cohort and the dashed lines represent the Historical cohort.

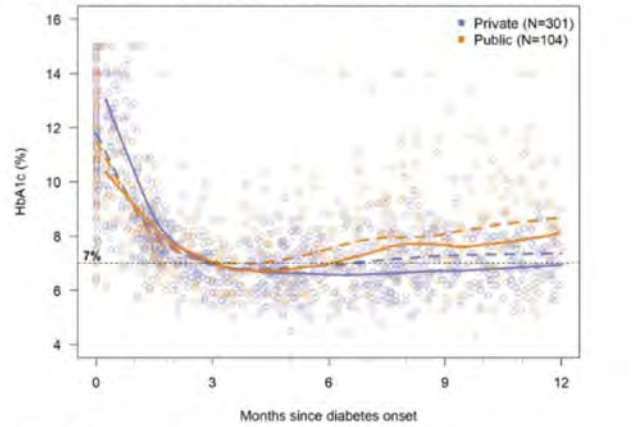
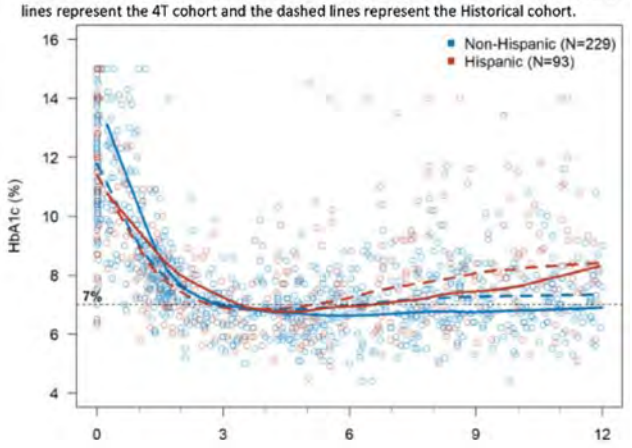


Figure 1b: Scatter plot of HbA1c values over the first 12 months of the study, with locally estimated scatter plot smoothing for Hispanic youth versus non-Hispanic youth. The solid lines represent the 4T cohort and the dashed lines represent the Historical cohort.



from racial/ethnic minority groups and youth with public insurance use CGM less and have higher HbA1c. To expand CGM access, all youth with T1D were offered CGM within one month of diagnosis through the 4T Study.

Methods: We recruited 135 youth with new-onset diabetes to the 4T study (diagnosed 2018-2020) and compared HbA1c levels with a historical cohort (diagnosed 2014-2016) over a 12-month period by race/ethnicity and insurance status. Utilizing locally estimated scatter plot smoothing, descriptive differences in HbA1c by groups were evaluated.

Results: Hispanic youth and youth with public insurance in the 4T cohort had an improvement in HbA1c when compared to historical counterparts (Figures 1a & 1b). Within the 4T cohort, compared to youth with private insurance, youth with public insurance had a lower HbA1c at diagnosis but higher HbA1c by 12 months (Figure 1a). Similarly, compared to non-Hispanic white youth, Hispanic youth had lower HbA1c at diagnosis but higher HbA1c by 12 months post-diagnosis (Figure 1b).

Conclusions: While Hispanic youth and youth with public insurance experienced improvements in HbA1c with the 4T intervention, disparities in HbA1c outcomes by race/ethnicity and public insurance persisted within the 4T cohort. Thus, expanding CGM access in this cohort improved, but did not eliminate HbA1c disparities by race/ethnicity and insurance status. These data support expanding CGM access to all youth with T1D and underscore the need to address additional drivers of diabetes disparities.

OP080 / #402

Topic: *AS05-Glucose Sensors*

ORAL PRESENTATIONS SESSION 5

AMBULATORY GLUCOSE PROFILE ACCORDING TO DIFFERENT PHASES OF MENSTRUAL CYCLE IN WOMEN LIVING WITH TYPE 1 DIABETES

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Background and Aims: Some women living with diabetes report variability in glycemic control according to the phases of menstrual cycle. The purpose of this study was to evaluate this through continuous glucose monitoring data in type 1 diabetes.

Methods: We analyzed 62 spontaneous menstrual cycles in 24 women living with type 1 diabetes. We selected 5 phases of 3 days for each cycle: (1) early follicular (menstruations), (2) mid follicular, (3) peri-ovulatory, (4) mid luteal and (5) late luteal phase. The primary outcome was time in range (TIR). Interclass correlation coefficient (ICC) was used to assess the intra patient variability between menstrual cycles. A linear mixed model was used for statistical analyses.

Results: Mean (± standard deviation) age was 34.3 ± 6.7 years, body mass index 26.6 ± 4.5 kg/m^2, diabetes duration 17.5 ± 10.9 years. ICC for TIR between different cycles in the 17 women with 3 consecutive cycles was 0.94 (95% confidence interval: 0.87-0.97). TIR decreased from early follicular phase to late luteal phase ($61 \pm 18\%$; $59 \pm 18\%$; $59 \pm 20\%$; $57 \pm 18\%$ and $55 \pm 20\%$, $p = 0.02$). Linear mixed model showed a decrease in mid luteal ($p = 0.03$) and late luteal phase ($p < 0.001$) compared to early follicular phase. Time above range (TAR) was significantly higher during the late luteal phase than in early follicular phase.

Conclusions: In women living with type 1 diabetes, glucose rises[jr1] in a linear way across the menstrual cycle to reach its maximum in the late luteal phase with a brutal decrease at the very beginning of the menstrual bleeding in most women. This should be taken into consideration to avoid hypoglycemia.

OP081 / #441

Topic: *AS05-Glucose Sensors*

ORAL PRESENTATIONS SESSION 5

THE RELATIONSHIP BETWEEN TIME-IN RANGE (TIR), MEAN CGM GLUCOSE AND HBA1C IN YOUTH WITH TYPE 1 DIABETES

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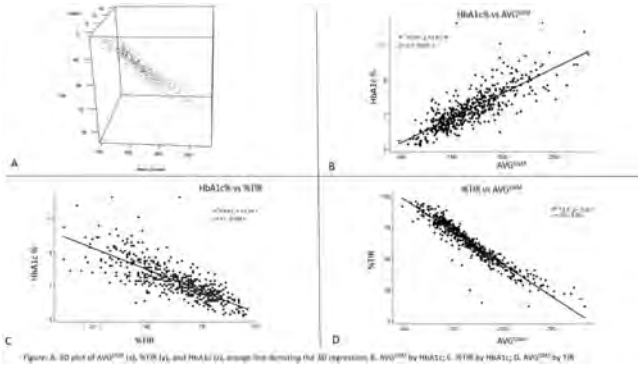
Background and Aims: Continuous Glucose Monitoring (CGM) percent time-in-range (%TIR) and mean CGM glucose (AVG^{CGM}) are used clinically as metrics for short term glucose control and proxies for HbA1c levels. Correlations of %TIR, AVG^{CGM} and HbA1c values have been validated in adults with



diabetes but there is limited associative data among these metrics in youth with diabetes. We provide data from an advanced, factory calibrated sensor to analyze the relationship between the three metrics in a pediatric population.

Methods: %TIR and AVG^{CGM} from Dexcom G6 sensors were collected and paired with clinically obtained HbA1c values from youth with type 1 diabetes (age 3-23 years) at scheduled points (Baseline, 3-, 6-, 9- and 12-month) in the first year of Tandem Control IQ use. Pairwise linear regressions between all three metrics were performed.

Results: Data were collected from 183 youth (mean age 13.1 years, 52% male). Average HbA1c was 7.61% (5.3-12.6%). Agreement was strongest between AVG^{CGM} and %TIR ($R^2 = 0.9$; Figure D), followed by AVG^{CGM} and HbA1c ($R^2 = 0.65$; Figure B). %TIR by HbA1c ($R^2 = 0.63$; Figure C) indicate that a 10% change in TIR was correlated with a 0.52% change in HbA1c. A TIR of 76.9% correlated with an HbA1c of 7%.

Conclusions: This is the first study examining the relationship between %TIR and HbA1c with pediatric data only, and importantly, indicates a higher %TIR may be necessary to achieve the HbA1c target in youth than in adults. Further studies should confirm and explore the clinical implications of these data.

OP082 / #444

Topic: ***AS05-Glucose Sensors***

ORAL PRESENTATIONS SESSION 5

TIME IN RANGE WITH FREESTYLE LIBRE (FSL); IMPACT ON GLYCAEMIC CONTROL AND RESOURCE UTILIZATION IN THE ASSOCIATION OF BRITISH CLINICAL DIABETOLOGIST NATIONAL AUDIT

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Background and Aims: The UK has seen increasing access to continuous glucose monitoring, particularly isCGM (FSL), with more than half of those with type 1 diabetes in England now using this technology. It is therefore essential to understand the effect of the FSL on glycaemic control and resource consumption in people living with diabetes

Methods: Clinicians from 106 NHS UK hospitals submitted FSL user data (16,034 participants living with diabetes (96% type 1 diabetes) of whom 6859 had follow-up), collected during routine clinical care to a web-based tool held within the NHS N3 network.

Results: Use of FSL was associated with a 67% reduction in hospital admissions due to hypoglycaemia, a 63% reduction in hospital admissions related to hyperglycaemia and/or DKA and an 85% reduction in paramedic callouts. At follow-up, 3250 (47%) had TIR reported. Of these, 1241 (38%) used the international consensus time in the range of 3.9–10 mmol/l (icTIR). HbA1c reduction was greater in those with a higher proportion of TIR with a reduction of 6.8 mmol/mol for TIR ≥50% and 9.8 mmol/mol for those with TIR ≥70%. None of the participants with TIR of ≥50% had hypoglycaemia related to hospital admissions during the follow-up period. The reduction in hospital admissions for hyperglycaemia/DKA and paramedic callouts was independent of the TIR achieved during follow-up.

Conclusions: In a large cohort of UK FSL users, we demonstrate a significant reduction in HbA1cand resource consumption which in the case of HbAic and hypoglycaemic events was associated with improved TIR

OP083 / #600

Topic: ***AS05-Glucose Sensors***

ORAL PRESENTATIONS SESSION 5

CONTINUOUS GLUCOSE MONITORING IN TYPE 2 DIABETES: DEMOGRAPHICS AND CHARACTERIZATION OF USE ACROSS A LARGE INTEGRATED HEALTHCARE SYSTEM

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Background and Aims: Continuous glucose monitoring (CGM) use in type 2 diabetes (T2D) is expanding despite limited data about real-world use. HealthPartners is a large integrated healthcare system containing clinical and insurance claims data for member-patients. This analysis describes clinical characteristics of member-patients prescribed CGM.

Methods: A retrospective, observational chart and claims review was conducted for T2D patients prescribed CGM, who receive care and insurance through HealthPartners. Aims: 1)

describe pre-CGM to post-CGM changes in HbA1c; 2) describe medication patterns pre-CGM to post-CGM; 3) quantify associations of change in HbA1c with CGM usage and demographics.

Results: From January 1, 2018 to December 31, 2020, CGM was prescribed to 2231 T2D patients (9.4% of total T2D population). 93.2% of prescriptions were filled (84% filled within 30 days). Pre-CGM HbA1c (closest HbA1c 0-6 months prior) was 8.9%+/-2.1%, versus post-CGM (closest HbA1c 8 weeks-12 months after CGM) 8.0%+/-1.7% (p=<0.0001). Pre-CGM, HbA1c <8.0% in 35.6% of patients, versus 52.8% post-CGM. GLP-1 agonist use increased regardless of baseline HbA1c; analog insulin use increased if pre-CGM HbA1c was >10%. Sulfonylurea use decreased if HbA1c ≤10%. Male sex, age, and filling CGM <30 days demonstrated significant HbA1c decrease; BMI, race, and number of medications did not correlate with HbA1c.

Conclusions: In a large cohort of patients with T2D, HbA1c decreased after filling CGM. Medication patterns also changed, suggesting CGM influenced therapeutic adjustments and possibly contributed to reducing HbA1c. Those who filled their CGM sooner saw the largest decrease in HbA1c, suggesting early patient engagement may be important for successful CGM use in T2D.

OP084 / #604

Topic: ***AS05-Glucose Sensors***

ORAL PRESENTATIONS SESSION 5

CONTINUOUS GLUCOSE MONITORING PATTERNS AMONG PEOPLE WITH TYPE 2 DIABETES ON HEMODIALYSIS TREATED WITH INSULIN.

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Background and Aims: There are limited data on CGM patterns among people with diabetes treated by chronic hemodialysis, particularly using newer Dexcom G6 systems.

Methods: Prospective observational study of people (> 18 years), with insulin-treated, type 2 diabetes, receiving chronic hemodialysis at Emory's kidney centers. Patients wore a Dexcom G6 Pro for 10 days. Outcomes of interest included mean CGM glucose, time-in-range (TIR), above (TAR) and below (TBR) range, and rates of overall hypoglycemia (lasting for at least 15 min), nocturnal (from 22-06hrs) and prolonged (lasting for at least 120 min).

Results: Among 34 patients (mean age 57.5 ± 10, 55% females), mean daily CGM glucose was 189 ± 47 mg/dl, TIR 52 ± 26.7%, TAR >180 mg/dl 47 ± 28%, TAR >250 mg/dl 30 ± 22%, TBR 1.2 ± 2.4%, and HbA1c 7.1 ± 1.5%. Hypoglycemic episodes <70 and <54 mg/dl occurred in 56% and 26% of patients, respectively; with nocturnal hypoglycemia occurring in 29% and 8.8% of subjects, respectively. Prolonged hypoglycemia <70 mg/dl and <54 mg/dl occurred in 8.8% of subjects. During 10 days, subjects with hypoglycemia <70 mg/dl, had a mean of 3.7 ± 4 episodes overall, 3.2 ± 4.3 nocturnal episodes, and 2.6 ± 1.8 episodes of <54 mg/dl. Up to 71% of patients had >5% CGM time in >250 mg/dl.

Conclusions: People with diabetes on chronic hemodialysis are exposed to large glycemic excursions, with tendency to persistent hyperglycemia, and less frequent -yet common- hypoglycemic episodes. There is a critical need for future interventional studies assessing better glycemic efficacy and safety in this population.

OP085 / #669

Topic: ***AS05-Glucose Sensors***

ORAL PRESENTATIONS SESSION 5

EFFECTIVENESS OF A STEPPED-CARE APPROACH VERSUS IMMEDIATE CONTINUOUS GLUCOSE MONITORING-BASED TECHNOLOGIES IN HYPOGLYCEMIA-PRONE PATIENTS WITH TYPE 1 DIABETES (ECSPECT-HYPO)

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Background and Aims: Guidelines suggest a stepped-care approach in the management of patients with IAH, initially with structured psycho-educational programs based on BGAT, progressing to diabetes technology in those with persisting need. We examined the clinical effectiveness of a stepped-care approach starting with HypoAware (adaptation of BGAT) and adding continuous glucose monitoring (CGM) as needed, versus immediate CGM in type 1 diabetes patients with IAH.

Methods: A pragmatic prospective, parallel-group, multicenter, controlled trial. The intervention group attended HypoAware. If IAH was still present after 6 months or a severe hypoglycemic event (SHE) had occurred, CGM was offered. Primary endpoint was the number of participants with self-reported SHE. Secondary outcomes, evaluated at 6 and 12 months, were HbA1c, the number of participants with IAH, time in clinically significant hypoglycemia (<3.0 mmol/L;TCSH).

Results: At 6 months, the primary endpoint had decreased significantly more in the CGM group compared to the stepped-care group:-63% vs -27% (p < 0.05). HbA1c decreased more in CGM group (-0.41 percentage points [-0.49 to -0.25], P < 0.05). The number of patients without IAH increased in both groups (+33% vs +32%). TCSH was lower in the CGM group (p < 0.05). In the stepped-care group n = 17 started CGM, n = 11 started isCGM, and n = 2 patients started neither CGM nor isCGM. At 12 months the number of patients reporting SHE was still higher in the stepped-care group compared to the CGM group (p < 0.05).

Conclusions: In individuals with type 1 diabetes with IAH and a high risk of SHE immediate start of CGM is more effective in reducing SHE risk.

OP086 / #739

Topic: ***AS05-Glucose Sensors***

ORAL PRESENTATIONS SESSION 5

THE USE OF FLASH GLUCOSE MONITORING REDUCES THE RISK OF HYPOGLYCEMIA IN PEOPLE WITH DIABETES ON MAINTENANCE HEMODIALYSIS

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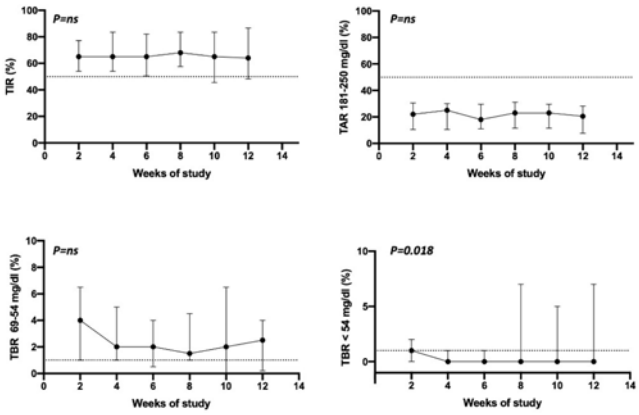
Background and Aims: Few prospective studies have examined the clinical accuracy of flash glucose monitoring (FGM) in people with diabetes (DM) on maintenance hemodialysis (HD). Furthermore, in these patients data on the impact of this technology on glycemic control are lacking.

Methods: A 12-week monocentric, pilot study was conducted in 13 DM subjects on HD (11 males; mean age 64 ± 12.6 years; dialysis vintage 2.9 ± 1.4 years). FGM (Freestyle Libre, Abbott) was applied and main traditional glycemic markers (HbA1c and fructosamine) and FGM-derived metrics were evaluated during the study. Paired SMBG-FGM glucose values were analyzed to calculate mean absolute relative difference (MARD).

Results: Overall, the median MARD was 19.2% (IQR, 9.9-29.9). After 12 weeks, a reduction in time below range (TBR) 54-69 mg/dl [2.5% (IQR, 0.2-4.0) vs. 4% (IQR, 1.0-6.5)] and TBR <54 mg/dl [0% (IQR, 0-7) vs. 1% (IQR, 0-2)] was observed (Fig.1). The number of hypoglycemic events also improved, from 6 (IQR, 1.5-9.5) to 2.5 (2.0-6.5) events/day after 10 weeks. Conversely, at the end of follow-up, time in range (TIR) [65 (IQR, 45.5-83.5) vs. 65% (IQR, 54-77)], TAR [(23 (11.5-29.5) vs. 22 (10.5-30.5)%)], HbA1c, and fructosamine were not significantly different compared to baseline. In ROC curve analysis, TIR (AUC = 0.686;P = 0.011) was a better predictor of glucose variability (coefficient of variation >36%) than HbA1c (AUC = 0.592; P = 0.372).

Conclusions: FGM is a clinically acceptable tool to assess glycemic control in DM on HD. Moreover, it is effective in reducing the time spent in hypoglycemia in this particular population.



OP087 / #480

Topic: ***AS09-New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices***

ORAL PRESENTATIONS SESSION 6

THE EFFECT OF GLUCAGON ON LOCAL SUBCUTANEOUS BLOOD FLOW IN HEALTHY VOLUNTEERS; A PROOF-OF-CONCEPT STUDY.

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Background and Aims: The subcutaneous tissue is the main site for insulin replacement therapy and continuous glucose monitoring for people with diabetes mellitus type 1. However, the delay in both insulin absorption and glucose sensing prevents strict and automated glucose control. A way of minimising these delays would be to increase the local blood flow. We have investigated the vasodilative properties of glucagon in this proof-of-concept study.

Methods: Twenty-two healthy subjects received subcutaneous injections of 0.1 mg, 0.01 mg glucagon (Glucagon, Novo Nordisk, Denmark), and saline on the abdomen. Blood flow was measured by a laser doppler blood flowmeter for 35 minutes after the injections.

Results: Injection of 0.1 mg glucagon resulted in a significant increase in blood flow compared with baseline for all time intervals. Significant increase was also observed after the 0.01 mg glucagon injection, except between two- and five-minutes post injection. The inter-individual variance was large and a third of the subjects did not show an apparent increase in local subcutaneous blood flow after the 0.1 mg glucagon injection.

Conclusions: This proof-of-concept study shows that glucagon increases the local subcutaneous blood flow on the abdomen of healthy subjects. If these results are transferrable to people with diabetes, micro-boluses of glucagon may potentially speed up the absorption of insulin and improve the performance of continuous glucose monitoring in the subcutaneous tissue and thereby enable stricter glucose control. However, the vasodilative effect of glucagon is not observed in all subjects.

OP088 / #536

Topic: ***AS09-New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices***

ORAL PRESENTATIONS SESSION 6

INFLUENCE OF BOLUS INJECTION DOSING FREQUENCY AND SMART PEN ENGAGEMENT ON GLYCAEMIC CONTROL IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Smart pen injection data can provide unique insight into routine diabetes treatment. NovoPen® 6 users may consent to share their injection and continuous glucose monitoring (CGM) data anonymously for research purposes. Here, based on real-world data from people with type 1 diabetes (T1D), we explored the association between the number of daily bolus doses, and smart pen engagement, with time-in-range (TIR).

Methods: We included adults with T1D in Sweden administering Fiasp® with a NovoPen® 6 device for days with bolus injections and CGM data (≥70% coverage). CGM parameters were used as glycaemic control measures. Smart pen engagement

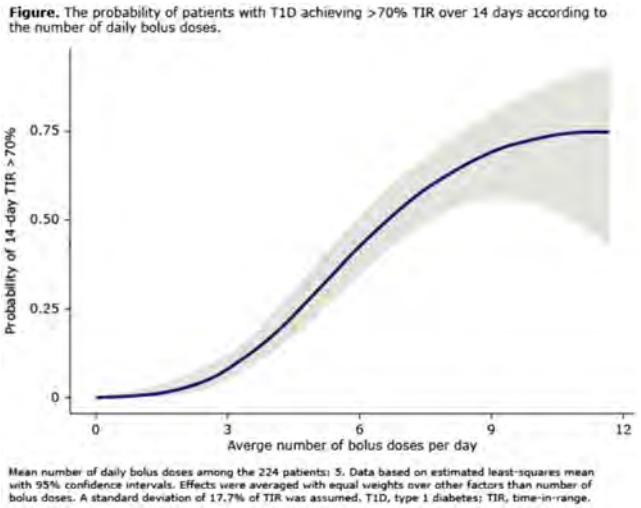

Figure. The probability of patients with T1D achieving >70% TIR over 14 days according to the number of daily bolus doses.

Mean number of daily bolus doses among the 224 patients: 5. Data based on estimated least-squares mean with 95% confidence intervals. Effects were averaged with equal weights over other factors than number of bolus doses. A standard deviation of 17.7% of TIR was assumed. T1D, type 1 diabetes; TIR, time-in-range.

was characterised by the number of injection data uploads over the previous 14 days. A linear mixed model was used to determine relationship between TIR and covariates, adjusted for known confounders.

Results: Overall, data from 224 patients were analysed. The number of daily bolus doses was significantly associated with improved TIR ($p < 0.0001$). Patients with an average ≤3 daily bolus had <10% chance of reaching the target TIR >70% (Figure). The number of uploads was also significantly associated with improved TIR ($p < 0.0001$). Days where uploads were conducted daily over the previous 14 days had 5% greater TIR than days without any uploads during the previous 14 days.

Conclusions: Daily bolus dose number and smart pen engagement are strong predictors of TIR. Most patients take too few bolus doses to reach treatment targets.

OP089 / #204

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

IMPACT OF X-RAY EXPOSURE FROM COMPUTED TOMOGRAPHY (CT) ON A WEARABLE INSULIN DELIVERY DEVICE

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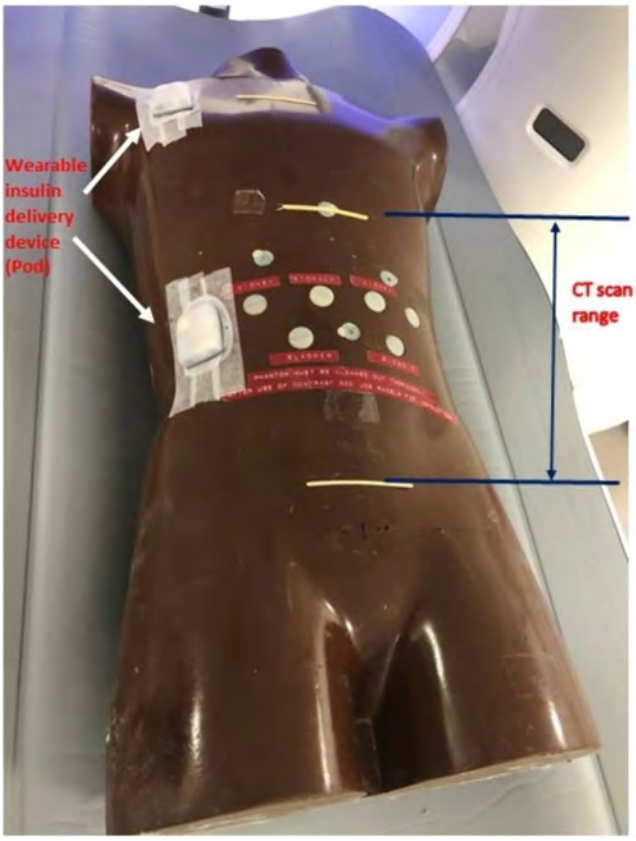
[1]Cleveland Clinic, Radiology, Beachwood, United States of America, [2]Insulet Corporation, Clinical And Medical Affairs, Acton, United States of America

Background and Aims: Wearable insulin delivery devices are popular among people living with diabetes. However, manufacturer's instructions for use requires the device be removed during a radiological procedure, which adds cost and inconvenience since the device cannot be reused. The aim of this study was to investigate the impact of radiation exposure from a CT scanner on the functionality and integrity of a wearable insulin delivery device.

Methods: One-hundred and sixty Omnipod DASH® Pods (Insulet, Acton, MA) were evenly divided into 4 groups: 1) control group (not irradiated); 2) typical exposure group (within a radiation field of a CT scan for an average patient size); 3) high exposure group (4x typical exposure); 4) scatter radiation group (indirect exposure outside the radiation field used for the high exposure group). The devices were placed on the abdomen (for direct exposure) and shoulder (for scatter radiation) regions of an anthropomorphic torso phantom (see **Figure below**). The functionality and integrity testing includes communication (activation, deactivation, and status update) and insulin delivery (basal delivery, bolus delivery, suspension and resume).



Results: All Pods passed the functionality and integrity tests, except for one from the scatter radiation group which alarmed during testing. An investigation identified the alarm was due to an occlusion in the insulin delivery path, not caused by radiation exposure.

Conclusions: Radiation exposures (direct or indirect) from a CT scanner had no impact on the functionality and integrity of Omnipod DASH Pods, even under the direct irradiation from 4x typical exposure in the abdomen/pelvis region.

OP090 / #212

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

EXTENDING THE LIFE OF INSULIN PUMP INFUSION SETS BY REMOVAL OF PHENOLIC EXCIPIENTS FROM INSULIN INJECTION

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Background and Aims: Insulin pump wearers frequently experience the phenomenon of unexplained hyperglycemia or ''site loss,'' where injections have minimal effect and are thus ''lost''. Site loss is typically observed between 48 and 72 hours of wear. We believe that one key reason for this lack of performance is the presence of toxic phenolic compounds in the insulin formulation, which are added in all commercially available insulin analogs as preservatives and stabilizers. Specifically, there are studies showing that exposure to phenolic excipients induces proinflammatory response and cell death, stimulating additional inflammatory processes, which decrease insulin efficacy overall. Therefore, insulin efficacy and infusion site longevity may be improved by removing phenolic excipients in the infusion set immediately before injecting into the body.

Methods: Phenolic excipients were removed from insulin in the cannula through electrochemical oxidization. As a proof of concept, we used a commercially available carbon screen printing electrode. We modified the electrode surface with biocompatible polyelectrolyte to prevent passivation of the electrode and ensure the integrity of insulin.

Results: Our chronoamperometry results showed that current decay reduced from 91.4% to 46.8% on a polyelectrolyte modified electrode comparing to bare electrode, indicating an improved resistance to passivation. 32% phenol was removed from solution in one hour on a modified electrode, whereas only 4.4% phenol was removed on a bare electrode. HPLC data confirmed that insulin remained intact through electrochemical removal of phenols.

Conclusions: Electro-oxidization of phenolic compound on polyelectrolyte modified surfaces can remove these preservatives while maintaining the integrity of insulin.

OP091 / #272

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

GLYCEMIC OUTCOMES BY AGE AND PREVIOUS INSULIN DELIVERY METHOD IN CONTROL-IQ TECHNOLOGY USERS: 9 MONTHS OF CLIO STUDY DATA

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Background and Aims: The Control-IQ Observational (CLIO) Study is currently an ongoing IRB-approved, single-arm, longitudinal study evaluating real-world use of Tandem's t:slim X2 insulin pump with Control-IQ technology in people with T1D (PWT1D). Previous publications from CLIO have shown glycemic improvements in ethnically diverse groups of PWT1D after 3 months of using Control-IQ technology.

Methods: We evaluated relationships between glycemic metrics, participants' age, and previous insulin delivery method at 9 months after CLIO study start. Participants (N = 1913) who had uploaded at least 21 days of Control-IQ feature usage data to Tandem's t:connect® web application (US only) and had ≥75% CGM use were included in the analysis. Impact of baseline factors on sensor glycemic outcomes were analyzed. Differences between baseline HbA1c and GMI were compared using a Wilcoxon test.

Participants' age group (years)	Previous insulin delivery Method	n	Baseline HbA1c	GMI using Control-IQ technology	Significance
6-13	Pump User	84	7.9(7.28-8.6)	7.55(7.15-7.97)	p<0.001
	MDI User	45	7.8(6.8-8.9)	7.25(7.0-7.63)	p=0.02
14-17	Pump User	163	8.1(7.2-9.0)	7.4(7.0-7.89)	p<0.001
	MDI User	63	7.8(6.8-9.0)	7.19(6.66-7.6)	p<0.001
18-30	Pump User	337	7.4(6.8-8.2)	7.13(6.88-7.46)	p<0.001
	MDI User	123	7.8(6.65-8.85)	6.99(6.68-7.4)	p<0.001
31-45	Pump User	415	7.2(6.55-8.0)	7.01(6.71-7.33)	p<0.001
	MDI User	100	8.25(7.0-9.65)	6.97(6.74-7.44)	p<0.001
46-64	Pump User	364	7.3(6.8-8.0)	6.95(6.69-7.23)	p<0.001
	MDI User	80	7.9(7.1-9.0)	6.98(6.71-7.31)	p<0.001
≥65	Pump User	124	7.0(6.6-7.52)	6.87(6.62-7.17)	p<0.001
	MDI User	15	7.5(6.85-7.95)	7.13(6.88-7.24)	p=0.02

Results: Baseline HbA1c (self-reported) for the overall sample was 7.4% (median, IQR = 6.8-8.3). At post with Control-IQ technology, GMI reflected significant glycemic improvement (7.06%, IQR = 6.75-7.42). Previous MDI users demonstrated 71.23% TIR (61.29-81.16) and overnight TIR = 75.26% (64.62-84.5) while previous pump users showed TIR = 70.43% (61.27-78.67) and overnight TIR = 76.39(65.46-85.12). Participants aged ≥65 years, transitioning from prior pump therapy showed the lowest GMI (median = 6.87, IQR = 6.62-7.17) and the highest sensor time in range (TIR) (77.94%, IQR = 69.29-83.8). Younger participants although reporting higher HbA1c at baseline (6–13-year-old, 7.8% (IQR = 7.1-8.6); 14–17-year-old, 8% (IQR = 7.1-9)) also showed significant glycemic improvements after 9 months of using Control-IQ technology (GMI = 7.4 and 7.35, respectively).

Conclusions: Long-term use of Control-IQ technology demonstrated improved glycemic metrics irrespective of participants' age and previous insulin delivery method.

OP092 / #459

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

CHARACTERIZATION OF CHANGES AT INSULIN PUMP INFUSION SITES IN T1D: THE DERMIS STUDY

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Background and Aims: There are no studies evaluating the human skin changes related to continuous subcutaneous insulin infusion (CSII). The aim of this study is to characterize changes

at CSII sites in patients with T1D using traditional histopathology and novel non-invasive skin imaging (optical coherence tomography; OCT).

Methods: 31 patients with T1D were enrolled. Demographics, diabetes data and blood samples were obtained. OCT assessments and punch biopsies were collected at: 1) current and 2) prior CSII sites and 3) control (never-used) site. Histologic changes were visually scored.

Results: Table 1 shows population characteristics. CSII sites showed a significant increase in epidermal thickness, inflammation, fibrin, fat necrosis and vascularity compared to control sites. OCT demonstrated a significant difference in vascular density (VD) and optical attenuation coefficient (OAC) between CSII and control sites (Table 2). No significant differences were observed between prior and current CSII sites.

Conclusions: Significant changes in the skin were observed by both histology and OCT at CSII sites. The impact of these changes on CSII function warrants further study.

Table 1

Male(n)	10
Female(n)	21
Age (Years, Mean±SD)	47±17.5
Diabetes Diagnosis (Years, Mean±SD)	30±15.9
Insulin pump use (Years, Mean±SD)	15.7±11.7
HbA1c (mg/dL, Mean±SD)	6.66±0.79

Table 2

	Current	Prior	Control
Histology			
Epidermal thickness*	0.075±0.031	0.071±0.026	0.042±0.011
Dermal thickness	4.26±0.82	3.83±1.04	3.76±0.79
Fibrosis*	1.63±0.75	1.54±0.68	0.5±0.62
Inflammation*	1.77±0.76	1.75±0.95	0.27±0.57
Fibrin*	1.18±1.09	1.53±1.00	0.27±0.57
Vascularity*	1.43±0.88	1.36±0.81	0.57±0.72
Fat necrosis*	1.30±0.68	1.04±0.89	0.13±0.36
OCT			
VD*	0.476±0.036	0.445±0.021	0.343±0.025
OAC*	1.23±0.35	1.48±0.43	2.08±0.34
Thickness	142.2±19.9	155.4±13.7	144.1±15.5

*p-value (Kruskal-Wallis rank sum test) <0.001

OP093 / #468

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

INEQUALITIES AND HETEROGENEITY IN ACCESSING DIABETES-RELATED TECHNOLOGY: DETERMINANTS OF UPTAKE AND ACCESS TO INSULIN PUMP THERAPY BY ADULTS WITH TYPE 1 DIABETES IN IRELAND.

K. Gajewska[1,2], R. Biesma[3], K. Bennett[4], S. Sreenan[5]

[1]University College Cork, School Of Public Health, Cork, Ireland, [2]Diabetes Ireland, Advocacy And Research, Dublin, Ireland, [3]University of Groningen, Faculty Of Medical Sciences, Groningen, Netherlands, [4]Royal College of Surgeons in Ireland, Population Health Sciences, Dublin, Ireland, [5]Royal College of Surgeons in Ireland, Diabetes Day Centre, Connolly Hospital, Blanchardstown, Dublin, Ireland

Background and Aims: Although continuous subcutaneous insulin infusion (CSII) therapy is recognized as effective and safe, its use remains heterogeneous globally and within countries. This study aimed to explore the determinants of uptake and access to insulin pump therapy by people with type 1 diabetes (PwD) in Ireland.

Methods: A multiphase mixed-methods research design was used. Quantitative (i) evidence on uptake of CSII (secondary data analysis of pharmacy claims data) and on availability of CSII (national survey of diabetes clinics), and qualitative (ii) exploration of the barriers and facilitators in accessing CSII [interviews with key stakeholders (health-care professionals-HCP, policy-makers etc.) and focus groups with PwD (from areas of low, medium and high uptake of CSII)] were synthesised using the Pillar Integration Process approach.

Results: In Ireland: 6.8% of adults with type 1 diabetes were using CSII in 2016 (range: 2% to 9.6%); one-third of diabetes clinics did not offer any type of CSII services; and less than half of clinics offered training to commence CSII. The synthesis of all findings (including qualitative: 21 interviews and 4 focus groups) provided the list of determinants: funding/reimbursement; dwelling location/availability in local clinics; structure of the health-service; capacity (resources/expertise); awareness/education; and impact of individual factors (PwD and HCP attitudes).

Conclusions: Despite the full reimbursement, local diversity in uptake and access to CSII was observed in Ireland. The results of this study can inform policy-makers, health-services planners, HCP and PwD on the complexity of the access to CSII and may help explain reasons for the variable uptake of CSII uptake worldwide.

OP094 / #476

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

LONG-TERM IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES IRRESPECTIVE OF BASELINE GLYCEMIC CONTROL AND PREVIOUS INSULIN DELIVERY METHOD WITH THE T:SLIM X2 PUMP WITH CONTROL-IQ TECHNOLOGY

H. Singh[1], G. Alencar[1], M. Manning[1], K. White[2], L. Mueller[3], J. Pinsker[2], S. Habif[1]

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Background and Aims: Patient-reported outcomes (PROs) are essential when evaluating patients' trust in their diabetes therapy and its long-term use. Previous publications from the Control-IQ Observational (CLIO) study (NCT04503174) have shown PRO improvements in people with type 1 diabetes (PWT1D) after three months of using Control-IQ technology.

Methods: We compared PROs at baseline (pre) and 6 months post Control-IQ technology use in CLIO participants. Repeated measures ANOVA was used to assess differences in PROs from pre to post.

Results: Sample included 2062 PWT1D. At baseline, 23% reported HbA1c ≥8.5%, and 63% were using a different insulin pump. After 6 months of Control-IQ technology (post),

participants reported significant reduction in the perceived negative impact of diabetes on their diabetes-specific quality of life (mean = 4.70 (SD = 0.88) vs. 4.40 (1.05), $p < 0.001$) with greatest improvement reported for ''freedom to eat as you wish''. Significant improvement in satisfaction with insulin-delivery device (IDD) was noted at post, with participants reporting higher satisfaction with Control-IQ technology (8.84 (1.14) vs. their previous IDD (7.21 (1.97)) ($p < 0.001$). Improved satisfaction was reported across all age groups (e.g., 6–12-year-old: 8.99 (1.01); 65+ years: 8.66 (1.33)). Additionally, reduced burden of diabetes was reported irrespective of previous IDD (MDI: 4.80 (1.85) vs. 3.15 (1.49); Pump users: 4.59 (1.81) vs. 3.10 (1.39); $p < 0.001$) and baseline HbA1c (<8.5%: 4.90 (1.84) vs. 3.05 (1.35); ≥8.5%: 4.88 (1.86) vs. 3.29 (1.50); $p < 0.001$).

Conclusions: Control-IQ technology users reported improved quality of life, reduced diabetes burden, and higher satisfaction with diabetes therapy irrespective of age, baseline HbA1c, and previous IDD.

OP095 / #522

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

ULTRASOUND MEASURED VASCULARIZATION AND ECHOGENICITY IN THE SUBCUTIS – A PROSPECTIVE STUDY SHOWING SKIN REACTIONS TO DIABETES DEVICES IN PEDIATRIC PATIENTS WITH TYPE 1 DIABETES

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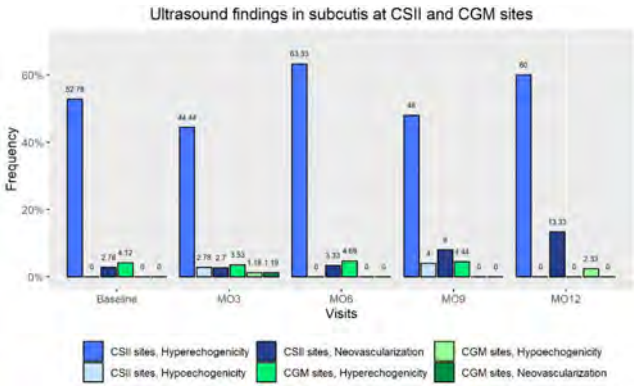
Background and Aims: Many pediatric Type 1 diabetic patients using continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM) have skin issues (1). The aim was therefore to investigate subcutis (Sc) as a measure of underlying skin.

Methods: Ultrasound during first year after initiation of a new CSII or CGM showed echogenicity and pathologic vascularization of the Sc at CSII and CGM sites. Binomial Generalized Linear Mixed Models was applied to detect significant changes in vascularization and echogenicity over time.

Results: These preliminary data consist of 124 CGM-participants and 66 CSII-participants with respectively 43 and 15 who completed last visit. The figure shows the proportion of vascularization, hyper- and hypoechogenicity of the Sc. The frequency of hyperechogenicity was more than 50% at all visits. The frequency of vascularization of the Sc at the pump sites was 3% at baseline and 13 % after 12 months but without significant change ($p = 0.131$). Sc changes were rare at CGM-sites. At the 12th month, mean HbA1c was 60.38 mmol/L and 48.4 mmol/L respectively for patients with and without hyperechogenicity at the pump site ($p < 0.001$).

Conclusions: The frequency of hyperechogenic CSII sites were quite high at all visits and were significantly associated with high HbA1c after 12 months. Vascularization were seen in more than 10 % of the CSII patients after 12 months. These findings



suggest that hyperechogenicity primary occurs at pump and not sensor sites and that it might help blood sugar control if a method to reduce hyperechogenicity was found.

OP096 / #611

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

THE EFFECT OF A SKIN CARE INTERVENTION ON FREQUENCIES OF SKIN PROBLEMS IN PEDIATRIC PATIENTS SIX MONTHS AFTER INITIATION OF DIABETES DEVICES

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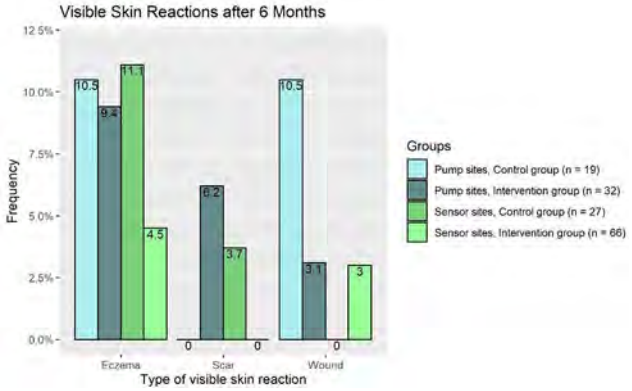
Background and Aims: Pediatric patients with type 1 diabetes are increasingly using devices to treat their disease. Unfortunately, many evolve skin problems, and especially eczema due to contact with these devices. This study investigated the effect of skin care in preventing skin problems in pediatric patients due to contact with diabetes devices.

Methods: A cluster-controlled interventional study of 119 pediatric patients was done after initiation of a diabetes device. The intervention consisted of information on proper skin care as well as delivery of a 70%-lipid lotion for daily use. Patients were seen every third month. Data on skin problems due to devices were obtained by visual inspection as well as interview. Chi-squared and Fischer Exact test were used as statistics.

Results: After six months, 30% and 32% of the patients in intervention and control group, respectively, had self-reported skin problems since last visit. Visible skin reactions recognized by trained personnel were seen in 27% of pump patients and 16% of sensor patients at six months, and the distribution of eczema, wound and scar in groups are shown in the figure. No significant differences were found among both self-reported and visible skin reactions in the intention-to-treat analysis but revealed tendencies towards protective effect of intervention.



Conclusions: After six months of device use, 30% of 119 described skin reactions and most of the reactions were seen in pump patients. After six months, the skin care intervention does not significantly prevent skin problems overall, but longer follow-up is needed.

OP097 / #789

Topic: ***AS07-Insulin Pumps***

ORAL PRESENTATIONS SESSION 6

MULTIPLE BASAL INFUSION RATES IN OPEN-LOOP INSULIN DELIVERY SYSTEMS: IS THERE METABOLIC BENEFIT?

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Background and Aims: The favorable impact of using more than 4 basal infusion rates (BIR) in open-loop delivery CSII systems remains unknown. The aim of this work was to evaluate glycemic control according to the number of daily BIR in T1D patients using CSII.

Methods: Cross-sectional study of patients treated with CSII for ≧6 months, using a flash glucose monitoring system. Patients were divided into groups 1 (G1) and 2 (G2), with ≦4 and >4 BIR/24h respectively, and compared according to HbA_1c, TIR, TAR, TBR, GMI, coefficient of variation (CV) and hypoglycemia. Regression models were performed.

Results: We included 99 patients. Median (IQR) age was 30(17) years, with 28(70) months of CSII use. The number of different BIR were 4(3): 3(2) in G1 (n = 55) and 6(2) in G2 (n = 44). Groups were similar in age, sex, scholarity, weight and insulin analogue used. G2 had longer disease duration (14.5(12) *vs* 12(14) years, p = 0.016), longer CSII use (51(77) *vs* 19.5(48) months, p < 0.001) and higher basal total daily dose/Kg (0.30(0.13) *vs* 0.26(0.11) U/kg, p = 0.006). No significant differences were found regarding HbA_1c, median glucose, GMI, TIR, TAR and CV. G2 patients had more hypoglycemia (47.4 *vs* 21.3%, p = 0.019), more asymptomatic hypoglycemia (16.7 *vs* 1.8%, p = 0.040) and higher TBR (6(9) vs 4(5)%, p = 0.049). After adjusting for confounders, G1 maintained a lower risk of asymptomatic hypoglycemia (OR 0.06, p = 0.035, 95% CI 0.004;0.819).

Conclusions: Programming open-loop CSII devices with >4 BIR didn't improve metabolic control, represented a risk factor for hypoglycemia and was an independent predictor of asymptomatic hypoglycemia.

OP098 / #21

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

THE IMPACT OF REAL-TIME CONTINUOUS GLUCOSE MONITORING ON TREATMENT SATISFACTION IN ADULTS WITH TYPE 2 DIABETES: FURTHER FINDINGS FROM THE MOBILE RANDOMIZED CLINICAL TRIAL

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Background and Aims: While real-time continuous glucose monitoring (RT-CGM) has been associated with greater glycemic improvement than traditional blood glucose monitoring (BGM) in T2D, little is known about the differential impact on glucose monitoring satisfaction over time in this population.

Methods: The MOBILE randomized controlled trial documented significantly greater glycemic benefits in RT-CGM (Dexcom™ G6 CGM System®) T2D participants (n = 108) than BGM T2D participants (n = 57). To compare change in satisfaction over time between RT-CGM and BGM users, participants completed three subscales of the Glucose Monitoring Satisfaction Survey (T2-GMSS): Openness, Emotional Burden and Behavioral Burden, at baseline and 8 months.

Results: Openness rose over time in both groups (ps<.01), though improvement was significantly greater in the RT-CGM (3.06 ± 0.78 to 3.83 ± 0.71) vs. BGM group (3.01 ± 0.78 to 3.37 ± 0.71), resulting in a moderate-to-large between-group effect size at 8 months (d = .67, p < .001). Emotional and Behavioral Burden fell in both groups (ps<.01), with no significant between-group differences. Change over time in all three subscales was associated in the expected direction with HbA1c improvements (rs = 0.39-0.47, ps<.001).

Conclusions: Both study arms evidenced significant gains in all three aspects of glucose monitoring satisfaction. However, RT-CGM users reported significantly greater improvement than BGM users along one of those dimensions, Openness, which represents how the monitoring system may unblock rather than constrain one's lifestyle. This is consistent with previous research illustrating how RT-CGM can enhance one's comfort and confidence with trying out new foods and activities, thereby allowing individuals to feel less restricted.

OP099 / #33

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

COSTS AND UNDERUSE OF INSULIN AND DIABETES SUPPLIES: FINDINGS FROM THE 2020 T1INTERNATIONAL CROSS-SECTIONAL WEB-BASED SURVEY.

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Kingdom, [3]Technical University of Denmark, Center For Biosustainability, Copenhagen, Denmark, [4]University College Cork, School Of Public Health, Cork, Ireland, [5]University College Dublin, School Of Sociology, Belfield, Ireland

Background and Aims: Despite the centennial of insulin's discovery by Frederick Banting, Charles Best, and colleagues at the University of Toronto in 1921, half of the people living with diabetes worldwide cannot access or afford it. The aim of this study is to present contemporary data concerning out-of-pocket expenses (OoPEs), the extent of insulin and supply underuse, and the degree of financial coverage people with type 1 diabetes (T1D) are experiencing across the world.

Methods: A web-based, cross-sectional survey was conducted from August to December 2020. The analysis included comparisons between responses from countries with no, partial, and full healthcare coverage.

Results: 1,066 participants from 64 countries took part in the study. ~25% of respondents reported having underused insulin at least once within the last year due to perceived cost. A significant correlation was observed between OoPEs and reported household income for respondents with partial healthcare coverage. 63.2% of participants reported disruption of insulin supplies and 25.3% reported an increase of prices related to the COVID-19 pandemic.

Conclusions: This study confirms previous reports of ~25% of people in the United States with T1D using less insulin and/or fewer supplies at least once in the last year due to cost, a trend associated with the extent of healthcare coverage. Similar trends were observed in some middle/low income countries. Moreover, patients reported an increase in insulin prices and disruption of supplies during the COVID-19 pandemic. This study highlights the importance of self-reported OoPEs and its association with underuse/rationing of insulin.

OP100 / #360

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

ATTITUDES TOWARDS A FULLY IMPLANTABLE BIONIC INVISIBLE PANCREAS: RESULTS OF A QUALITATIVE STUDY IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: The EU project ''FORGETDIABETES'' (supported by H2020-FETPROACT Project FORGETDIABETES, n.951933) aims at developing a fully implantable system for automated insulin delivery (AID). It will consist of an intraperitoneal pump and an implantable CGM sensor. Insulin will be refilled via an insulin pill and the pump will be charged wirelessly. It aims at providing fully automated diabetes management with minimal user interaction. To explore human factors of the bionic invisible pancreas (BIP), we performed a qualitative study.

Methods: Semi-structured interviews were conducted with people with type 1 diabetes. All participants provided written informed consent and were shown a video illustrating the components and functionality of the BIP. Participants were asked about aspects of life that could benefit from the BIP and aspects of life that could become more complicated.

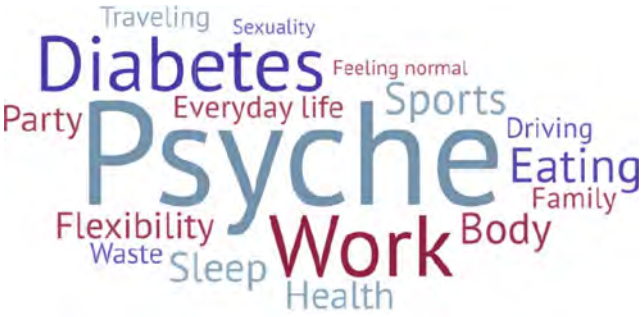

Figure 1. Aspects of life that would benefit from a bionic invisible pancreas

Figure 2. Aspects of life that could become more complicated with a bionic invisible pancreas

Results: Interviews from 38 people with type 1 diabetes were analysed. The most frequently mentioned aspect that could benefit from using the BIP was psychological with expected positive effects on quality of life, reduced diabetes distress, and less thinking about diabetes. Also, better glycaemic control and improvements regarding long-term complications (termed ''Diabetes'' in Figure 1) were also frequently mentioned as aspects that could benefit. Aspects that might become more complicated related mostly to technical aspects such as the implantation procedure, taking an insulin pill, and being dependent on the technology. Loss of control was also named as a big issue (Figure 2).

Conclusions: Psychological aspects such as improvements in quality of life but also loss of control are important human factors for future AID systems.

OP101 / #423

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

HYBRID THERAPY IN YOUTH WITH TYPE 1 DIABETES - CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) COMBINED WITH LONG-ACTING INSULIN: A REAL-LIFE EXPERIENCE

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Background and Aims: The utilization of CSII in type 1 diabetes (T1D) is associated with increased risk of diabetic ketoacidosis (DKA). The rationale behind using hybrid modality, long-acting insulin for basal coverage and CSII for boluses, is the prevention of insulin delivery failure and subsequent hyperglycemia and DKA. To explore the hybrid treatment modality in clinical practice in youth with T1D.

Methods: Multicenter, observational study of youth with T1D who initiated hybrid modality between 2013 and 2020. Extracted from the medical records were data on sociodemographic characteristics, reason for hybrid treatment initiation, glycemic metrics, HbA1c and frequency of DKA episodes, collected at initiation, after 6 months, and at last visit.

Results: Fifty-five patients (52.7% males) were treated with hybrid therapy, median [IQR] age at initiation 14.5years [12.4, 17.3], HbA1c 9.2% [8.2, 10.2], mean glucose levels 221mg/dL [181, 226] and treatment duration 18 months [12, 47]. Hybrid treatment was initiated due to fear of sustained hyperglycemia in 41.8%, DKA episodes in 30.8%, refusal to use CSII continuously in 14.6%. HbA1c did not significantly change throughout follow-up ($P=0.262$ and $P=0.195$). Mean glucose levels decreased after 6 months ($P=0.034$), and remained stable thereafter ($P=0.274$). Frequency of DKA decreased after 6 months and at last visit as compared with 6 months preceding initiation of hybrid therapy (number of events/number of patients: 4/4 and 10/10 vs. 24/14, $P=0.002$ and $P=0.031$, respectively).

Conclusions: Our findings suggest that this hybrid therapy is a feasible option in the management of youth with T1D, which may reduce the risk of DKA episodes.

OP102 / #519

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

NOVEL VISUAL TOOL TO ASSESS THE PREVALENCE OF HYPOGLYCAEMIA SYMPTOMS IN TYPE 1 DIABETES

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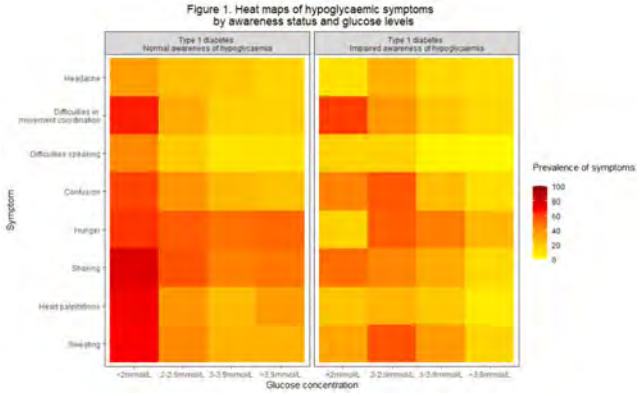
Background and Aims: There is variability in the experience of symptoms of hypoglycaemia, within- and between- individuals with diabetes. We report preliminary data on the prevalence of hypoglycaemic symptoms across glucose ranges by hypoglycaemia awareness status using our novel smartphone HypoMETRICS app.



Methods: Participants with type 1 diabetes (T1D) used the app to report all episodes of hypoglycaemia experienced over the 10-week study, recording glucose level and grading symptoms. The symptoms included sweating, heart palpitations, shaking, hunger, confusion, headache, difficulties in speaking and difficulties in movement and coordination. Heat maps of symptoms were generated based on their prevalence at each glucose level by awareness status, assessed by Gold Score, using R.

Results: 2804 hypoglycaemic episodes were reported by 97 participants, mean (SD) age was 46.0 (14.6) years and diabetes duration was 22.9 (15.0) years. 72.2% used Flash glucose monitoring. 75 participants had normal awareness of hypoglycaemia and 22 had impaired awareness of hypoglycaemia (IAH). The most common symptoms were hunger (49.9%), shaking (45.1%), sweating (34.2%) and heart palpitations (28.1%). As shown in Figure 1, episodes with lower glucose were associated with more symptoms and a lower percentage of episodes in IAH were symptomatic in each glucose category.

Conclusions: Heat maps generated from the HypoMETRICS app data provide a visual, quantitative representation of subjective experiences of hypoglycaemia. As the heat maps can be generated for individuals as well as groups, the app offers a novel tool for objective evaluation of hypoglycaemia awareness in T1D, clinically as well as in research.

OP103 / #583

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

YOU'RE NOT WRONG, BUT YOU'RE NOT ENTIRELY RIGHT: HOW PATIENTS' BELIEFS INFLUENCE HOW THEY ARE PERCEIVED

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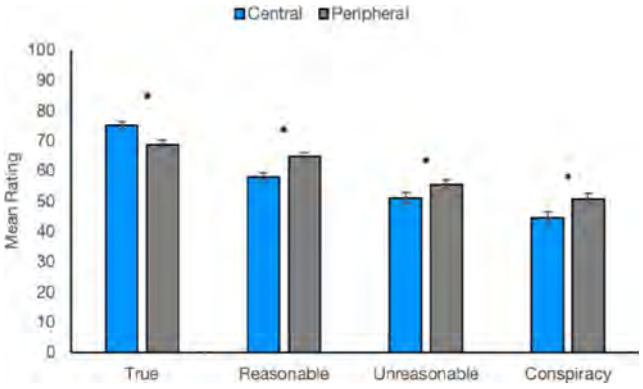
Background and Aims: New technologies aim to aid diabetes management with personalized insights. However patients bring existing beliefs, which may conflict with new information, and which they may not readily share with their doctors. To understand patient perceptions, we conducted large-scale online studies examining lay beliefs about patient information sharing.

Methods: Across four experiments, we recruited U.S residents aged 18-64, who do not work in healthcare (N = 1125 in analysis). Participants saw vignettes about a person who was recently diagnosed with T2D and shares a health belief with their new doctor. The beliefs varied in reasonableness (true, reasonable, unreasonable, conspiracy theory) and centrality to diabetes management (central, peripheral), and the experiments varied characteristics of the patient (e.g., race, gender). Participants rated three key aspects of a medical encounter: doctor perception of patient, patient efficacy, and patient trust.

Results: Across all experiments, the less reasonable a patient's beliefs were, the more participants thought they would be negatively perceived by their doctors, less effective at managing their diabetes, and less trusting of doctors. As shown in the figure, patients were also penalized more for incorrect beliefs central to diabetes. Interestingly, there was no effect of race or gender.

Conclusions: Providing information to patients without understanding their existing beliefs may be ineffective. However we find that people perceive significant possible negative impacts of information sharing. Our follow-up studies with primary care doctors suggest these fears may be well-founded. Thus, there is an urgent need for clinicians to understand and address these perceptions.



OP104 / #630

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

GLYCEMIC OUTCOMES IN ADULTS FROM RACIAL/EDUCATION/SOCIOECONOMIC MINORITIZED POPULATIONS WITH TYPE 1 DIABETES IN A PIVOTAL AUTOMATED INSULIN DELIVERY (AID) TRIAL

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Background and Aims: This pivotal parent study (NCT03563313) showed an overall increase in time in target range (TIR) of 11% [95%CI 9 to 14; $p < 0.001$] favorable to AID use compared to sensor-augmented pump (SAP) therapy, which contributed to the FDA's authorization of its commercialization. However, such technology is utilized less among Black, Indigenous, and People of Color (BIPOC) and lower socioeconomic status (SES) individuals. This study investigated improvements in glycemic outcomes for participants of different racial and SES groups while using AID vs SAP in this trial

Methods: Case summaries of participants differing in income, education, and race/ethnicity were analyzed to determine each group's percentages of TIR (70-180mg/dL), time in hyperglycemia (>180mg/dL), and time in hypoglycemia (<70mg/dL) while using AID vs SAP therapy.

Results: The majority of participants in the trial were White and from higher income and education groups. TIR percentages using SAP compared to AID increased 18.6% for individuals making <$50,000 (7.1% of participants), compared to a 9.7% and 9.6% increase for those making $50,000-$100,000 (29.8%) and >$100,000 (61.7%), respectively. Those without (10.6% of participants) and with a bachelor's degree (57.6%) spent 26.7% and 13.4% less time in hyperglycemia using AID, respectively. BIPOC individuals (10.6% of participants) spent 51.8% less time in hypoglycemia, whereas White individuals (87.6%) spent 43.9% less time <70 mg/dl. No group differences were significant.

Conclusions: Although BIPOC and lower SES populations were underrepresented in this trial, data indicates that these groups achieved similar glycemic outcomes compared to higher income/education and Caucasian participants showing a potential equalizing benefit from this type of technology.

OP105 / #639

Topic: ***AS14-Human factor in the use of diabetes technology***

ORAL PRESENTATIONS SESSION 7

DIABETES RESPONSE SPECIALISTS ASSOCIATED WITH IMPROVED BLOOD GLUCOSE CONTROL FOR A LARGE DIABETES POPULATION USING A CONNECTED BLOOD GLUCOSE METER

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Background and Aims: Health coaching has shown to reduce HbA1c and blood glucose (BG) excursions, and lifestyle recommendations are more accepted during teachable moments. This study investigated the impact of Diabetes Response Specialists' (DRS) real-time feedback during BG-triggered alerts on estimated A1c (eA1c) improvement.

Methods: This retrospective cohort study used data from participants enrolled in a remote diabetes program (RDP) for a minimum of 12-months, which offered education and self-management tools through mobile technology. Improvement in eA1c was defined as a reduction ≥0.3%. Multivariable logistic regression was used to analyze the associations of number of successful DRS interactions and scheduled certified diabetes care and education specialists (CDCES) coaching on eA1c improvement at 12-months adjusting for participant demographics, characteristics, and program utilization.

Results: Participants (N = 167,095) were 47% women with mean age of 55 years old [SD 11.7]. A majority were individuals with type 2 diabetes mellitus on oral medications only (59%) with 3% utilizing CDCES coaching. DRS interaction was utilized by 33% of participants who received a mean of 9.5 successful DRS contacts. The number of successful DRS contact was significantly associated with eA1c improvement at 12-months with odds ratio of 1.63 (95% CI: 1.51, 1.84). The number of scheduled CDCES coaching sessions was not associated with eA1c improvement 1.03 (95% CI: 0.94, 1.12).

Conclusions: DRS interactions during BG excursions were associated with improved glycemic control in a RDP and may reach members not served by scheduled CDCES coaching.

OP106 / #249

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ORAL PRESENTATIONS SESSION 7

REAL-WORLD PERFORMANCE EVALUATION OF A SMARTPHONE BASED BOLUS CALCULATOR APPLICATION

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Background and Aims: Automated bolus calculators (ABCs) help PwD with calculating insulin doses. Clinical studies have consistently shown the clinical benefits of ABCs. However, ABCs differ in terms of their design and mathematical approaches but the real-world impact of such differences was never evaluated. We evaluate the real-world impact of a significant change introduced to the algorithm of an over-the-counter ABC that is integrated into a mobile health application.

Methods: We use a retrospective pretest-posttest design to evaluate changes in glycemic control and patient reported outcomes (PROs) after 3 months of using an updated ABC. We test for clinical relevant changes in mean glucose, coefficient of variability and hypoglycemic episodes calculated from self-monitored blood glucose data. Diabetes Treatment Satisfaction Questionnaires (DTSQ) are sent at device initiation (baseline) and at 3 month follow-up.

Results: Improvements in glucose control and PROs are expected as a result of the updated algorithm. At the moment of writing, baseline surveys were sent to 6872, received by 4414 (65%) and completed by 720 (17%) users out of which 50% are expected to complete the follow-up survey. Analysis is ongoing and preliminary results are expected by the end of the year.

Conclusions: We evaluate the real-world impact of a significant design change introduced to the algorithm of an over-the-counter ABC on glycemic control and treatment satisfaction. High exclusion rates are accounted for by the analysis of a comparably large population. Preliminary results are expected by the end of the year.

OP107 / #576

Topic: ***AS16-COVID-19 and Diabetes***

ORAL PRESENTATIONS SESSION 7

CAN PHYSICAL ACTIVITY AS AN INDEPENDENT PARAMETER INFLUENCE TIR?

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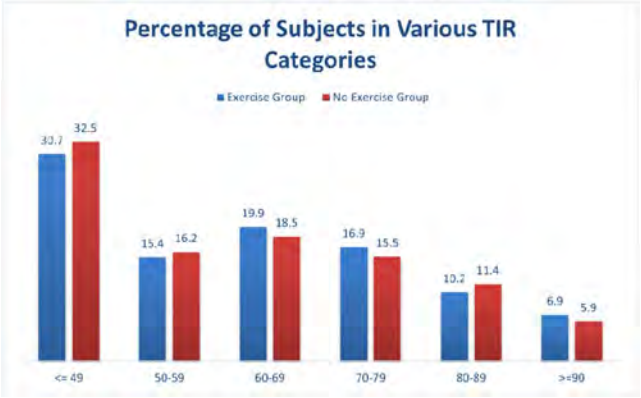
Background and Aims: A large subset of PWD assume that physical activity alone can bring glycemic control irrespective of the stage of diabetes. During Covid, there was an increased emphasis on physical activity in PWD. People with uncontrolled diabetes were avoiding physical visits to hospitals due to the fear of contracting the disease. In this scenario, we analysed the effects of physical activity on glycemic control as measured by CGM in terms of TIR.

Methods: We analysed the EMR of T2D patients who performed CGM atleast once from March 2021 - June 2021 after the lockdown period and extracted data on exercise (type, frequency and duration of exercise), BMI and TIR. Out of 603 T2D, 332 (those who performed at least one kind of physical activity) were categorised into the study group (SG) and 271 (those without any physical activity) into the control group (CG).



Results: TIR was compared between SG and CG using analysis of covariance model with TIR as the dependent variable, treatment as a fixed effect and BMI as a cofactor. There was no significant difference (p = 0.7305) in TIR between the groups. When taken together, 16.3% achieved a TIR >70% and 6.5% achieved a TIR >90% irrespective of physical activity. Percentage of patients in various TIR categories is shown(Fig.1)

Conclusions: Physical activity alone as an independent parameter may not have a significant role in improving TIR. The findings emphasize the fact that physical acvity should be combined with medical nutrition therapy and therapeutic interventions for better optimal outcomes in the management of diabetes.

OP108 / #323

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

ORAL PRESENTATIONS SESSION 8

PREVALENCE OF DIABETIC RETINOPATHY SCREENED BY ARTIFICIAL INTELLIGENCE BASED DEEP LEARNING ALGORITHM WITH HIGH SENSITIVITY: A MULTICENTRIC CROSS SECTIONAL STUDY FROM INDIA

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Background and Aims: The prevalence of diabetic retinopathy (DR) is increasing at an alarming rate in India. All diabetes patients need regular retina screening. The primary issue is the grading of fundus images by retina specialists, whose numbers are very scarce compared to the load of patients. Many patients are based in rural areas and cannot visit an ophthalmologist. Such limitations created interest in assessment of images using fully automated Artificial Intelligence based grading systems. The study aims to evaluate the effectiveness of a deep learning algorithm in screening of DR and assess the prevalence of DR screened at multiple centers across Kolkata, West Bengal, India.

Methods: It is a multicentric cross sectional study. A total of 725 diabetes patients were screened for DR using Artificial Intelligence based Diabetic Retinopathy Screening System (AIDRSS) developed by ARTELUS™. The AIDRSS graded fundus images based on the ICDR Scale (**DR0, DR1, DR2, DR3, DR4**). The fundus images captured were also assessed by retina specialist and reports were compared to evaluate the sensitivity and specificity of the AIDRSS.

Results: The **prevalence of DR** screened using AIDRSS was **27.17% (DR1 = 17.38%, DR2 = 9.52%, Referable DR : DR3 and DR4 = 0.27%)**. The AIDRSS performed well with overall **97% sensitivity** and **92% specificity**; and **100% sensitivity** in detecting referable DR when compared against fundus image reported by a retina specialist.

Conclusions: The study establishes a high prevalence of diabetic retinopathy. AIDRSS developed by ARTELUS™ has a high sensitivity and specificity and is an effective solution for routine screening and early detection of diabetic retinopathy in India.

OP109 / #470

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

ORAL PRESENTATIONS SESSION 8

DIABETES NOVEL SUBGROUP ASSESSMENT (DIANA)- ADVANCED MACHINE LEARNING-BASED TOOL TO CLASSIFY INDIVIDUALS WITH NEWLY DETECTED TYPE 2 DIABETES INTO SPECIFIC SUBGROUPS AND ASSESS DRUG RESPONSE

R.M. Anjana[1], *S. Jebarani*[2], *C. Palmer*[3], *M. Siddiqui*[3], *M. Arun Vignesh*[2], *E. Pearson*[3], *V. Mohan*[1], *R. Pradeepa*[4]

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Background and Aims: **M**achine learning (ML) has been applied to many aspects of medical health. In this study, we aimed to develop a tool to classify individuals with newly detected type 2 diabetes(T2D) into specific subgroups recently identified in Indians.

Methods: The DIAbetes Novel subgroup Assessment (DIANA) tool has been developed in R-Shiny. The tool has been trained and tested using unsupervised ML model (K-means clustering with k value of 4 using k-means function(max iteration = 10 000) in R V.3.6.0 in a dataset of 19,084 individuals with T2D (aged 10–97 years) with diabetes duration of <5 years at the time of first clinic visit. Age at onset of diabetes, BMI, waist circumference, Hba1c, serum triglycerides, serum high-density lipoprotein cholesterol, fasting and stimulated C-peptide were used in this ML approach. Distinctly labelled clusters were trained using supervised ML algorithms for prediction.

Results: Four novel subgroup clusters of T2D were identified using the tool: Severe Insulin Deficient Diabetes (SIDD), Insulin Resistant Obese Diabetes (IROD), Combined Insulin Resistant and Deficient Diabetes (CIRDD) and Mild Age-Related Diabetes (MARD). There was high concordance between the unsupervised and supervised ML approaches(Cohen's Kappa Statistic, 0.99) with 99% of prediction accuracy(83% accuracy if C-Peptide was not included in the model).

Conclusions: Identification of phenotypic subgroups of T2D using the DIANA tool, developed based on real world clinical data, could help clinicians understand aetiology of T2D and with the help of additional individualised prediction models, decide upon the most effective forms of therapy for the patient, an important first step towards precision/ personalised diabetes care.

OP110 / #596

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

ORAL PRESENTATIONS SESSION 8

PREDICTING HYPOGLYCEMIA AND IDENTIFYING RISK FACTORS DURING AND FOLLOWING PHYSICAL ACTIVITY IN TYPE 1 DIABETES USING EXPLAINABLE MODELS

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Oregon Health and Science University, Biomedical Engineering, Portland, United States of America

Background and Aims: Glucose during physical activity (PA) is highly variable among people with T1D oftentimes leading to increased hypoglycemia risk. We used explainable mixed-effects models to (1) learn key factors associated with short- and long-term PA-related hypoglycemia and (2) predict hypoglycemia in the 24-hours after start of exercise.

Methods: We leveraged the free-living Tidepool Big Data Donation Dataset (Tidepool, Palo Alto, CA, USA) comprised of time-matched continuous glucose measurement, insulin, and PA data from 50 people with T1D (6,448 PA sessions; training: 5,457 and validation: 991). We fitted mixed-effects logistic regression (MELR) and random forest (MERF) models to predict the probability of hypoglycemia during and up to 24 hours following PA. We assessed model accuracy using area-under-the-curve (AUC).

Results: There was no significant difference in accuracy between MELR and MERF. AUCs on the validation dataset were $AUC_{MIXED} = 0.83$, and $AUC_{FIXED} = 0.65$. Both models showed overall hypoglycemia risk peaking one hour and 5-10 hours after PA. Key risk factors significantly associated with hypoglycemia included glucose and insulin-on-board at start of PA, low blood glucose index 24-hours before PA, and exercise duration and intensity. Time effects differed between strength and other types of PA.

Conclusions: Results from this study can be used for decision support and insulin delivery scheduling in automated delivery systems to mitigate PA-related hypoglycemia. Significance of random effects indicates that personalization and modeling the correlation between the hours after the same PA session to capture probability of repeat hypoglycemia may help improve accuracy of hypoglycemia prediction following PA.

OP111 / #501

Topic: ***AS01-Closed-loop System and Algorithm***

ORAL PRESENTATIONS SESSION 8

MEAL DETECTION AND SIZE ESTIMATION USING MACHINE LEARNING: TOWARDS FULLY AUTOMATED INSULIN DELIVERY SYSTEMS

C. Mosquera-Lopez, W. Hilts, L. Wilson, J. Castle, P. Jacobs

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Background and Aims: We present a multioutput fully connected neural network model that detects meals and estimates carbohydrate content using continuous glucose monitoring (CGM) and insulin data in type 1 diabetes (T1D) both *in-silico* and on a real-world dataset.

Methods: The algorithm detects meals less than 60 minutes after intake. Input features were derived from 2-hour history of CGM, insulin-on-board 60 minutes prior to prediction time, and time of day. We used the UVA-Padova and the Oregon Health and Science University (OHSU) simulators for algorithm development. We simulated 100 + 99 virtual subjects during 14 days under real-world meal scenarios. Glucose control was simulated using the OHSU's model predictive control (MPC) automated insulin delivery system. Dataset split was 60:40 for algorithm development and validation, respectively. The Tidepool Big Data Donation dataset (150 closed-loop users) was used for validation on real-world meal data.

Results: *In-silico* results showed the algorithm detected 94.70% of higher-carbohydrate meals (72.33 ± 30.10 g, $t_{detection} = 22.9$ min) with 0.11 false-positives/day (FPD) and 65.44% of lower-carbohydrate meals (46.54 ± 26.96 g, $t_{detection} = 27.5$ min) with 0.26 FPD. On the Tidepool dataset, the algorithm detected 82.48% meal candidates with 0.78 FPD. When used in a fully automated closed-loop *in-silico* trial, automated meal detection improved time-in-target-range (70-180 mg/dL) from 71% (no dosing for meals) to 77% (automated meal detection), <2% time in hypoglycemia.

Conclusions: An accurate meal detection and meal size estimation algorithm can facilitate fully automated insulin delivery and improve time in range maintaining percent time in hypoglycemia <2% on average in T1D.

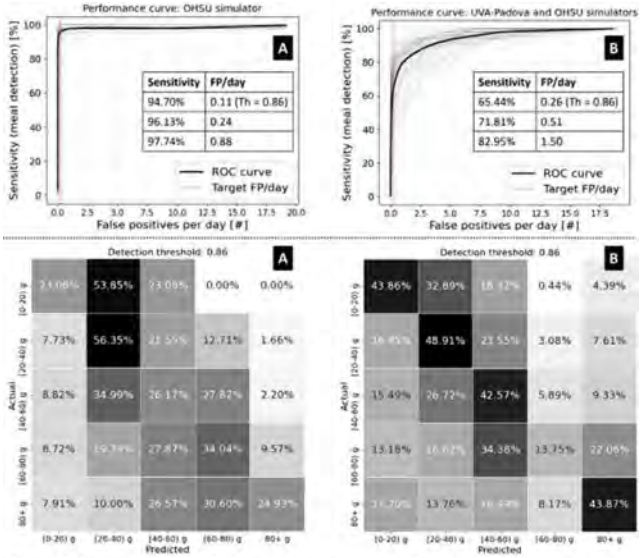

Figure 1. Performance of the algorithm. ROC curve (TOP) and confusion matrix for carbohydrate estimation (categorization) at 0.86 detection threshold (BOTTOM). (A) Tested on 40% held-out subjects simulated using the OHSU simulator, high-carb meal scenarios. (B) Tested on a 40% held-out set of simulated virtual subjects with UVA-Padova and OHSU simulators, low-carb meal scenarios.

OP112 / #632

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

ORAL PRESENTATIONS SESSION 8

REMOTE PATIENT MONITORING IN YOUTH WITH TYPE 1 DIABETES (T1D) PREDICTED TO EXPERIENCE A RISE IN A1C%: COMPARISON TO A CLINIC-DERIVED, PROPENSITY SCORE-MATCHED CONTROLS

D. Williams[1], D. Ferro[2], E. Dewit[2], B. Lockee[2], M. Barnes[2], S. Carrothers[2], C. Vandervelden[2], S. Patton[3], R. Mcdonough[2], L. D'Avolio[4], M. Clements[2]

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Background and Aims: To determine if 1) remote patient monitoring (RPM) can improve glycemic control among youth with T1D who are predicted to experience a rise in A1c% using logistic regression and 2) propensity-score (PS) matching (PSM) RPM youth to non-RPM youth can control for confounding bias.

Methods: We collected data from 2-18-year-olds attending a tertiary care network of diabetes clinics in the Midwestern USA from 11/2018-9/2021. Eligible youth had baseline A1c% ≥7.2, predicted 90-day rise in A1c% ≥0.3 via advanced machine learning, and follow-up A1c% measured 70-180 days after baseline. Criteria used to calculate PS included sex, ethnicity, race, insurance, technologies, age, T1D duration, baseline A1c%, and predicted 90-day A1c% change. We compared each RPM-youth with three matched, non-RPM youth identified using a PS within ±0.05.

Results: We matched 201 non-RPM youth to 67 RPM youth. The final cohort was 60% female, 4% Hispanic, 76% White, 54% private insurance, 37% on CGM and insulin pump, median age 13.4 years (IQR = 10.3,16.0), T1D duration 44.6 months (17.6,84.7), baseline A1c% 7.9 (7.5,8.8), and predicted 90-day A1c% change 0.39 (0.33,0.48). After PSM, we found no significant differences for RPM and non-RPM youth (p's = 0.10-0.99), suggesting this method may be appropriate for creating a balanced clinic-derived control sample. However, 64% of RPM youth experienced no rise in A1c ≥0.3% compared to 53% of non-RPM youth (p = 0.10).

Conclusions: Youth receiving RPM may experience improved glycemic control relative to a clinic-derived control sample based on PSM, but these results require verification in a large multisite traditionally controlled study.

OP113 / #821

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

ORAL PRESENTATIONS SESSION 8

ENABLING INFORMED DECISION MAKING IN THE ABSENCE OF DETAILED NUTRITION LABELS: A MODEL TO ESTIMATE FOODS' ADDED SUGAR CONTENT IN A DIABETES-TAILORED WEIGHT MANAGEMENT PROGRAM

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Background and Aims: Evidence suggests that increased added sugar consumption increases fasting glucose, insulin, and risk of type 2 diabetes. Yet, added sugar disclosure is not currently required in countries outside of the United States, even though nutritional content information can positively influence consumption behavior.

Methods: We hypothesized that computational science could be leveraged to develop an accurate, scalable model to estimate added sugar content of foods based on their macro- and micronutrient profile. We collected comprehensive nutritional information for 69,769 foods. We used 80% of this data to train a gradient boosted tree model to estimate added sugar content, holding 20% out to assess the model's predictive accuracy.

Results: Model performance on the test data explained 94.3% of the variance in added sugar content at the default serving size. The mean absolute error of the estimation was 0.28g or 1.12kcal per 100 kcal**.** Total sugar was the strongest predictor of added sugar. Additional predictors of higher added sugar content included lower protein and fiber content.

Conclusions: This model can be scaled to deliver estimates of added sugar through digital devices in countries where this information is not required to be disclosed, thus enabling consumer awareness of added sugar content of a wide variety of foods. This model was incorporated into a cutting edge nutrition algorithm as part of a newly developed, commercially available digital weight management program from WW (formerly Weight Watchers), tailored for individuals living with diabetes. Using data science methods in digital applications can provide important nutritional information to people with diabetes.

OP114 / #251

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

ORAL PRESENTATIONS SESSION 8

REAL LIFE ESTIMATION OF POSTPRANDIAL GASTRIC RETENTION, GLUCOSE ABSORPTION AND INSULIN SENSITIVITY IN TYPE 1 DIABETES USING MINIMALLY INVASIVE TECHNOLOGIES AND COMPUTATIONAL MODELING

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Background and Aims: Understanding the effect of meal composition on glucose excursion would be key in designing decision support systems (DSS) for type 1 diabetes (T1D) management. In fact, the amount of carbohydrates, lipids and proteins in a meal significantly affects postprandial gastric retention (GR), glucose absorption (GA) and insulin sensitivity (SI). Such variables can be estimated, in hospitalized setting, from plasma glucose and insulin data using the Oral Minimal Model (OMM, Dalla Man et al., 2002). Here, we developed a model to estimate those quantities in daily life conditions, using minimally invasive technologies (MI-OMM), and validated it against OMM.

Methods: Data collected from 47 patients with T1D (weight = 77 ± 10kg, age = 41 ± 13yr) in a closed loop clinical trial (Luijf et al., 2013) were used for model development and validation. Each participant underwent three randomized 23-hour visits (one open- and two closed-loop), during which plasma glucose and insulin were frequently collected, together with continuous glucose monitoring (CGM) and insulin pump

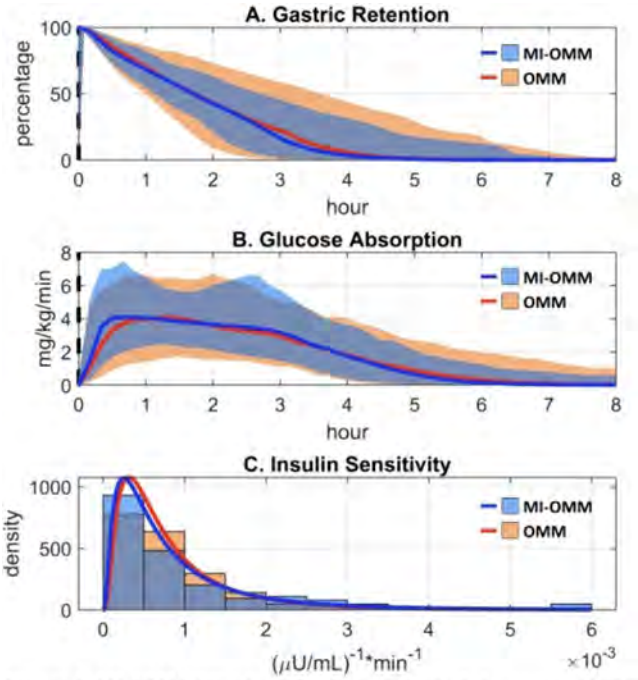

Figure 1. MI-OMM (blue lines and light-blue shaded areas) vs OMM (red lines and orange shaded areas). *Panel A:* median profiles (thick lines) and 90% predicted intervals (shaded areas) of gastric retention. *Panel B:* median profiles (thick lines) and 90% predicted intervals (shaded areas) of glucose absorption. *Panel C:* Estimated (thick lines) and empirical (histograms) insulin sensitivity distributions.

(IP) data. MI-OMM was identified from CGM and IP data using a Bayesian maximum a posteriori estimator, while OMM, identified from plasma glucose and insulin data, was used as reference.

Results: Both models fitted the data well and provided precise parameter estimates. Estimated GR, GA, and S_I, obtained with the two methods, are compared in Figure 1.

Conclusions: MI-OMM provided accurate estimates of GR, GA and SI using CGM and IP data. Therefore, it is usable to assess the effect of meal composition on those quantities in daily life conditions and potentially exploitable in DSS for T1D management.

OP115 / #407

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

ORAL PRESENTATIONS SESSION 8

EFFICACY OF THE INSULIN PEN SMART CAP INSULCLOCK® IN PEOPLE WITH NON-CONTROLLED TYPE 1 DIABETES MELLITUS (T1DM): A MULTICENTER, RANDOMIZED CLINICAL TRIAL

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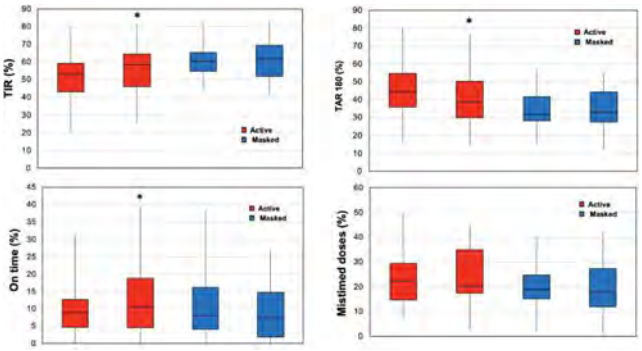
[1]Hospital General de Segovia, Endocrinology And Nutrition Unit, SEGOVIA, Spain, [2]Cruces University Hospital, Endocrinology And Nutrition, Bilbao, Spain, [3]Hospital Arquitecto Marcide, Ferrol (A Coruña), Endocrinoly And Nutrition, Ferrol,, Spain, [4]Hospital Universitario Central de Asturias, Endocrinology And Nutrition, Oviedo, Spain, [5]Insulcloud S.L., Research And Development Unit, Madrid, Spain

Background and Aims: *Insulclock®* system includes an insulin pen smart cap and a digital platform to improve diabetes self-management, integrating insulin doses and CGM information. The study aimed to assess the efficacy of the Insulclock® system on improving glycemic control, treatment adherence, and quality of life in T1DM.

Methods: This multicenter, open-label, randomized, controlled trial in T1DM wearing a CGM device comprised a 4-week run-in period and a 6-week follow-up phase (participants were randomized to the active - used all functionalities, including alarm setting, data management and sharing with caregivers- or masked group). Glycemic control, glycemic variability, treatment adherence and the insulin treatment satisfaction questionnaire (ITSQ) were evaluated from the run-in to the follow-up period and compared between active and masked groups.

Results: Seventy-five participants were randomized, and 55 were analyzed (active group: 26; masked group: 29). The increase in time in range (TIR, primary outcome) was higher in the active vs the masked groups (+5.2% vs -0.8%; p = 0.016). The active group showed a higher reduction in mean glucose (-8.7 mg/dL; p = 0.024), eHbA1C (-0.31%; p = 0.039), time above range (TAR) 180 mg/dL (-5.5%; p = 0.018) and high blood glucose index (HBGI) (-1.4; p = 0.029). A higher increase in the insulin doses on time was observed in the active group (10.4% to 12.9%), masked group (12.2% to 8.7%)(p = 0.017). Most ITSQ items improved in both groups.

Conclusions: *Insulclock®* use was associated with improved glycemic control, glycemic variability, hyperglycemia risk, and insulin treatment adherence in people with uncontrolled type 1 diabetes. ClinicalTrials.gov NCT04847778



OP116 / #649

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

ORAL PRESENTATIONS SESSION 8

GLYCEMIC CARE OPTIMIZATION IN THE HOSPITAL USING CLINICAL DECISION SUPPORT HELPS REDUCE LENGTH OF STAY

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[1]Penn State College of Medicine, Department Of Medicine, Division Of Endocrinology, Hershey, United States of America,

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Background and Aims: Dysglycemia impacts resources utilization and outcomes in hospitalized patients. Clinical Decision Support (CDS) assists in overcoming barriers to care. We aimed to study the impact of an alert-based CDS tool addressing insulin use and glucose control on hospital length of stay (LOS).

Methods: A Clinical Decision Support tool was embedded in the electronic medical record. It captured gaps in glycemic care using data driven algorithms and provided real-time glucose management and insulin utilization guidelines to providers. The tool was available intermittently in records of hospitalized adults over a 12-months period. LOS during active and inactive periods of the tool, each lasting 6 months, was compared invoking a linear model for repeated measures.

Results: Among a total of 4,788 admissions, average LOS was shortened in patients with dysglycemia while the tool was active compared to conventional care. LOS was reduced in patients with gaps in glycemic care in the following manner: in all admissions -5.7 hours ($p = 0.057$); patients with diabetes and hyperglycemia, -6.4 hours ($p = 0.054$); stress hyperglycemia, -31.0 hours ($p = 0.\ 054$); recurrent hypoglycemia, -29.1 hours ($p = 0.074$); and patients admitted to medical services, -8.4 hours ($p = 0.039$).

Conclusions: A Clinical Decision Support tool embedded in the electronic medical record addressing dysglycemia in the hospital contributes to reducing LOS, which represents a clinical and an economic outcome. Our study highlights the importance of developing comprehensive programs and testing outcomes associated to Clinical Decision Support beyond process improvement and intermediary outcomes. Our findings are relevant to the domains of quality, safety, efficiency, and equity in hospital care.

OP117 / #65

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ORAL PRESENTATIONS SESSION 8

ASSOCIATION BETWEEN CHANGE IN HBA1C AND PROFESSIONAL CGM USE IN ADULTS WITH TYPE 2 DIABETES ON NON-INSULIN THERAPIES–A REAL WORLD EVIDENCE STUDY

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Dexcom, Health Economics And Outcomes Research, Global Access, SanDiego, United States of America

Background and Aims: Previous studies have shown clinical benefits in patients who used professional Continuous Glucose Monitor (CGM). However, the effect of professional CGM use in non-insulin Type-2 Diabetes (T2D) patients having poor glycemic control in real world settings has not been studied. We examined the association between HbA1c and professional CGM in T2D patients with poor glycemic control using multiple non-insulin therapies.

Methods: This retrospective analysis used healthcare claims data from Optum® Clinformatics,® comprised of commercial and Medicare Advantage members between 01-January 2018 to 31-October 2020. T2D patients ≥18 years of age were identified using ICD-9/ICD-10 codes having an HbA1c between 7.8–10.5%, using ≥2 non-insulin therapies, with no prior CGM or professional CGM use, and 6-months of continuous enrollment pre and post index date. Index date was defined as acquisition of professional CGM identified through CPT codes 95250 and 95251. The outcome was mean HbA1c change between baseline and up to 6-months post-index date.

Results: Data from 15,474 eligible patients were assessed (Professional CGM users, $n = 677$; Non-users, $n = 14,797$). A significant decrease in mean HbA1c from baseline was observed for professional CGM users (-0.78) vs. non-users (-0.32), $p < 0.0001$ (difference-in-differences estimate, -0.50; 95% CI,-0.61 to -0.39; $p < 0.0001$).

Conclusions: Findings suggest T2D patients with poor glycemic control using multiple non-insulin therapies may benefit from professional CGM resulting in reduction in HbA1c over a 6-month period compared to usual care. Professional CGM can inform clinicians about their patients' glycemic patterns and help to tailor diabetes management strategies for patients.

OP118 / #687

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

ORAL PRESENTATIONS SESSION 8

MY DIABETIC: SERIOUS GAME TO SUPPORT CHILDREN'S EDUCATION IN DIABETES MELLITUS I

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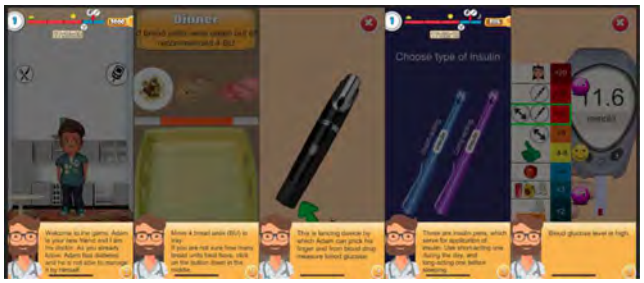
Background and Aims: Gaming applications that are used for purposes beyond entertainment, defined as serious games, with the intention to educate and resolve a problem, may be one timely method to promote healthy diabetes management behaviors within children affected by T1D. The aim of the serious game My-Diabetic is to teach players not only the relationship between food, insulin, and sports but also to pass on knowledge related to working with a glucometer insulin pen and more advanced technology like, injection of glucagon, measurement of ketoacidosis, continuous glucose measurement and insulin pump.

Methods: Supporting patient motivation (compliance, adherence) was achieved by a combination of several approaches as tailoring, observational learning, social and family support, decision-making practice, and rewards systems.

Results: The game was tested tested on 80 children (60 of diabetics). We met with positive response from children who tested the game and their parents. The game was also presented to



20 schoolmates of T!D's children who appreciated better understanding of the desease and opportunity to support more efficiently their friends in T1D compensation.

Conclusions: The game is especially suitable for newly diagnosed children because it acquaints them in a fun way with new terminology, they are able to try, for example, glycemic measurements in an interactive way. The game was also designed for children who cannot read yet because the game includes a guide (e.g. a female family doctor) that describes by her voice the main underlying principles behind the game. The game is available in Google Play and Apple Store markets.

The study was supported by the Research Centre for Informatics, grant number CZ.02.1.01/0.0/16_019/0000765

OP085A / #641

Topic: ***AS03-Artificial Pancreas***

ORAL PRESENTATIONS SESSION 5

DEMONSTRATING THE EFFECT OF DAILY PHYSICAL ACTIVITIES ON BLOOD GLUCOSE LEVEL VARIATION IN TYPE 1 DIABETES

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Background and Aims: Physical activity perturbs blood glucose (BG) concentration both during and after the activity session, for up to 15 hours, making BG management in type 1 diabetes (T1D) challenging. Motivated by this, we investigate the effect of physical activity on BG prediction [1].

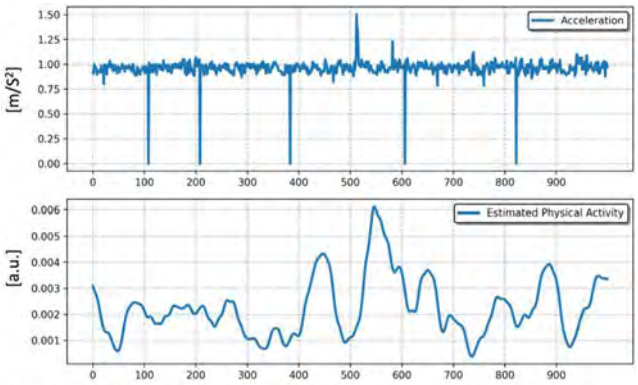

Fig 1. Representative patient from OHIOT1DM-2020 dataset.

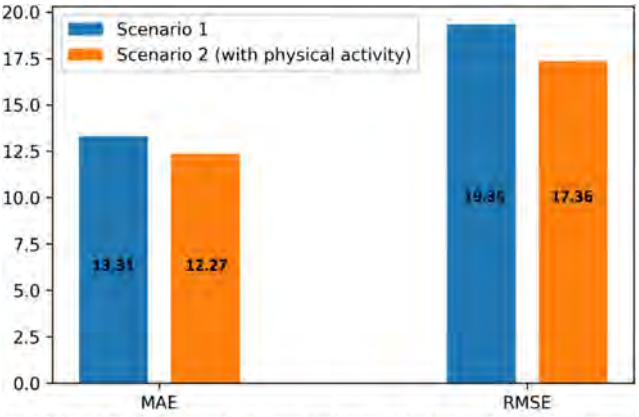

Fig 2. MAE and RMSE for scenario 1, excluding and scenario 2,including estimated phytsical activity, for future BG level prediction.

Methods: In this study, we leverage the method introduced in [1], to estimate the physical activity from three axis accelerometer (ACC) obtained from OHIOT1DM 2020 dataset [2]. Then we integrate it into a deep neural network (DNN)-based BG predictive model, along BG level, meal, and insulin intakes.

Results: We show that including the estimated physical activity level improves the performance of the BG predictive model in terms of mean absolute error (MAE), from 13.31 to 12.37 [mg/dL], and root mean square error (RMSE) from 19.35 to 17.36 [mg/dL], respectively.

Conclusions: In consequence, we hypothesize that, behavioral interventions, namely, appropriate physical activity sessions, would help in obtaining better glucose control in T1D patients. **References** Cescon, Marzia, Divya Choudhary, Jordan E. Pinsker,et al. "Activity detection and classification from wristband accelerometer data collected on people with type 1 diabetes in free-living conditions." *Computers in Biology and Medicine* 135 (2021): 104633. Marling, Cindy, and Razvan Bunescu. "The OhioT1DM dataset for blood glucose level prediction: Update 2020." In *CEUR workshop proceedings*, vol. 2675, p. 71. NIH Public Access, 2020.

EP001 / #102

Topic: ***AS01-Closed-loop System and Algorithm***

BENEFITS OF AN ADVANCED HYBRID CLOSED-LOOP SYSTEM IN A HIGH FREQUENCY OF HYPOGLYCAEMIA TYPE 1 DIABETES SUBPOPULATION

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Background and Aims: The Advanced Hybrid Closed-Loop system (AHCL) MiniMed™ 780G infuses microboluses and autocorrection boluses according to sensor glucose values. The aim was to analyse the outcomes achieved in the subpopulation of people with type 1 diabetes with a high frequency of hypoglycaemia.

Methods: Out of 143 subjects using the AHCL, the ones with baseline time <70mg/dl ≥4% or time <54mg/dl ≥1% were selected.

Results: 60 subjects were included: 70% females, age: 33 ± 15 years, 25% <18 years-old, diabetes duration: 21 ± 12 years, baseline HbA1c: 7.0 ± 0.8%, baseline treatment: 32% (n = 19) MDI, 68% (n = 41) sensor-augmented pump, 8% with history of SH, time on AHCL: 7.5 [6-11] months.

The autocorrection feature was activated in all the subjects, the glucose target was 100 mg/dl in 85% and active insulin time was 2 hours in 82% of the individuals. At the end of the follow-up, time in automode was 96 ± 5% and autocorrection insulin was 28 ± 13% of bolus inulin. The percentage of subjects with time <70mg/dl ≥4% decreased from 80% at baseline to 57% at the end of the follow-up and the percentage with time <54mg/dl ≥1% decreased from 97% at baseline to 63% at the end of follow-up; the percentage of people with the optimal combination of TIR >70% and time <70mg/dl <4% increased from 10% to 28% and the percentage with TIR >70% and time <54 mg/dl <1% increased from 8% to 30% (all $p < 0.02$).

Table 1. Outcomes at the end of follow-up compared to baseline

	Baseline	End of follow-up	p
GMI (%)	6.8 ± 0.4	6.6 ± 0.3	< 0.0005
TIR 70-180 mg/dl (%)	69.2 ± 10.0	78.9 ± 7.7	< 0.0005
Time < 70 mg/dl (%)	6.2 ± 3.6	4.0 ± 3.2	< 0.0005
Time < 54 mg/dl (%)	1.9 ± 1.5	1.0 ± 1.2	< 0.0005
Time > 180 mg/dl (%)	24.4 ± 11.3	17.1 ± 8.0	< 0.0005
Time > 250 mg/dl (%)	5.0 ± 5.0	2.7 ± 2.6	< 0.0005
Sensor glucose (mg/dl)	146 ± 19	137 ± 13	< 0.0005
Standard deviation of sensor glucose (mg/dl)	53 ± 9	47 ± 9	< 0.0005
Coefficient of variation of glucose (%)	37 ± 4	34 ± 5	< 0.0005
Sensor use (%)	85 ± 10	92 ± 10	< 0.0005
Hipoglycaemia alarms (n/day)	7 ± 5	5 ± 4	0.001
Hiperglycaemia alarms (n/day)	3 ± 3	2 ± 2	0.003
Carbohydrate intake (gr/day)	144 ± 76	138 ± 79	0.567

Conclusions: Subpopulations with a high frequency of hypoglycaemia are able to reduce their frequency of hypoglycaemia and hyperglycaemia by using AHCL systems.

EP002 / #106

Topic: ***AS01-Closed-loop System and Algorithm***

IMPROVEMENT IN HBA1C AFTER 8 WEEKS OF OMNIPOD® 5 AUTOMATED INSULIN DELIVERY SYSTEM USE IN ADULTS WITH TYPE 2 DIABETES: FROM INJECTIONS TO CLOSED-LOOP THERAPY

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Background and Aims: Automated insulin delivery (AID) has rarely been studied in adults with type 2 diabetes (T2D), despite the significant burden of disease. We enrolled adults with T2D, previously on either basal-only or basal-bolus insulin injections, with or without CGM, with A1C >8%, to start AID with the Omnipod 5 System in a multicenter outpatient feasibility trial.

Methods: Participants completed 2 weeks of sensor data collection with their standard therapy (ST), then 8 weeks of AID. Prior basal-only users additionally used the system in basal-only Manual Mode for 2 weeks between ST and AID. Any anti-hyperglycemic agents were continued throughout. Primary safety outcomes were percent time with sensor glucose <54mg/dL (<3.0mmol/L) and ≥250mg/dL (≥13.9mmol/L) during AID.

Results: Participants (N = 24) were aged (mean±SD) 61 ± 8y with BMI 33.5 ± 4.4kg/m^2, baseline A1C 9.4 ± 0.9% (range: 8.1-11.7%), and diabetes duration 19 ± 9y. Percent time ≥250mg/dL (≥13.9mmol/L) decreased by 8.5% and 21.3% for prior basal-bolus and basal-only users, respectively, corresponding to 2.0 and 5.1 fewer hours/day in this range (both $p < 0.05$). Time <54mg/dL (<3.0mmol/L) remained low and unchanged. Most glycemic measures improved from ST to AID, including an additional 3.4 and 5.9 hours/day in target

Table. Glycemic outcomes and insulin use for 24 participants with type 2 diabetes during 8 weeks of Automated Insulin Delivery (AID), compared to 2 weeks of Standard Therapy (ST) (Basal-Bolus Injections [Group A, n=12], or Basal Injections [Group B, n=12])

Glycemic Outcomes		Group	ST† (2 weeks)	AID (8 weeks)	Change
HbA1c, %		A	9.4 ± 1.0	8.1 ± 0.8	**-1.2 ± 0.7***
		B	9.5 ± 0.8	8.1 ± 0.6	**-1.4 ± 0.7***
		Overall	9.4 ± 0.9	8.1 ± 0.7	**-1.3 ± 0.7***
Mean sensor glucose, mg/dL		A	193 ± 28	176 ± 17	**-17 ± 19***
		B	223 ± 43	182 ± 24	**-41 ± 33***
		Overall	208 ± 39	179 ± 21	**-29 ± 29***
Sensor Glucose Percent Time in Ranges (%)					
mg/dL	mmol/L				
<54	<3.0	A	0.03 [0.00, 0.11]	0.02 [0.00, 0.07]	0.00 [-0.11, 0.01]
		B	0.00 [0.00, 0.00]	0.00 [0.00, 0.01]	0.00 [0.00, 0.01]
		Overall	0.00 [0.00, 0.06]	0.00 [0.00, 0.03]	0.00 [-0.02, 0.01]
<70	<3.9	A	0.31 [0.06, 0.66]	0.10 [0.03, 0.29]	**-0.27 [-0.47, -0.05]***
		B	0.01 [0.00, 0.24]	0.04 [0.02, 0.07]	0.01 [-0.18, 0.03]
		Overall	0.13 [0.00, 0.51]	0.06 [0.02, 0.15]	**-0.08 [-0.41, 0.02]***
70-180	3.9-10.0	A	46.5 ± 17.9	60.5 ± 14.3	**14.1 ± 11.2***
		B	32.2 ± 19.6	56.6 ± 17.7	**24.4 ± 15.0***
		Overall	39.3 ± 19.7	58.6 ± 15.9	**19.2 ± 14.0***
>180	>10.0	A	52.6 ± 17.9	39.3 ± 14.3	**-13.3 ± 11.2***
		B	67.6 ± 19.7	43.3 ± 17.7	**-24.2 ± 15.1***
		Overall	60.1 ± 19.9	41.3 ± 15.9	**-18.8 ± 14.1***
≥250	≥13.9	A	17.8 ± 14.4	9.3 ± 5.6	**-8.5 ± 10.4***
		B	33.0 ± 24.1	11.7 ± 11.3	**-21.3 ± 18.1***
		Overall	25.4 ± 20.9	10.5 ± 8.8	**-14.9 ± 15.9***
Insulin Use		**Group**	**ST (3 days)**	**AID (8 weeks)**	**Change**
Total Daily Dose (Units)		A	92.4 ± 44.0	63.1 ± 26.4	**-29.3 ± 26.9***
		B	30.6 ± 21.9	42.1 ± 38.4	11.5 ± 33.4

*p-value <0.05; Data are mean ± SD or median [IQR]; †During the ST phase, the continuous glucose monitor (CGM) used for data collection was blinded for those not using real-time CGM as part of their ST

range 70-180mg/dL (3.9-10.0mmol/L) for prior basal-bolus and basal-only users, respectively (Table). HbA1c decreased by 1.3% overall ($p < 0.05$). AID was used for median 94.4% of time. There was no change in BMI ($p > 0.05$). No related serious adverse events occurred.

Conclusions: This study provides a novel evaluation of the safety and effectiveness of AID in adults with T2D with sub-optimal glycemic management, treated with either basal or basal-bolus insulin therapy.

EP003 / #107

Topic: ***AS01-Closed-loop System and Algorithm***

PERFORMANCE OF THE OMNIPOD® 5 AUTOMATED INSULIN DELIVERY SYSTEM WITH AND WITHOUT PRE-MEAL BOLUS

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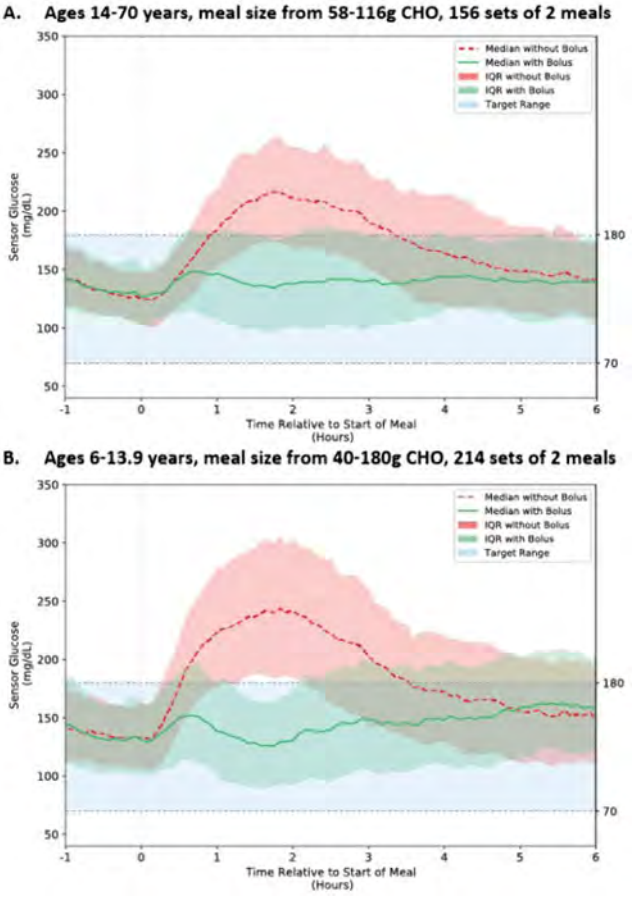
Background and Aims: The Omnipod 5 Automated Insulin Delivery (AID) System is designed to be used with pre-meal boluses; however, in real-life settings boluses may be missed. AID systems can partially compensate for these missed boluses by delivering additional insulin in response to rising glucose levels. We evaluated the performance of this system following sets of two identical meals with and without a bolus during AID.

Methods: During a 3-month trial of the AID system in type 1 diabetes, a subset of participants ate two sets of matched meals. Each meal set consisted of the exact same meal, unique to each person, consumed on different days with and without a meal bolus. Meal challenges were completed on the same days as exercise challenges. Resulting postprandial glycemic profiles were assessed over 6 hours.

Results: Eighty adults/adolescents (14-70y, 156 matched meal sets) and 110 children (6-13.9y, 214 matched meal sets) participated in the challenges. Estimated meal sizes were (mean±SD)



67 ± 12g CHO (range 58-116g) in adults and 74 ± 21g (40-180g) in children. Following meals without bolus, median glucose increased from 125 to 214mg/dL (6.9 to 11.9mmol/L) after 1.7h and returned <180mg/dL (<10.0mmol/L) after 3.4h in adults, and increased from 129 to 241mg/dL (7.2 to 13.4mmol/L) after 1.8h and returned <180mg/dL (<10.0mmol/L) after 3.6h in children (Figure). Following meals with bolus, median glucose remained within target range (70-180mg/dL; 3.9-10.0mmol/L) through 6 hours post-meal.

Conclusions: Optimal glycemic outcomes were achieved following meals with a bolus, and with a missed bolus a median glucose <180mg/dL (<10.0mmol/L) was achieved in about 3.5 hours.

EP004 / #111

Topic: ***AS01-Closed-loop System and Algorithm***

CANADIAN HEALTHCARE PROVIDERS' ATTITUDES TOWARDS AUTOMATED INSULIN DELIVERY SYSTEMS

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Background and Aims: We aimed to assess the current experience and attitudes towards Commercial and Do-it-yourself (DIY) automated insulin delivery (AID) systems among healthcare providers (HCP) across Canada.

Methods: We conducted a cross-sectional study through electronic distribution of an anonymous survey via; place of work, specialist interest platforms and social media, to HCP licensed to practice in Canada looking after people with type 1 diabetes(T1D).

Results: Responses included 204 HCP across the multi-disciplinary team; dieticians (32.8%), nurses (31.9%), and endocrinologists (28.4%) looking after adults (51%), children (23%) or both (26%), mainly in urban areas (85.7%). Respondents reported a median 100-500 patients with T1D per practice, with a median 6-24 current users/practice of Commercial compared to a median 1-5 current users/practice of DIY AID. The majority of HCP (72.7%) were comfortable supporting Commercial AID, whereas only 21.6% reported comfort supporting DIY AID use. A significant, although moderate correlation between HCP experience and comfort was seen;Commercial $r = 0.57 (p < 0.0001)$ and DIY $r = 0.45 (p < 0.0001)$. Respondents reported more barriers to DIY, relative to Commercial AID($p = 0.001$); unfamiliarity/lack of exposure and medico-legal risks were highlighted with DIY systems. Respondents suggested AID system education (both Commercial and DIY), for HCP and users, to improve HCP confidence.

Conclusions: Despite documented benefits for glycemia and quality of life, AID systems are not widely used in Canada. HCP uncertainty around DIY systems suggests clarification of medico-legal guidance would be helpful. Education to improve Commercial and DIY AID familiarity, is needed for both HCP and users, to facilitate greater access to the benefits of AID for people with T1D in Canada.

EP005 / #122

Topic: ***AS01-Closed-loop System and Algorithm***

GLYCEMIC OUTCOMES AND SAFETY WITH MINIMED 780G SYSTEM IN CHILDREN WITH TYPE 1 DIABETES AGED 2-6 YEARS

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Background and Aims: Treatment of type 1 diabetes (T1D) in small children is challenging. In children over 7 years, Minimed 780G advanced HCL system improved TIR without increasing time-below-range (TBR). This study evaluates the efficacy and safety of the aHCL system on glycemic control in children aged 2.6 years with T1D.

Methods: In this investigator-initiated, prospective, non-randomized, single-arm study, 35 small children with T1D initiated aHCL. Primary endpoint: change in TIR after aHCL system initiation. Secondary endpoints: safety, HbA1c, TBR, and mean sensor glucose (SG). The inclusion criteria: TDD (total insulin daily dose) ≥8 units, HbA1c < 85 mmol/mol, capability of parents to use pump and the CGM, and time from diabetes diagnosis >6 months. The study is conducted at pediatric diabetes outpatient clinics of Helsinki University Hospital. Fig. 1. This study has been approved in Helsinki University Hospital Ethics committee. Clinical Trials registration number NCT04949022.

Results: Patients have been recruited by the end of October 2021. Study closure visit of patient 35 will be in February 2022, and the results are presentable at ATTD2022 meeting. Baseline characteristics: Table1.

Conclusions: We expect to see improved TIR and smaller glucose excursions in small children using Minimed780G system.

Figure 1: Flow chart of the study

Table 1. Baseline characteristics

	Mean (SD)
Number (n)	35
Male sex (n)	19
CSII / MDI (n)	32 / 3
Age (years)	4.3 (1.2)
Diabetes duration (months)	28 (15)
Insulin dose (ky / kg)	0.67 (0.14)
HbA1C (mmol/mol)	57.3 (7.2)
TIR (%)	59 (13.8)
TBR (%)	3 (1.7)
Mean SG (mmol/l)	9 (1.1)

EP006 / #177

Topic: ***AS01-Closed-loop System and Algorithm***

CHANGES IN QUALITY OF LIFE AND PSYCHOLOGICAL WELL-BEING IN PATIENTS WITH T1DM UNDERGOING TRANSITION FROM MDI AND SMBG TREATMENT DIRECTLY TO MINIMED™ 780G AHCL SYSTEM

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Background and Aims: The aim was to evaluate whether the transition from Multiple Daily Injections (MDI) and Self-Monitoring of Blood Glucose (SMBG) directly to MiniMed™ 780G Advanced Hybrid Closed Loop (AHCL) system has an impact on the QoL and psychological well-being of the patients.

Methods: The trial was a two-center, randomized controlled, parallel group study. 41 T1DM patients managed with MDI/SMBG at baseline were enrolled and randomized either to AHCL or MDI/SMBG groups. 37 participants (20 in AHCL and 17 in the MDI/SMBG groups) completed the study (age 40.3 ± 8.0 years; duration of diabetes 17.3 ± 12.1 years; HbA1c 7.2 ± 1.0). QoL was measured at baseline and End of Study with the use of QoL-Q Diabetes Version 2[1] and psychological well-being with the State-Trait Anxiety Inventory (STAI)[2] questionnaire.

Results: The AHCL group reported an increase in their QoL in 4 scales: Feeling well (2.3; CI: 0.1-4.6; p = 0.042); Working (2.8; CI: 0.7-4.9; p = 0.012); Eating as I would like (3.1; CI: 0.8-5.4, p = 0.011); Doing normal things (2.8; CI: 0.2; 5.4; p = 0.0343). The level of anxiety decreased in AHCL group STAI1 scores (-6.8; CI: -11.8 –1.8 p = 0.009), STAI 1 stens (-1.4; CI: -2.5 - - 0.3; p = 0.013); STAI 2 scores (-3.5; IC: -6.5 - -0.5; p = 0.022). All between groups differences were adjusted for baseline values.

Conclusions: The results indicate that transitioning from MDI/SMBG treatment to AHCL may significantly improve the QoL and psychological well-being of the patients within 3 months. The rapidity of these changes suggests that they may be related to the significant improvement in glycemic outcomes[3].

EP007 / #234

Topic: ***AS01-Closed-loop System and Algorithm***

TIME OF INITIATION OF ADVANCED HYBRID-CLOSED LOOP THERAPY AND RELATED GLYCEMIC OUTCOMES IN PEOPLE WITH TYPE 1 DIABETES TRANSITIONING FROM MULTIPLE DAILY INJECTIONS

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Background and Aims: Advanced hybrid closed-loop systems (AHCL) have demonstrated long-term benefits in all people with diabetes (PWD). However, unpublished reports suggest that PWD using multiple daily injections (MDI) might delay activation of AHCL because of concerns around managing pump therapy.

Methods: We retrospectively studied first 90 days of pump activation in MDI users with type 1 diabetes transitioning to t:slim X2™ insulin pump with Control-IQ® technology. Participants (age 34 ± 20, 52% female) were categorized into 3 groups: G1 initiated Control-IQ technology within 2 days of pump start, G2 initiated between 2-14 days, and G3 initiated within 15-90 days. Hypoglycemia and time in range (TIR) sensor glycemic (SG) metrics for Control-IQ technology use were retrieved from Tandem's t:connect® web application. Group differences were analyzed using Mann Whitney U and Kruskal-Wallis tests.

Results: 81% of users, initiated Control-IQ technology within 2 days of pump start (G1, n = 14222) followed by G2 (14%, n = 2448), and G3 (5%, n = 870). Groups did not differ on baseline HbA1c. With Control-IQ technology, no differences were noted for SG <54mg/dL (median (IQR): G1 = 0.13(0.04-0.3), G2 = 0.12(0.04-0.31), G3 = 0.13(0.04-0.32) and SG <70mg/dL: G1 = 0.87(0.36-1.8), G2 = 0.84(0.38-1.7), G3 = 0.89(0.37-1.72). There were no differences between G1 and G2 on TIR (70-180mg/dL): G1 = 68.6(57.8-78.1), G2 = 69.5(59.1-79.1). However, G3 showed significantly lower TIR: 66.6(55.6-77.9) (p = 0.003). Overall, 99.5% of participants continued to use Control-IQ technology at the time of this analysis.

Conclusions: 95% of MDI users (G1, G2) successfully initiated Control-IQ technology within 14 days of pump start. While all groups experienced success with Control-IQ technology, G3 showed lower TIR with delayed initiation.

EP008 / #257

Topic: ***AS01-Closed-loop System and Algorithm***

WHO IS USING DO-IT-YOURSELF ARTIFICIAL PANCREAS SYSTEMS AND WHY

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Background and Aims: Do-it-yourself artificial pancreas systems automatically or semi-automatically adjust insulin

dosage based on user-controlled algorithms. Because use is off-label and user-directed, little is known about who uses these systems and why.

Methods: As a team of scientists, clinicians, innovators, and people living with type 1 diabetes, we conducted an online English-language survey of people using do-it-yourself systems March 16-Aug 3, 2021, recruiting on relevant social media (Facebook, Twitter, Gitter, Slack, Telegram.) We analyzed data descriptively.

Results: 662/825 people (80.2%) completed the survey. Respondents (mean age 44.2 years, SD 11.6 years; 57.8% women, 39.2% men) lived in a range of countries, most commonly the US (43.9%), Canada (14.9%), or the UK (10.8%). Respondents were predominantly white (86.6%) with a postsecondary education (87.1%). Most (69.7%) were using a system themselves; many (27.4%) were caregivers to children using a system; some (0.4%) were in both categories. Systems used included Loop (70.4%), AndroidAPS (22.5%) and OpenAPS (2.0%). Most respondents (91.2%) set up the systems themselves, using written instructions (94.4%), help from others online (28.4%), and videos (25.3%). Respondents use automated insulin delivery systems to improve glycemic control and reduce diabetes burden. They use do-it-yourself systems for their transparency, interoperability, availability, safety, and the ability to set custom target ranges.

Conclusions: Do-it-yourself artificial pancreas systems offer nontraditional diabetes management options which are selected by individuals with higher levels of education. Health professionals should be aware of systems patients may choose to use as well as advocating for equitable access to treatments for all people with type 1 diabetes.

EP009 / #262

Topic: ***AS01-Closed-loop System and Algorithm***

CASE REPORT: HYBRID CLOSED LOOP (MEDTRONIC MINIMED 780G) INITIATED DURING A TWIN PREGNANCY

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Background and Aims: Hybrid closed loop (HCL) devices can achieve tight glycemic control but are rarely used in pregnancy which remains an off-label indication. The aim is to communicate the clinical course and outcomes of a case where HCL was initiated during pregnancy.

Methods: This is a case report describing the maternal, glycemic and fetal outcomes of a twin pregnancy that required starting HCL (MiniMed 780G) to achieve an optimal control. Visits were scheduled with both endocrinologist and trained nurses. The information was obtained from clinical records and glucose monitor reports were obtained using CareLink platform.

Results: A type 1 diabetic 35-year old woman presented an unplanned twin pregnancy being her HbA1c 6,6%. The patient was treated with multiple doses of subcutaneous insulin and flash glucose monitor. At the end of second trimester, insulin requirements were rapidly increasing and pregnancy glycemic control targets were not achieved. Moreover, ultrasound showed two large for gestational age fetuses. A sensor-augmented pump therapy with MiniMed 780G was started at week 26 and entered automode in HCL at week 27. Successful results in glycemic control were obtained with an improvement in time in range (63-140 mg/dl) from 20% to 60 % and time above range (>140 mg/dl) from 79% to 38%. At week 35 a healthy baby boy and girl with normal weight were born through cesarean delivery.

Conclusions: This case shows the successful off-label use of HCL during pregnancy in a patient with T1DM and multiple pregnancy.

EP010 / #263

Topic: ***AS01-Closed-loop System and Algorithm***

ADJUSTING INSULIN THERAPY TO FASTER INSULIN ANALOGS LEADS TO IMPROVED GLUCOSE CONTROL: AN IN SILICO ANALYSIS

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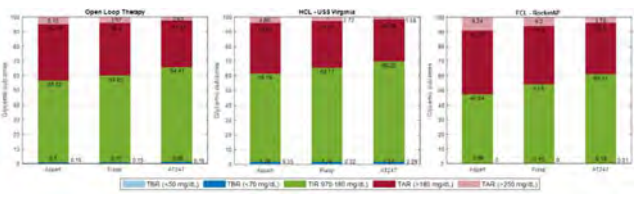
Background and Aims: Ultra-rapid-acting insulins (URIs) with faster pharmacokinetic (PK) and pharmacodynamic (PD) profiles have been developed to improve postprandial glucose control and achieve greater flexibility in insulin dosing. The aim of this work is to illustrate that properly adjusting insulin therapy to faster PK/PD profiles is key to improving glucose control using URIs when combined with automated insulin delivery (AID) algorithms.

Methods: Subcutaneous insulin transport models for standard insulin aspart (Aspart) and two products with faster PK/PD profiles (Fiasp and AT247) were built using data collected from glucose clamp tests, and then integrated into the UVA/Padova simulator. Therapy parameters (carbohydrate-ratio and correction-factor) used in standard basal-bolus open-loop (SBOL) therapy and the aggressiveness of our AID algorithms (USS-Virginia and RocketAP) were adjusted according to the PK/PD properties of each insulin. Simulations involving multiple meals and metabolic variability were performed to evaluate performance of both open- and closed-loop strategies when switching from Aspart to Fiasp or AT247.

Results: Postprandial percentages of time in the range [70,180] mg/dL were improved with the SBOL therapy, USS-Virginia, and RocketAP AID when switching from Aspart to Fiasp (+3.34 [3.20,3.48], +3.92 [3.86,3.98], and +6.97 [6.79,7.15]) and from Aspart to AT247 (+8.90 [8.63,9.16], +8.43 [8.29,8.57], and +13.70 [13.40,14.01]). Only negligible differences were observed in time below 70 mg/dL (Aspart-Fiasp: +0.02 [0.00,0.04], +0.05 [0.03,0.08], +0.10 [0.09,0.11], and Aspart-AT247: +0.18 [0.16,0.21], -0.01 [-0.04,0.02], +0.07 [0.04,0.10]).

Conclusions: *In silico* results suggest that properly adjusting insulin therapies to faster PK/PD profiles of URIs can lead to clinically significant improvement in glucose control.



EP011 / #282

Topic: ***AS01-Closed-loop System and Algorithm***

WHICH DO-IT-YOURSELF ARTIFICIAL PANCREAS SYSTEMS (DIYAPS) AND USED IN THE UNITED KINGDOM? INSIGHTS FROM THE ASSOCIATION OF BRITISH CLINICAL DIABETOLOGIST'S (ABCD) AUDIT PROGRAMME

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Background and Aims: DIYAPS is an unlicensed automated insulin delivery system developed by people with diabetes #WeAreNotWaiting. Three systems are commonly encountered, utilising different combinations of insulin pump and sensor. This abstract reports the frequency of use of each system, pump and sensors in our cohort including the funding and warranty status.

Methods: Data from the ABCD DIYAPS audit tool are presented using simple descriptive statistics for the frequency of use of each DIYAPS system, pump and sensor and warranty and funding status where applicable. Analyses were performed in Stata 16.

Results: Some data of interest were available for 101 users. 55.5% were men, 90.3% were white British and median diabetes duration was 25.5 years (IQR 17-33.5). The most frequently encountered system was AndroidAPS (61%, 55/90), followed by Loop (27%, 24/90) and OpenAPS (12%, 11/90). DANA pumps were most frequently encountered (40%, 25/62) followed OmniPod (18%, 11/62) Roche Combo (15%, 9/62), Roche Insight (13%, 8/62), MedTronic Paradigm Veo (8%, 5/66) then other (6%, 4/62). NHS-funded pumps were used by 87% (53/61). Only 18% (11/60) were using an out-of-warranty pump. FreeStyle Libre with an adjunctive MiaoMiao scanner was used by 42% (28/66) with slightly fewer using the Dexcom G6 (39% 26/66). The majority of sensors were NHS-funded (59%, 34/58).

Conclusions: AndroidAPS appears to be the most commonly used DIYAPS in our cohort. Users often continue to access NHS-funding for equipment. Out-of-warranty pump use is infrequent: it is unclear whether this introduces any additional risk of adverse events. Ongoing surveillance will be needed.

EP012 / #320

Topic: ***AS01-Closed-loop System and Algorithm***

WHAT DO PRESCHOOL CHILDREN WITH TYPE1 DIABETES (T1D) GAIN BY USING ADVANCED HYBRID CLOSED LOOP SYSTEM?

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Background and Aims: The MiniMed 780G, first Advanced Hybrid Closed Loop (AHCL) pump available in Poland, has CE mark approval for children with T1D from 7 yrs of age . The goal was to analyse glycemic control parameters in T1D children under 7 years of age treated with the AHCL in relation to previous pump therapy.

Methods: We compared continuous glucose monitoring (CGM) records of 11 T1D children, aged 5.66 ± 1.24 yrs, who switched from sensor augmented pump (SAP; personal insulin pump with real time continuous glucose monitoring) to AHCL. SAP records from the two weeks preceding the AHCL connection were compared to the records of the first four weeks in the automatic insulin dose adjustment system (SmartGuard) – divided into two two-week periods[pjc1] . The initial training period was excluded from analysis.

	PIP +rtCGM	AHCL The first two weeks	AHCL The second two weeks
AvgSG[mg/dl]	146.11±18.19	133.36±12.90	133.19±11.30
TDI [u.]	15.81±4.41	15.35±4.36	16.13±5.21
GMI [%]	6.80±0.43	6.50±0.30	6.50±0.27
Percent of sensor glucose values in range [%]			
>250mg/dl	5.54±4.80	3.95±3.03	3.15±2.05
180-250mg/dl	20.36±7.81	14.54±4.17	14.91±4.07
140-180mg/dl	21.42±4.23	19.00±3.03	19.48±3.00
70-140mg/dl	46.35±10.94	54.20±6.85	54.88±5.26
54-70mg/dl	4.29±2.53	6.04±3.52	5.47±3.45
<54mg/dl	2.03±2.51	2.27±2.38	2.10±2.01

Avg SG-Average sensor glucose, TDI-Total Daily Insulin GMI-Glucose Management Indicator AvgSG and GMI decreased significantly between SAP and AHCL ($p<0.05$), while TDI remained unchanged. The sensor glucose profile shifted significantly towards the TIR (70–140 mg/dl) ($p<0.005$).

Results:

Conclusions: In preschool children, AHCL system effectively and safety improves glycemic control by increasing TIR (70-140 mg/dl) and decreasing the average glucose concentration compared to SAP.

EP013 / #326

Topic: ***AS01-Closed-loop System and Algorithm***

IMPROVED GLYCEMIC OUTCOMES AFTER 6 MONTHS OF USE IN REAL-WOLRD OF AN ADVANCED HYBRID CLOSED-LOOP SYSTEM IN ADOLESCENTS AND ADULTS WITH TYPE 1 DIABETES

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Background and Aims: The Advanced Hybrid Closed Loop (AHCL) MiniMed™ 780G is a new generation of artificial pancreas systems. The aim of the study was to evaluate real-world outcomes afther 6 months of using this AHCL system.

Methods: T1D patients using an insulin pump (MiniMed™ 640G) and flash glucose monitoring system (FreeStyle Libre 2) were upgraded to AHCL. Glycemic outcomes at baseline and after 6 months on AHCL were analyzed. A glucose target of 100 mg/dL and an active insulin time of 3 hours were set.

Results: 45 T1D patients were included (mean age 40.4 ± 13 years, 58.7% females, diabetes duration 28 ± 11 years, HbA1c 6.9% ± 0.8%, insulin pump use 6 ± 3 years and FGM use 2 ± 1.3 years. Time in range (TIR) 70–180 mg/dL increased from 63.2 ± 20.5% at baseline to 73.4 ± 15.5% at 6 months (p = 0.001). Time in hyperglycemia >180 mg/dL decreased from 23% (12-39) at baseline to 15% (9-29.5) at 6 months (p = 0.008). Time in hypoglycemia <70 mg/dL decreased from 4% (1-7) to 2% (1-3) (p = 0.001) at 6 months. Coefficient of variation was reduced from 36.1% ± 8 to 31.6 ± 3.6 (p < 0.001) at 6 months. GMI and mean sensor glucose were reduced from 7 ± 0.8% to 6.7 ± 0.5% and from 156.4 ± 36.8% to 141.8 ± 20.8% at 6 months respectively (p = 0.003). Time in Auto Mode was 98% (92-100). Auto-correction boluses represented 17% (13-31) of bolus insulin.

Conclusions: The AHCL MiniMed™ 780G system enables the achievement of recommended glycemic targets in adults with T1D after 6 months of use in a real-world clinical setting.

EP014 / #344

Topic: ***AS01-Closed-loop System and Algorithm***

REAL-WORLD USE OF CONTROL IQ HYBRID CLOSED-LOOP SYSTEM IN TYPE 1 DIABETES

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Background and Aims: The t:slim X2 insulin pump with Control-IQ technology is an advanced hybrid closed-loop system which has shown to improve glycemic control in type 1 diabetes. Pivotal trials showed an increase of 10% in time in range (TIR: 70-180 mg/dl) compared to sensor-augmented pump. The aim of our study was to analyze data of patients who changed from Basal-IQ to Control-IQ.

Methods: A retrospective analysis of Control-IQ users who uploaded data to Diasend application was performed. Users with type 1 diabetes who changed from Basal-IQ to Control-IQ with >2 weeks of CGM data pre-and 6 months post-Control-IQ technology initiation were included.

Results: 34 patients were included. The mean age was 46.4 ± 11.7 years and 71% were female. With Basal-IQ, mean TIR was 68.8 ± 9.8% and increased to 80.6 ± 7.0% with Control-IQ (p < 0.001), with a mean increase of 11.8%. TIR >70% was achieved in 38% of patients with Basal-IQ and in 88% of patients with Control-IQ. Time below range (TBR) was similar: <70 mg/dl: 2.3 ± 2.3% versus 2.2 ± 1.7%, and <54 mg/dl: 0.3 ± 0.7% versus 0.4 ± 0.6%. A significant improvement was observed in GMI (7.0 ± 0.3% versus 6.7 ± 0.3%, p < 0.001). The coefficient of variation changed from 35.3 ± 5.4% to 32.7 ± 4.8% (p = 0.001). Overall, good glycemic control (TIR >70%, <70 mg/dl <4% and <54 mg/dl <1%) was achieved in 32% of patients with Basal-IQ and in 65% with Control-IQ.

Conclusions: - Type 1 diabetes patients who upgraded from Basal-IQ to Control-IQ showed an 11.8% increase in TIR with no significant increase in TBR. - The majority of patients achieved the glycemic targets (65% vs 32%).

EP015 / #388

Topic: ***AS01-Closed-loop System and Algorithm***

SAFETY AND GLYCEMIC CONTROL IN CHINESE ADOLESCENTS AND ADULTS WITH TYPE 1 DIABETES (T1D) IN A MINIMED™ 770G SYSTEM CLINICAL TRIAL

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Background and Aims: While evidence supports glycemic control benefits for individuals with T1D using hybrid closed-loop (HCL) systems,[1-3] this automated insulin delivery therapy has not been evaluated in China. This study evaluated safety and effectiveness of in-home HCL use in Chinese adolescents and adults aged 14-75 years with T1D.

Methods: Participants (N = 62, baseline HbA1c of 7.1 ± 1.0%) underwent a baseline run-in (~2 weeks) of open-loop (pump +

Table. Glycemic outcomes of Chinese study participants with T1D using the MiniMed™ 770G system.

	Study Participants (N=62, Aged 33.4 ± 13.3 years)		
	Baseline	Study	P
SG, mg/dL	139.5 ± 20.8	140.5 ± 9.7	.143
SD of SG, mg/dL	48.0 ± 10.1	43.2 ± 7.8	<.001
CV of SG, %	34.3 ± 3.9	30.6 ± 4.2	<.001[a]
Percentage of time spent at sensor glucose ranges			
<50 mg/dL	0.5 ± 0.5	0.2 ± 0.3	<.001
<54 mg/dL	0.9 ± 0.8	0.4 ± 0.4	<.001
<70 mg/dL	4.7 ± 3.2	2.2 ± 1.5	<.001
70-180 mg/dL	75.3 ± 12.4	80.9 ± 7.5	<.001
>180 mg/dL	20.1 ± 13.4	16.9 ± 7.5	.289
>250 mg/dL	3.7 ± 5.0	2.4 ± 2.4	.103
>350 mg/dL	0.3 ± 0.8	0.1 ± 0.2	.175
TDD, units/kg	0.7 ± 0.2	0.7 ± 0.3 (N=60)	.007
Weight, kg	61.0 ± 10.5	61.0 ± 10.1 (N=60)	.887
BMI, kg/m²	22.1 ± 3.0	22.1 ± 2.9 (N=60)	.831

Data are shown as mean±SD.
Time in HCL during study period was 93.5%.
[a]Paired *t*-test.
SD=Standard deviation, SG=Sensor glucose, CV=Coefficient of variation, TDD=Total daily insulin dose, BMI= Body mass index.
[1]Garg et al. *Diabetes Technol Ther* 2017;19(3):155-163.
[2]McAuley et al. *Diabetes Care* 2020;43(12):3024-3033.
[3]Berget et al. *Diabetes Obes Metab* 2021;23(9):2048-2057.

continuous glucose monitoring [CGM]) insulin delivery with the MiniMed™ 770G system with the Guardian™ Sensor (3) glucose sensor followed by a study period (4 weeks, N = 60) with Auto Mode enabled. Analyses compared CGM data and insulin delivered during the run-in versus study period (Wilcoxon signed-rank test or t-test). Safety data were summarized.

Results: Glucose, glucose variability and other results are shown in the table. Time in range (70-180 mg/dL) increased from 75.3% to 80.9% and time at <70 mg/dL reduced from 4.7% to 2.2%, compared with baseline therapy. There were no serious adverse, severe hypoglycemic or diabetic ketoacidosis events and no unanticipated adverse device effects.

Conclusions: Chinese participants safely achieved significant improvement in glycemic outcomes after MiniMed™ 770G system use. Data suggest HCL therapy benefits for these study participants, similar to benefits observed in system users with T1D from regions outside of China.

EP016 / #395

Topic: ***AS01-Closed-loop System and Algorithm***

MINIMED 780G HYBRID CLOSED-LOOP SYSTEM RAPIDLY IMPROVES METABOLIC CONTROL IN TYPE 1 DIABETES INDIVIDUALS PREVIOUSLY TREATED WITH INSULIN PUMP

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Background and Aims: Hybrid-closed loop (HCL) systems have demonstrated improvement in glucose control in clinical trials. The aim was to evaluate the impact of the implementation of the Minimed 780G system in type 1 diabetes (T1D) individuals previously treated with insulin pump during routine clinical practice.

Methods: Prospective study that includes T1D individuals previously treated with insulin pump without continuous glucose monitoring (CGM) that started Minimed 780G system in June/21. Patient characteristics, retrospective CGM and pump data, blood test and Diabetes Quality of Life (DQOL) and Clarke's tests were collected baseline. CGM data were collected 1 and 3 months after therapy initiation, and all data were collected 6 months after initiation again.

Results: 26 T1D individuals (48.5 -40-57.3- years with 25 -14-35- years of diabetes duration) were included. Mean glucose, coefficient of variation, time in range and time below and above the range improved 1 month after initiation. Improvement in time below range became not statistically significant at 3 months (Table 1). No differences were observed in total insulin dose.

Conclusions: HCL therapy with Medtronic 780G System in T1D individuals improves glycemic control after 1 and 3 months of initiation. Results at 6 months and QOL parameters will be evaluated in December/21.

	Basal	1 month	3 months	P value basal - 1 month	P value basal – 3 months
Mean glucose (mg/dL)	161.5 (144.8-171)	145 (137.5-153.5)	144.5 (136.8-150.3)	0.002	0.001
Standard deviation (mg/dL)	53.1 (49.5-64.5)	49 (44-57)	48 (41.3-54.8)	0.024	<0.001
Coefficient of variation (%)	34.6 (31.3-38.3)	33.3 (30.6-38)	31.4 (29.6-37.5)	0.170	0.021
TIR 180-250mg/dL (%)	64 (53.8-733)	75 (70.8-82)	78.5 (72-81)	<0.001	0.001
Time >180 mg/dl (%)	26.6 (18-31.3)	18 (12.8-22.3)	17 (13.3-20.8)	0.002	0.025
Time >250mg/dL (%)	6.5 (3-10.3)	4 (1.8-5)	3.5 (13.3-20.8)	0.004	0.004
Time <70mg/dL (%)	2 (1-4.4)	1.5 (1-3)	1.5 (1-3)	0.040	0.306
Time <54mg/dL (%)	0 (0-1)	0 (0-0)	0 (0-0)	0.025	0.159
Total Insulin Dose (UI/day)	34.9 (27.4-47.9)	34.9 (27.4-47.9)	36.7 (27.5-49.8)	0.170	0.210
% basal insulin	46 (19.8-53)	46 (19.8-53)	41.5 (36.3-51.5)	0.330	0.190

EP017 / #409

Topic: ***AS01-Closed-loop System and Algorithm***

HYPOGLYCEMIA OCCURRENCE DURING THREE MONTHS OF ADVANCED CLOSED LOOP SYSTEM USE: A MONOCENTRIC CASE-CONTROL STUDY

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Background and Aims: Advanced Hybrid Closed-Loop (AHCL) have demonstrated benefits in glucose control and quality of life for people with type 1 diabetes. Aim of this case-control retrospective study is to compare glycemic outcomes and hypoglycemic risk emerged during 3 months use of AHCL and sensor augmented pump with Predictive Low-Glucose Suspend (PLGS).

Methods: The study included 56 patients from FBF-Sacco center in Milan, divided into two groups of 28 patients: group A (AHCL, Medtronic Minimed ™ 780G), group B (Medtronic Minimed ™ PLGS algorithm system). Data have been extrapolated from Medtronic Carelink ™ System platform and hypoglycemic events calculated with CSV file analysis. Each parameter refers to 90 days evaluation time.

Results: Baseline mean age (45.9 ± 13.2 vs 50.2 ± 18.8 years) and HbA1c (56.6 ± 7.9 vs 56.3 ± 11.0 mmol/mol) didn't differ between groups. Analysis of glucose metrics revealed the following differences (group A vs group B): GMI (6.7 ± 0.2 vs 7.1 ± 0.4%, $p < 0.0001$), TIR 70-180mg/dl (78.4 ± 6.7 vs 66.7 ± 10.5%, $p < 0.0001$), TAR >180mg/dl (19.1 ± 6.3 vs 31.1 ± 11.2%, $p < 0.0001$), number of weekly daytime hypoglycemia (time slot 06:00-0:00, 4.3 ± 2.0 vs 3.0 ± 2.3, p 0.028). No significant differences emerged in TBR (<70mg/dl 1.9 ± 0.9 vs 1.7 ± 1.8%, <54mg/dl 0.5 ± 0.6 vs 0.4 ± 1.0%) and in the number of weekly nighttime hypoglycemia (0:00-6:00). No severe hypoglycemia occurred in both groups. In the AHCL group an inverse correlation was found among overall hypoglycemic events and % automode use (r -0.44, p 0.017).

Conclusions: Our results confirm improvement of glycemic outcomes derived from AHCL use with low nighttime hypoglycemic risk. Daytime and likely post-prandial hypoglycemia remains a potential area of improvement for AHCL systems.

EP018 / #412

Topic: ***AS01-Closed-loop System and Algorithm***

GLYCEMIC OUTCOMES IN PEDIATRIC AND ADULT INDIVDUALS WITH TYPE 1 DIABETES (T1D) DURING MINIMED™ 780G SYSTEM USE WITH THE GUARDIAN™ 4 SENSOR

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Background and Aims: The MiniMed™ advanced hybrid closed-loop (AHCL) pivotal trial was conducted with an investigational system using the Guardian™ sensor 3 (GS3), which required a minimum of 2 calibrations/day. In this extension study phase, safety and effectiveness outcomes were evaluated following transition of participants to the MiniMed™ 780G system with the Guardian™ 4 sensor (G4S).

Methods: Pediatric and adult participants (N = 176, aged 7-75 years) from the AHCL trial transitioned to the Conformitè Europëenne-marked MiniMed™ 780G system with the G4S, which does not require calibration. Safety events and glycemic outcomes were collected over three months. Effectiveness endpoints included mean sensor glucose (SG), coefficient of variation (CV) of SG, and percentage of time in SG ranges. Safety endpoints were summarized.

Results: With the MiniMed™ 780G system, glycemic outcomes in both groups met or exceeded consensus guideline recommendations (Table). Overall TIR (70-180 mg/dL) was 72.8% (Pediatric: 70.7%, Adult: 76.3%) and overall TBR (<70mg/dL) was 1.9% (Pediatric: 2.2%, Adult: 1.6%). There was no DKA or severe hypoglycemia.

Table 1. Interim analysis outcomes during MiniMed 780G system use by individuals aged 7-75 years with type 1 diabetes

	Overall Group (N=176)	Aged 7-17 years (N=109)	Aged 18-75 years (N=67)
Time in closed loop, %	91.0 ± 7.5 (89.9, 92.1)	91.4 ± 6.2 (90.2, 92.5)	90.4 ± 9.2 (88.1, 92.6)
CGM use, days	12,899	8,194	4,704
SG, mg/dL	151.6 ± 13.6 (149.6, 153.7)	154.0 ± 13.4 (151.5, 156.5)	147.8 ± 13.1 (144.6, 151.0)
CV of SG, %	34.8 ± 4.8 (34.1, 35.5)	36.5 ± 4.4 (35.6, 37.3)	32.2 ± 4.2 (31.1, 33.2)
Percentage of time spent at sensor glucose ranges			
<54 mg/dL	0.4 ± 0.4 (0.3, 0.4)	0.4 ± 0.4 (0.3, 0.5)	0.3 ± 0.3 (0.2, 0.3)
<70 mg/dL	1.9 ± 1.4 (1.7, 2.2)	2.2 ± 1.4 (1.9, 2.5)	1.6 ± 1.1 (1.3, 1.9)
70-140 mg/dL	48.6 ± 9.0 (47.3, 49.9)	47.5 ± 8.2 (45.9, 49.0)	50.4 ± 10.0 (48.0, 52.9)
70-180 mg/dL	72.8 ± 8.8 (71.5, 74.2)	70.7 ± 8.1 (69.2, 72.2)	76.3 ± 9.0 (74.2, 78.5)
>140 mg/dL	49.5 ± 9.5 (48.0, 50.9)	50.3 ± 8.6 (48.7, 52.0)	48.0 ± 10.5 (45.4, 50.6)
>180 mg/dL	25.2 ± 9.0 (23.9, 26.5)	27.1 ± 8.3 (25.5, 28.7)	22.1 ± 9.3 (19.8, 24.3)
>250 mg/dL	6.1 ± 4.5 (5.4, 6.8)	7.3 ± 4.7 (6.4, 8.1)	4.3 ± 3.6 (3.4, 5.2)

Data are shown as mean ± SD (95% CI)
CGM=Continuous glucose monitoring, SG=Sensor glucose, CV=Coefficient of variation

Conclusions: This interim analysis demonstrates that participants with T1D, regardless of age, safely achieved glycemic targets using the MiniMed™ 780G system with the G4S, similar to that observed in the pivotal trial of the AHCL system with GS3.

EP019 / #435

Topic: ***AS01-Closed-loop System and Algorithm***

SELF-REPORTED SLEEP OUTCOMES REVEAL POTENTIAL INFLUENCE OF AUTOMATED INSULIN DELIVERY SYSTEMS ON SLEEP DISTURBANCE AMONG U.S. ADULTS WITH DIABETES

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Background and Aims: Sleep disturbances are common in people with diabetes (PWD) and can result from blood glucose level fluctuations and their associated symptoms. Advancements in insulin delivery automation can reduce the need for manual input to manage blood glucose at night. The present study aims to understand the association between the type of insulin delivery system and PWD's self-reported sleep quality.

Methods: Adults living with diabetes in the United States completed an online survey in June 2021 and responded to the 8-item PROMIS Sleep Disturbance Short Form. Respondents also indicated their diabetes technology use. Complete PROMIS responses for PWD on intensive insulin therapy (n = 1,945, 84% type 1, 68% female) were subsequently scored and interpreted.

Results: PWD on multiple daily injections (MDI) and a continuous glucose monitor (CGM) (n = 488) were more likely to report mild (21%) or moderate (2%) sleep disturbance and less likely to have none to slight sleep disturbance (78%), compared to those on an automated insulin delivery (AID) system consisting of an integrated insulin pump and CGM (n = 974). Non-integrated pump and CGM users (n = 483) were also more likely than AID users to have mild sleep disturbance (19%). MDI and CGM users were more likely than AID users to report restless sleep (31%), trouble staying asleep (32%), and poor sleep quality (24%), but there were no differences in difficulty falling asleep or whether respondents got enough sleep.

Conclusions: Greater automation of insulin delivery may be associated with lower levels of self-reported sleep disturbance and improved sleep quality for PWD on intensive insulin.

EP020 / #446

Topic: ***AS01-Closed-loop System and Algorithm***

ASSESSING THE USE OF THE COMPOSITE METRIC OF MEAN GLUCOSE AND GLUCOSE VARIABILITY AS AN ALTERNATIVE TO HBA1C FOR DETERMINING OVERALL GLYCEMIC CONTROL

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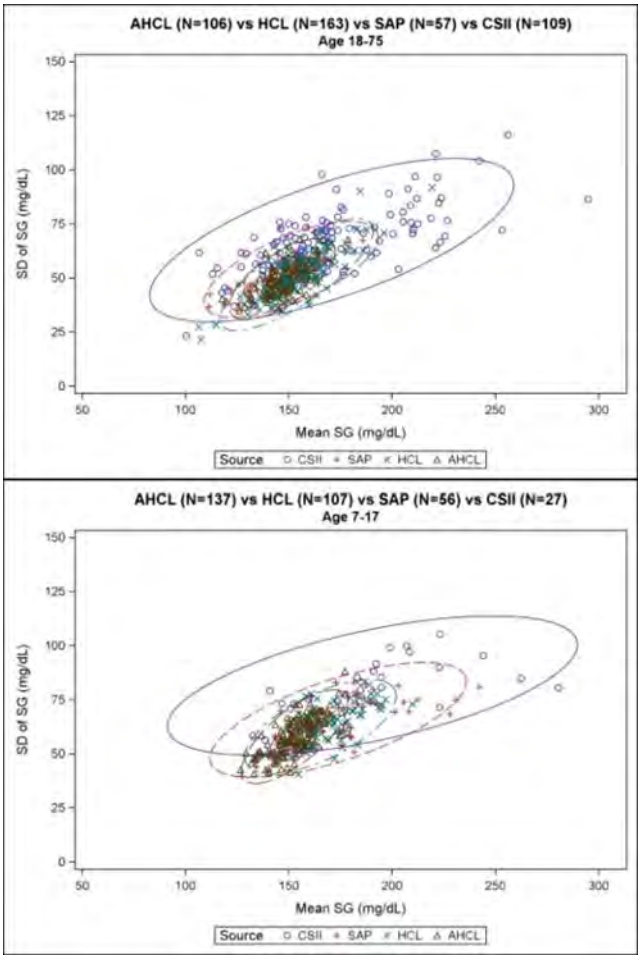
Background and Aims: Glycemic variability (GV) may be an independent risk factor for short- and long-term diabetes complications, which may not be captured by an HbA1C. By comparing progressively more sophisticated insulin delivery systems, we assessed if the composite of mean glucose and standard deviation (SD) could be used as an alternative to HbA1C for determination of overall glycemic control.

Methods: Sensor glucose (SG) and SD of SG from devices used in two Medtronic studies were analyzed: continuous subcutaneous insulin infusion (CSII): N = 136; sensor-augmented pump (SAP): N = 113; hybrid closed loop (HCL): N = 270; advanced hybrid closed loop (AHCL): N = 243. Prediction ellipses of subject-level data were prepared for pediatric and adult subjects for each therapy.

Results: Prediction ellipses became tighter and migrated toward better mean SG and SD of SG as the AID system improved (Figure). For example, in the transition from CSII (n = 27) to AHCL (n = 137), mean SG (SD of SG) for pediatric patients decreased from 190.5 ± 36.7 (81.6 ± 11.9) mg/dL to 153.0 ± 10.4 (57.9 ± 8.7) mg/dL, respectively.

Conclusions: The combination of sensor-derived mean SG and SD of SG may be a better alternative to HbA1C in demonstrating overall glycemic control by introducing GV as an analytic variable.



EP021 / #463

Topic: ***AS01-Closed-loop System and Algorithm***

TIME IN RANGE AFTER 1 YEAR USING TELEHEALTH IN TYPE 1 DIABETES TREATED WITH HYBRID CLOSE LOOP THERAPY DURING THE COVID-19 PANDEMIC.

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Background and Aims: Literature supports efficacy and safety of Hybrid Close loop (HCL) system in type 1 diabetes (T1D) patients. Limited data are available showing the short and long-term outcomes of telehealth. Our study described efficacy and safety of HCL system at one year of follow-up through telehealth during COVID-19 pandemic.

Methods: A prospective observational cohort study including T1D patients previously treated with multiple doses of insulin or sensor augmented pump therapy started on HCL system during COVID-19 pandemic. Virtual training and follow-up were done through telehealth. CGM data were analyzed to compare the time in range (TIR), time below range (TBR) and glycemic variability, GMI at base line, 3,6,9 and 12 months of virtual follow-up. Use of automatic mode (AM) was also evaluated.

Results: 134 patients were included (54.9% female, baseline A1c 7.66% ± 1.15). 48.8% hypoglycemia was the main indication of HCL therapy. 32.6% had hypoglycemia unawareness and 40.5% had ≥1 severe hypoglycemia event in the last year. TIR at the end of the virtual training was 78 ± 0.14%. After 3,6,9 and 12 months of follow-up TIR was 78.5%, 77.6%, 76.8% and 77%, respectively. Coefficient of variation was 31.4 ± 6.05% at 12 months. TBR <70mg/dl and <54mg/dl was 2.39 ± 0.14% and 0.54 ± 0.07%, respectively. Use of AM was 80.7 ± 24.7% and percentage of use of sensor was 90.3 ± 7.3%. No severe adverse events were reported.

Conclusions: HCL systems allows T1D patients to improve TIR, TBR and glycemic variability independently of previous treatment. Long term follow-up through virtual modality allows to maintain TIR with low TBR and adherence to AM of 80%.

EP022 / #508

Topic: ***AS01-Closed-loop System and Algorithm***

IMPACT OF DBLG1 SYSTEM ON T1D PATIENTS WHO SPEND MORE THAN 5% OF TIME IN HYPOGLYCEMIA IN OPEN LOOP

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Background and Aims: This study evaluate the impact of the use of Diabeloop's DBLG1 System on the Time In Hypoglycemia <70 mg/dL (TIH) for T1D patients who spend more than 5% of TIH in Open Loop (OL) (threshold proposed by CGM international recommendation). This retrospective cohort study is based on clinical trials NCT02987556 [1] arm 2 (SP7), NCT04190277 arm 1 (SP8) and NCT03671915 (SP9).

Methods: For each study, we select the patients with a glycemia <70 mg/dL more than 5% of the time during the OL phase. It represents 9 patients among 30 for SP7, 28 patients among 145 for SP8 (7 are 14- to 17-year-old), and 8 children among 21 for SP9 (6- to 12-year-old). For each study, we compare the average TIH during the OL and Closed Loop (CL) phases.

Results: During the CL phases, the TIH is reduced for all the patients. For SP7, the average TIH goes from 8.30% to 3.31% (reduction of 4.99 ± 2.40 points). For SP8, it goes from 7.90% to 3.08% (reduction of 4.82 ± 2.00 points, 5.22 ± 1.64 for the teenagers). And for SP9, it goes from 7.43% to 3.46% (reduction of 3.97 ± 1.57 points). The global reduction is of 4.70 ± 2.00 points with an average TIH of 7.90 ± 2.39% in OL versus 3.20 ± 1.63% in CL.

Conclusions: To conclude, the use of DBLG1 System for T1D patients who spent more than 5% of TIH decreases the TIH of 59.53% on average.

EP023 / #510

Topic: ***AS01-Closed-loop System and Algorithm***

RESULTS OF DBLG1 SYSTEM LAUNCH IN GERMANY BETWEEN APRIL AND SEPTEMBER 2021

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Background and Aims: This study aims to assess the performance of DBLG1 -Closed Loop- System on new patients equipped with DBLG1 System in Germany. 998 patients gave their consentment to join this study. These patients are equipped with an Accu-Chek Insight insulin pump (Roche).

Methods: The glycemic data of the patients are analyzed between April and September 2021, in order to compute the Time In Range 70-180 mg/dL (TIR), the time in hypoglycemia <70 mg/dL and <54 mg/dL.

Results: An average of 61.04 (±39.79) days and a median of 56.00 days [26.25 - 92.00] per patient are obtained from these data. The averaged TIR is 71.98% (± 11,47), the average time in hypoglycemia <70 mg/dL is 1.46% (± 1.42) and <54 mg/dL is 0.30% (± 0.44). The medians for each statistic are respectively 73.42% [65.30 - 80.11], 1.05% [0.51 - 1.90] and 0.16% [0.05 - 0.36]. These results are consistent with previous clinical trials NCT02987556 [1] (SP7) and NCT04190277 (SP8) on patients using DBLG1 System, using Cellnovo and Kaleido pumps (SP7 arms 1 & 2) and DANA Diabecare-i pump (SP8), that confirm the interoperability of DBLG1 system.

Conclusions: To conclude, the launch of DBLG1 System in Germany shows encouraging results, in compliance with the recommendations for the time in range and the time in hypoglycemia, on a significant number of patients and for a duration up to 5 months.

EP024 / #518

Topic: ***AS01-Closed-loop System and Algorithm***

VALIDATION OF THE FRENCH VERSION OF THE AUTOQUESTIONNAIRE ADULTCARBQUIZ IN A POPULATION OF 130 INDIVIDUALS LIVING WITH TYPE 1 DIABETES

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Background and Aims: Despite technological progresses in the treatment of type 1 diabetes (T1D), the management of post prandial glycemic period remains difficult. Especially closed-loop systems require patients' knowledge about carbohydrates and their counting. The aim of our study was to validate the autoquestionnaire AdultCarbQuiz translated in French and readapted for French food habits.

Methods: This is an observational, prospective, multicenter study (3 centers). The autoquestionnaires were filled by individuals living with T1D using continuous glucose monitoring. We have correlated the results of questionnaires with their 14-days ambulatory glucose profile (primary outcome: time in range (TIR)).

Results: We included 130 persons (men 44%; age 41 ± 15 years; diabetes duration 14 ± 5,1 years; A1C 7,3 ± 1,2%) treated with insulin multiple daily injections (n = 12), insulin pump (n = 73), insulin pump with hypo minimizer (n = 14) or closed loop system (n = 31). Their TIR were respectively 56 ± 17, 56 ± 19, 48 ± 20 et 72 ± 10% ($p < 0{,}0001$). Their total AdultCarbQuiz score (maximum 43) were 28 ± 6, 31 ± 5, 29 ± 6 et 32 ± 5 ($p > 0.05$). This score was positively correlated with the TIR ($r = 0.1747$; $p = 0.0468$). The mean absolute error of the ability to count the carbohydrate in a meal was negatively correlated with the TIR ($r = -0.3468$; $p = 0.004$). This mean absolute error by TIR quartiles (Q1 34.3 ± 11.2; Q2 53.5 ± 4.25; Q3 65.8 ± 3.52; Q4 81.7 ± 7.43%) was 17.8 ± 10.0; 19.7 ± 11.2; 13.4 ± 10.0 et 11.2 ± 9.24 g of carbs respectively ($p = 0.0040$).

Conclusions: This study validates the French version of AdultCarbQuiz with the positive correlation to the TIR. Carbohydrate counting errors are associated to lower TIR. This autoquestionnaire could be proposed for the evaluation of carb counting knowledge and competences in patients living with T1D.

EP025 / #531

Topic: ***AS01-Closed-loop System and Algorithm***

THE DEEP LEARNING MODULE TO REPLACE THE PHYSIOLOGICAL ALGORITHM MODULE IN DBLG1 SYSTEM IMPROVES GLYCEMIC CONTROL IN SIMULATION

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Background and Aims: In order to improve glycemic control for T1D patients using Diabeloop's DBLG1 system, we present a deep learning (DL)-based controller that uses real time patient's predicted glycemia.

Methods: The model is trained using the glycemic data of patients from two clinical trials NCT02987556[1] and NCT04190277. Patients from both trials are randomly assigned to train or test sets. The model is then hyperoptimized using a k-fold on the train set. The DL model is then used in combination with a control algorithm in DBLG1 System, in replacement of the physiological-based control module. To analyze the performance of the new algorithm, 121 virtual patients are simulated over 10 days using both modules. The Time In Range 70-180 mg/dL (TIR), time in hyperglycemia >180 mg/dL, time in hypoglycemia <70 mg/dL and <54 mg/dL and mean glycemia.

Results: Improved indicators are (see Table 1): (i) the TIR goes from 69.00% up to 73.96%, (ii) both times in hyperglycemia and hypoglycemia decrease, from 27.67% to 23.15% for hyperglycemia, from 3.33% to 2.89% for hypoglycemia <70 mg/dL and from 1.51% to 1.34 for hypoglycemia <54 mg/dL and (iii) the average glycemia decreases from 159.04 mg/dL to 152.22 md/dL.

Conclusions: The use of the DL model in DBLG1 System improves the statistics of the virtual patients during simulations.

[1] Benhamou PY, et al. Closed-loop insulin delivery in adults with type 1 diabetes in real-life conditions: a 12-week multicentre, open-label randomised controlled crossover trial. Lancet Digit Health. 2019 May;1(1):e17-e25. doi: 10.1016/S2589-7500(19)30003-2.

Table 1. Comparison of Physiological Algorithm Module vs Deep Learning Module

KPI	Physiological Algorithm Module	Deep Learning Module
Time in range 70-180 mg/dL	69.00 (±0.83)	73.96 (±0.76)
Time in hyperglycemia > 180 mg/dL	27.67 (±0.82)	23.15 (±0.75)
Time in hypoglycemia < 70 mg/dL	3.33 (±0.24)	2.89 (±0.22)
Time in hypoglycemia < 54 mg/dL	1.51 (±0.14)	1.34 (±0.13)
Mean glycemia	159.04 (±1.15)	152.22 (±1.16)

EP026 / #534

Topic: ***AS01-Closed-loop System and Algorithm***

ANALYSIS OF DBL-HU SYSTEM CLOSED-LOOP DATA DURING PREGNANCY IN A PATIENT WITH TYPE 1 DIABETES

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Background and Aims: Introduction: Closed-loop data during pregnancy in patients with type 1 diabetes (T1D) are very few. The objective of this study is to report metabolic data in a patient with a closed-loop system from the preconception period to the end of breastfeeding.

Methods: 29-year-old patient, T1D since age of 3 with microangiopathic complications and highly unstable diabetes, indication of islet transplant discussed not retained; start of Diabeloop DBL-hu closed-loop system one year before pregnancy. Analysis of time in target (63-140 mg/dL, TIR), time in hyperglycemia, time in hypoglycemia data as recommended for 5 periods: 5 weeks before pregnancy, from early pregnancy to 12 WA, from 13 to 24 WA, 25 to 32 WA, 33 to 38 WA, and during breastfeeding.

Results: TIR improved reaching 80.3% during the period from 33 to 38 WA, starting at 25.96% in preconception, increasing to 28.84%, 49.02%, 57.24%, 80.33% for the 4 next periods. The estimated HbA1c (GMI) also improved reaching a minimum value of 5.54% between 33 and 38 WA. Time in hypoglycemia was kept below 0.28% during pregnancy, <0.14 during all periods except 13-24 WA. Glycemic variability improved from 26.48 ± 4.03 to 19.71 ± 3.08 in late pregnancy. The patient gave birth at 38 WA +1 day of a baby with a birth weight of 4070 g.

Conclusions: Conclusion: These data show that the closed-loop treatment was accompanied by a clear optimization of metabolic indicators, in a context of unstable diabetes. Despite this optimization, macrosomia is observed, related to the delay in metabolic optimization in early pregnancy.

EP027 / #544

Topic: ***AS01-Closed-loop System and Algorithm***

SYSTEM MINIMED 780G PROVIDES SATISFACTORY GLUCOSE CONTROL IN ADOLESCENTS WITH TYPE 1 DIABETES DURING FOOTBALL SPORTS CAMP

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Background and Aims: Exercise is a significant challenge for people with type 1 diabetes. The aim of this study was to test whether System MiniMed 780G including an automatic insulin delivery together with using temporary target is effective at obtaining satisfactory glucose control and protecting against hypoglycemia during moderate and intensive exercise.

Methods: An observational study on 10 adolescents with type 1 diabetes treated with System MiniMed 780G was performed during football sports camp. Patients were monitored for physical activity using triaxial accelerometer (Actigraph WGT3X-BT) before and during camp. During everyday two camp trainings, additional heart rate monitoring was collected (Polar H10). CGM metrics were computed using GlyCulator 3.0 software, and physical activity metrics (% time in moderate-to-vigorous physical activity - %MVPA) - using ActiLife 6.0 software.

Results: Mean age was 14.8 years, (95%CI: 13.9–16.1), diabetes duration 8.8 years (6.2–11.5). %MVPA increased during camp compared to the preceding week (available data from 6 patients) ($p = 0.0425$). During the camp time in range (TIR) was 80.1 ± 8.2%, TBR <70 = 5.9 ± 3.5%, TBR <54 = 1.5 ± 1.4, TAR >180 = 13.5 ± 7.4, TAR >250 = 3.1 ± 2.2. No significant or clinically relevant differences in glycemic control were observed for before and during summer camp. Physical activity did not correlate with CGM metrics (Spearman's correlation p-value

>0.05). Change in physical activity (%MVPA) before and during summer camp did not correlate with change in CGM metrics (Spearman's correlation p-value >0.05).

Conclusions: System MiniMed 780G provided satisfactory glucose control during moderate and intensive exercise in adolescents with type 1 diabetes at sports camp.

EP028 / #547

Topic: ***AS01-Closed-loop System and Algorithm***

DIABELOOP GENERATION 1 (DBLG1) HYBRID CLOSED-LOOP ARTIFICIAL PANCREAS SYSTEM IN PATIENTS IN SUBOPTIMALLY CONTROLLED TYPE 1 DIABETIC PATIENT WITH GASTROPARESIS: A CASE REPORT

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Background and Aims: Gastroparesis is an important complication of diabetes that may have a major impact on the quality of life as a result of upper gastrointestinal symptoms and impaired glycaemic control. Hybrid closed-loop (HCL) systems improve glucose control and quality-of-life but evidence for their use in people with diabetic gastroparesis is limited.

Methods: We present a case report of a patient with poorly controlled type 1 diabetes and gastroparesis. We compare glycemic control before and during therapy with Diabeloop Generation-1 (DBLG1) closed-loop system, a medical device that connects 3 components: a Dexcom G6 Continuous Glucose Monitoring (CGM), an insulin pump and a locked-down handset hosting Diabeloop algorithm. Data were analyzed using electronic patient records and diabetes management platforms (Clarity - YourLoops).

Results: Before HCL therapy, the patient was using CSII therapy (Accu-chek Insight) and Dexcom G6 CGM. Despite optimised prokinetic therapy, she reported gastroparesis-related symptoms and a greater tendency toward hyperglycemia caused by insulin underdosage in fear of post-prandial hypoglycemia. After starting therapy with DBLG1 system, she had an improvement in percentage time in target glucose range (TIR), increasing from 38,4% (% time CGM is active: 93%) to 66% during HCL use (%f time CGM is active:96%); significant reductions in HbA1c (74 mmol/mol to 55 mmol/mol) and mean glucose (203 ± 86 mg/dL to 171 ± 61 mg/dL). Time Below Range (TBR) decreased from <4% to <3% and Glycemic variability (%CV) from 42,3% to 27%.

Conclusions: Hybrid closed-loop systems may represent a valuable approach to improve glycemic control for people with type 1 diabetes and gastroparesis.

EP029 / #566

Topic: ***AS01-Closed-loop System and Algorithm***

UNSUPERVISED ANOMALY DETECTION ALGORITHMS TO IDENTIFY MISSED MEAL ANNOUNCEMENTS IN HYBRID CLOSED LOOP ARTIFICIAL PANCREAS SYSTEMS

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Background and Aims: A hybrid artificial Pancreas (AP) is a closed-loop system for type 1 diabetes treatment that requires information about the upcoming meals. Missed meal announcements, and the consequent missed injection of insulin boluses, might affect the hybrid AP safety and effectiveness. This work proposes a novel approach to detect unannounced meals using unsupervised anomaly detection algorithms.

Methods: The procedure is tested in 30 days of simulated data for 100 virtual subjects using the UVA/Padova T1D simulator, with 12.5% missed meal announcements. Insulin dosing is computed by a hybrid artificial pancreas using a model predictive controller based on averaged linearized physiological model and quadratic cost function. From these data, we extracted several features capable to describe the patient dynamics, highlighting anomalous status due to failures. Then, we apply the anomaly detection algorithm, that returns an anomaly score for each sample, indicating how much it differs from previous data. An alert is issued when the anomaly score exceeds a threshold, set using the FP/day-Recall Curve. Different anomaly detection algorithms are compared.

Results: The best performance is achieved with Histogram-based Outlier Score (HBOS) and Isolation Forest (IF): missed meal announcements are detected with a sensitivity of 80% and 78%, while the methods produce 0.11 and 0.17 false positives per day, respectively.

Conclusions: Unsupervised anomaly detection algorithms are promising for detection of unannounced meals and to improve the safety of the AP.

EP030 / #581

Topic: ***AS01-Closed-loop System and Algorithm***

BMI CHANGES AND CARBOHYDRATE INTAKE IN TRAINED T1D PATIENTS SWITCHING TO AHCL MINIMED 780G MEDTRONIC

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Background and Aims: Advanced Hybrid Closed Loop (AHCL) systems are the newest tool to improve metabolic control in type 1 diabetes (T1D) patients, requiring announced meals with carbohydrate (CHO) counting. We examined T1D patients trained by the multidisciplinary diabetes team switched to Medtronic MiniMed® 780G AHCL in order to evaluate if the metabolic control improvement was associated with changes in body mass index (BMI), daily insulin requirement and CHO intake.

Methods: BMI, daily insulin requirement and CHO intake were evaluated together with HbA1c and time in range (TIR) at baseline, 3 months and 6 months after switching to AHCL in 35 T1D patients (18 M, age 15.6 ± 7.6y, T1D duration 9.3 ± 6.1y, HbA1c 7.2 ± 0.7%, 9 multiple daily injections, 26 pump). T test for paired samples was used to compare means with SPSS Statistics.

Results: at AHCL start BMI was 19.5 ± 3.2, BMI z-score was 0.07 ± 0.9, insulin dose UI/kg/day was 0.7 ± 0.2, mean daily CHO intake was 206.2 ± 99.2 grams. TIR improved 3 and 6 months

after AHCL (68.5 ± 11% at baseline vs 78.3 ± 7.8% and 76.5 ± 8.9%, p < 0.0001), as well as HbA1c (7.2 ± 0.7% vs 6.7 ± 0.5%, p < 0.0001), without significant difference in BMI z-score, units/kg/day and daily CHO consumption.

Conclusions: switching to this AHCL allowed patients to achieve optimal metabolic control at 3 and 6 months, without BMI increase and changes in daily insulin requirement and CHO intake. These findings underline the importance of appropriate nutritional education to avoid weight gain due to ''I count-I inject-I eat''.

EP031 / #591

Topic: ***AS01-Closed-loop System and Algorithm***

MINIMAL CHANGE IN DIETARY INTAKE AND PHYSICAL ACTIVITY WITH 670G INITIATION

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Background and Aims: Initiation of a hybrid closed loop (HCL) system may allow for increased flexibility in one's diet, lessening of dietary restraint with increased caloric and/or carbohydrate intake, or changes in physical activity. We assessed changes in diet and physical activity pre- and post-initiation of the MiniMed 670G HCL insulin delivery system.

Methods: In this sub-study, thirty-six participants with T1D initially randomized to the control condition (current diabetes therapy- Continuous Subcutaneous Insulin Infusion, Multiple Daily Injections, or Sensor Augmented Pump) were placed on HCL for six months during a ''continuation period''. Interviewers assessed dietary intake via four 24-hr dietary recalls, two immediately prior to HCL initiation and two during the last month of the continuation period. Moderate-to-vigorous physical activity was assessed by the Previous Day Physical Activity Recalls.

Results: A total of 34 adults completed diet recalls and 15 adults completed physical activity recalls (age = 48 ± 14.60 years, 66% female, and 97% white). This pilot study found no statistically significant changes in diet and physical activity during six months of HCL use (Table 1).

Conclusions: Our pilot findings suggest that changes in behaviors related to weight management are not inevitable with use of an HCL. Given that the 670G system was a first generation HCL system and prior studies found increased BMI with initiation of HCL, further studies with larger sample sizes in newer HCL systems are needed to clarify potential changes in diet and physical activity that may accompany HCL use.

Table 1
Changes in Outcomes over the 6-Month Continuation Period

		Pre-continuation period		End of continuation period	Mean difference over 6-month continuation period	
Outcomes	*n*	Mean (± SE)	*n*	Mean (± SE)	Mean (± SE)	*p*
BMI (kg/m^2)	34	30.21 (1.05)	34	30.22 (1.03)	0.0062 (0.17)	.97
HbA1c (%)	34	7.32 (0.12)	34	7.42 (.096)	0.097 (0.061)	.12
Energy intake (kcal)	34	1851.16 (90.37)	34	1888.68 (97.67)	37.51(92.99)	.69
Fat (g)	34	85.11 (4.66)	34	87.86 (5.12)	2.75 (6.12)	.66
Carbohydrate (g)	34	187.58 (12.86)	34	186.41 (11.18)	-1.17 (10.24)	.91
Protein (g)	34	82.12 (6.59)	34	82.28 (6.75)	0.16 (4.74)	.97
Moderate Activity (min)	15	244.0 (53.27)	15	164 (34.14)	-80.0 (58.30)	.19
Vigorous Activity (min)	15	12.0 (10.09)	15	18.0 (8.29)	6.0 (10.65)	.58

Data presented as mean ± SE
Paired t-tests were used. Significance set at $p<0.05$

EP032 / #607

Topic: ***AS01-Closed-loop System and Algorithm***

THE DANISH LOOP-DIY STUDY: THE EFFECT OF LOOP-DIY IN DANISH CHILDREN WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Treatment of Type 1 Diabetes Mellitus (T1DM) has become increasingly technical, with insulin pumps and continuous blood glucose sensors replacing daily insulin injections and capillary blood glucose measurements. Furthermore, integration of pumps and sensors to regulate insulin dosage is a rapidly developing field, and patient initiated open-source solutions (Do-It-Yourself automated insulin delivery systems, LOOP-DIY) has become increasingly popular amongst people with diabetes. LOOP-DIY integrates sensor values with insulin delivery through specified algorithms. Studies have shown increased glycemic control and mental wellbeing among people using LOOP-DIY. We are conducting a cross-sectional retrospective study which will be the first to assess the effect, safety and use of LOOP-DIY in Danish children aged 2-18 with T1DM. The aim of the study is to estimate 1) prevalence of the use of LOOP-DIY among children with diabetes in Denmark, 2) effect of LOOP-DIY on daily glycemic control (HbA1c, Time in Range etc.), 3) risk of LOOP-DIY evaluated by frequency of ketoacidosis and severe hypoglycemia, 4) effect of LOOP-DIY on everyday life in children and parents, including mental wellbeing, sleep, self-efficacy, and fear of hypoglycemia (FOH).

Methods: The participants will be included through pediatric diabetes outpatient clinics throughout Denmark. Current and retrospective data on daily glycemic control will be collected from patient records. Mental wellbeing, sleep, self-efficacy and FOH will be measured through questionnaires to patients and their parents and compared to a matched control group.

Results: Expected ready for ATTD Conference

Conclusions: This study is specifically relevant regarding the rapid development within diabetes technology

EP033 / #637

Topic: ***AS01-Closed-loop System and Algorithm***

EVALUATION OF THE NEW CONTROL IQ TECHNOLOGY SYSTEM IN 36 TYPE 1 DIABETES PATIENTS USING SENSOR AUGMENTED LOW GLUCOSE SUSPEND PUMP

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Background and Aims: Our aim was to evaluate clinical effects and safety of the new Control Iq Closed Loop Technology.

Methods: 36 T1D patients using LGS (Low glucose suspend) system changed to CLC (closed loop control) system (control IQ, Novalab). Basal age was 48.31+-11.01years (31-74), 33 % of them female. Mean BMI was 27.65 +-5.28, time of diabetes

30. 44 +-13.61 years , being treated with insulin pump for 8.88 +-5.92 years. Mean HbA1c was 6.89% +-1.01 (5-10.4 %) A complete educative program was followed by the patients and after 3 months using the CLC system metabolic data were analysed.

Results: Mean glucose was lower after using the CLC system compared to LPLG system(143.09+-15.5mg/dl vs 151 +-26.32 vs ; p = 0.004) and so were variability markers (cv = 32.51 +-13.4 vs 34.17+-5.15 p = 0.003)(sd: 45.57+-11.76 vs 52.21 +-13.4 p = 0.0001). HbAc also lowered with CLC system (6.78 +-0.65 vs 6.89 +-1.01% p = 0.003) Regarding CGM metrics TIR (70-180mg/dl) was improved(78.06 +-9.97 vs 70.02 +-13.73 % p: 0.001) ,TAR(180-250mg/dl) was lowered (15.48 +-6.58 vs 19.32 +-8.45% p: 0.001)and TAR (>250 mg/dl)was reduced(4.12 +-4.70 vs 7.03 +-9.11 p: 0.01). No differences were found in TBR (<70 mg/dl or <54 mg/dl) . No adverse events were reported.

Conclusions: Following the use of LGS system, switching to a CLC System (Control IQ Novalab) during 3 months, reduced TAR, improved TIR and lowered HbA1c, while hypoglicemia remained similarly reduced with both systems. General satisfaction with the technology wass high.

EP034 / #685

Topic: ***AS01-Closed-loop System and Algorithm***

EMOTIONAL AND PHYSICAL HEALTH IMPACT IN CHILDREN AND ADOLESCENTS AND THEIR CAREGIVERS USING OPEN-SOURCE AUTOMATED INSULIN DELIVERY: QUALITATIVE ANALYSIS OF LIVED EXPERIENCES.

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Background and Aims: Given the limitations in access and license status of commercially developed automated insulin delivery (AID) systems, open-source AID systems are becoming increasingly popular amongst people with diabetes, including children and adolescents. This study focused on lived experiences, physical and emotional health implications of children and their caregivers following the initiation of open-source AID, their perceived challenges, and sources of support, which have not been explored by the existing literature.

Methods: Data were collected through two sets of open-ended questions of a web-based multinational study survey from 60 families from 16 countries. The narratives were thematically analysed and a coding framework was identified through an iterative alignment.

Results: A range of emotions, improvements of quality of life and physical health were reported as open-source AID enabled the families to shift their focus away from diabetes therapy. Caregivers were less worried about hypoglycemia at night-time and outside of their family home, leading to increased autonomy for the child. Simultaneously, glycemic outcomes and sleep quality of both child and caregiver improved. Nonetheless, the acquisition of suitable hardware and technical set-up could be challenging. The #WeAreNotWaiting community was the primary source of practical but also emotional support.

Conclusions: Our findings show the benefits and transformative impact open-source AID and peer-support have on children with diabetes, their caregivers, and families, where commercial AID systems are not available or suitable. Further efforts are required to improve effectiveness, usability, and facilitate access for children with diabetes worldwide to benefit from this innovative treatment.

EP035 / #733

Topic: ***AS01-Closed-loop System and Algorithm***

DURABLE HIGH GLUCOMETRIC PERFORMANCE OF THE MINIMED 780G ADVANCED HYBRID CLOSED LOOP SYSTEM IN REAL WORLD EVALUATION IN A VALUE BASED DIABETES CENTER (DIABETER NETHERLANDS)

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Background and Aims: We evaluated sustainability of MiniMed™ 780G system outcomes in people with T1DM treated in Diabeter, a value-based diabetes clinic, in real-world conditions.

Methods: Retrospective analysis including patients with T1DM who initiated the MiniMed™ 780G system between SEP-2020 and NOV-2021 (N = 359). All patients received structured education before start and multiple (eHealth)HCP contacts during use. We present 6-months follow-up data (means), with at least 10 days of SG data in each month.

	1st Month	2nd Month	3rd Month	4th Month	5th Month	6th Month
Users, *n*	111	111	111	111	111	111
Time in AHCL, %	92.8	95.7	95.0	94.8	93.0	95.2
Mean SG, *mmol/L*	7.9	7.9	8.0	8.0	8.0	8.0
GMI, %	6.7	6.7	6.8	6.8	6.8	6.8
Users with GMI<7%, %	89.2	84.7	81.1	81.1	78.4	75.7
Users with TIR>70%, %	82.0	82.0	76.6	77.5	77.5	76.6
Users with TBR<3.9mmol/L<4%, %	81.1	83.8	85.6	86.5	90.1	87.4
Time in ranges, %	4.1 / 16.5 / 76.8 / 2.1 / 0.5	4.4 / 16.5 / 76.8 / 1.9 / 0.5	4.7 / 16.8 / 76.2 / 1.9 / 0.5	4.7 / 16.4 / 76.4 / 1.9 / 0.5	5.2 / 17.1 / 75.4 / 1.8 / 0.5	5.2 / 17.2 / 75.4 / 1.8 / 0.5

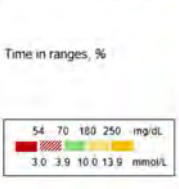

Figure: Longitudinal analysis of AHCL results. Optimal TIR (77.2-80.1%) with a low TBR (2.0-2.5%) results were obtained using a glucose target of 100 mg/dL and 2 hours AIT. Adherence parameters showed change of infusion set every 2.7-2.8 day, and 6.0-6.2 boluses per day.

Results: These patients (n = 111, 41.4% male, 49.0% aged ≤15 years) achieved mean TIR above 70%, mean GMI below 7% and mean TBR below 4% in each month, with >90% of time in AHCL (figure). AHCL settings of target SG were in most cases set at 100 mg/dL (5.5 mmol/L) and Active Insulin Time (AIT) at 2 hours. TIR percentage did not differ between users ≤15 years (n = 53) and >15 years over the observation period: 75.0-76.4% and 75.6-77.6%, respectively. TBR was 2.4-3.0% and 2.1-2.3% respectively.

Conclusions: Users of the MiniMed™ 780G system achieved a high TIR which sustained over the 6-month observation period. Results of glucometrics did not significantly differ between users aged ≤15 years and those aged >15 years. Optimal results were obtained in those with a target of 100 mg/dL and an Active Insulin time of 2 hours

EP036 / #746

Topic: ***AS01-Closed-loop System and Algorithm***

DEEP REINFORCEMENT LEARNING FOR ELIMINATING CARBOHYDRATE ESTIMATION IN GLUCOSE REGULATION IN TYPE 1 DIABETES

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Background and Aims: Carbohydrate (CHO) estimation adds substantial cognitive burden to people with Type 1 Diabetes in existing insulin treatment methods. We focused on developing a glucose control algorithm with an aim to use the historical glucose and insulin infusion data along with meal announcements to eliminate CHO counting. Deep Reinforcement Learning (DRL) was applied in this work as a Machine Learning algorithm that learns a control strategy through its intelligent interaction with a simulator.

Methods: We evaluated the in-silico performance of our algorithm using an open-source simulator (Simuglucose) developed based on the FDA approved UVA/Padova 2008 model. A meal protocol comprising of breakfast (30–60g), 3 snacks (20–40g each), lunch (70–100g), and dinner (70–110g) was simulated for 10 adult subjects. Subjects were tested for 100 trials spanning 26 hours each, where the trial start time, mealtimes, amounts, and occurrence were random. Trials where glucose dropped less than 40mg/dL were terminated and considered as a failure.

Results: The algorithm successfully eliminated the requirement of CHO counting under a challenging realistic meal protocol and achieved a satisfactory mean Time in Range (68.19%), while maintaining a moderate risk profile (Low and High Blood Glucose Indices of 2.65 and 9.56, respectively). The observed failure rate of 11.8% calls for additional safety mechanisms.

Conclusions: DRL shows promise in controlling glucose, and future research is required to ensure safety, improve interpretability of learned control strategies, and explore research translation to real life. **Acknowledgement** – This research was funded by the Australian National University and the Our Health in Our Hands initiative.

EP037 / #786

Topic: ***AS01-Closed-loop System and Algorithm***

SLEEP DISTURBANCES IN PATIENTS WITH TYPE 1 DIABETES WHO ARE SWITCHING TO ADVANCED HYBRID CLOSED LOOP (AHCL) THERAPY

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Background and Aims: Sleep disturbances are common in patients living with type 1 diabetes and this is determined by physiological, psychosocial and behavioral factors. We aimed to evaluate the impact of an aHCL on the perception of the quality of sleep of the patients.

Methods: Psychometric data were collected on day 28 and at 6 months using a self-reported questionnaire (Pittsburgh Sleep Quality Index PSQI). Times in range were recorded at baseline, day 28, and 6 months for assessment of glycemic control.

Results: Nine patients were included. Mean age was 31.4 ± 12.8 years and mean BMI was 24.9 ± 4.0 kg/m^2, with disease duration of 17.3 ± 7.6 years. Previous treatment was HCL for 7 and PLGM for 2 patients. TIR increased from 70.4 ± 11.4% to 77.2 ± 7.2% (p = 0.012), Time below range 54mg/dL decreased from 0.9 ± 0.8 % to 0.6 ± 0.5% (p = 0.027) and Time above range 180-250 mg/dL, decreased from 20.9 ± 6.4% to 15.8 ± 4.8% (p = 0.011). Regarding the perception of sleep quality, there was no significant difference in the scores. The results of the first week were 19 points and 20 points at six months of use of the therapy on a global scale (with a score close to 0 indicating there are no sleep difficulties and a score of 21 indicating serious sleep difficulties).

Conclusions: Patients on aHCL achieve optimal glycemic control. The quality of sleep perceived by these patients is not related to glycemic control. Factors responsible for this alteration need to be assessed and further researched.

EP038 / #79

Topic: ***AS01-Closed-loop System and Algorithm***

RAPID IMPROVMENT IN TIME IN RANGE AFTER THE IMPLEMENTATION OF ADVANCED HYBRID CLOSED LOOP SYSTEM IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: Advanced hybrid closed-loop (AHCL) systems represent the next step of automation intended to maximize normoglycemia in people with type 1 diabetes (T1D). In the AHCL MiniMed 780G system, different algorithm glucose targets for insulin infusion are available and autocorrection boluses are delivered. The aim was to retrospectively evaluate the impact of the implementation of this AHCL system in a clinical setting.

Methods: T1D subjects using a sensor-augmented pump with predictive low-glucose suspend (SAP-PLGS) and insulin pump with free style Libre, were upgraded to AHCL. Baseline, every 3 days, 2-week and 1-month sensor and pump data were downloaded. Glucose target was set to 100 mg/dL and active insulin time to 2:30 h for all the subjects. Time in different glucose ranges was compared.

Results: Sixty T1D subjects were included (age: 20-62 years, 55% females, diabetes duration: 27 ± 10 years, HbA1c: 8.5% ± 0.9%, time in SAP-PLGS). Time in range (TIR) 70–180 mg/dL increased from 65% ± 13 % at baseline to 79% ± 7% at 1 month. Time in hyperglycemia >180 and >250 mg/dL decreased from 29% ± 15% to 17% ± 8.0% and from 6% to 2.5% respectively. Decrease in time in hypoglycemia <70 or <54 mg/dL were found. Similar increase in TIR were seen in group using free style Libre. Time in Auto Mode was 97% ± 2%, and autocorrection insulin was 30% ± 14% of bolus insulin. No severe hypoglycemia or diabetic ketoacidosis episodes occurred.

Conclusions: AHCL systems demonstrated T1D patients to rapidly increase their TIR. The most aggressive settings allow optimal outcomes in TIR, without increasing hypoglycemia frequency and reducing the burden of diabetes and improving the quality of life.

EP039 / #802

Topic: ***AS01-Closed-loop System and Algorithm***

EXPERIENCE WITH SWITCHING FROM PREDICTIVE INSULIN SUSPENSION TO HYBRID-AID WITH TANDEM SYSTEM: THE UNIQUE STUDY SWITCH GROUP

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Background and Aims: Tandem control IQ is the second commercially available Hybrid-AID-System in Germany. Before commercialization, this study was performed to gain experience with the system. In total 50 patients were included in this trial, whereas 25 already using Basal IQ with the t:slim X2 pump, 25 were on any other therapy.

Methods: We present data of the switch group. In this group 25 consecutive patients from our outpatient clinic at Children's Hospital AUF DER BULT in Hannover were offered to update their pump from Basal IQ to Control IQ. All patients received training by a diabetes educator nurse, experienced with AID therapy. Therapy data and questionnaire for patient related outcomes were obtained before update and after 3 months.

Results: 25 children and adolescents were recruited. One adolescent girl stopped using the system after one month due to allergic contact dermatitis to DexCom adhesive. For demographic data and metabolic outcomes see table 1. Time in range increased 3 months after switch by decreasing TAR <250, also the number of patients reaching the treatment goal of TIR >70% increased. Standard deviation and coefficient of variation decreased showing less glycemic variability.

Conclusions: After switch to a Hybrid-AID-System from a PLGM system, patients from a well-treated collective still benefit from improving metabolic control, especially in glycemic variability and time in range by decreasing time in target.

Table1: demographic parameters

n=24	before	after	significance
Age	12.2±3.4		
Sex (female) [%]	29.1		
Diabetes Duration	6.2±4.3		
BMI z-score	0.578±0.959		
HbA1c [%]	6.9±0.6	6.8±0.6	ns
TDD insulin [U/kgBW/d]	0.99±1.53	0.94±0.29	ns
TIR [%]	62.1±15.1	67.7±10.1	0.006
N TIR >70% [%]	7	11	0.046
TBR 54-<70 [%]	2.7±1.8	1.9±1.6	ns
TBR <54 [%]	0.5±0.7	0.5±1.0	ns
Episodes <70 mg/dl [n]	9.1±6.6	8.3±6.6	ns
TAR 181-250 [%]	24.0±8.5	21.5±6.6	ns
TAR >250 [%]	10.7±9.9	8.0±5.2	0.045
Mean [mg/dl]	161±27	157±17	ns
SD [mg/dl]	60±12	56±10	0.011
CV	37.1±45.5	35.7±59.4	0.028

EP040 / #807

Topic: ***AS01-Closed-loop System and Algorithm***

EXPERIENCE WITH STARTING HYBRID-AID TANDEM SYSTEM: THE UNIQUE STUDY START GROUP

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[1]AUF DER BULT, Diabetes-center For Children And Adolescents, Hannover, Germany, [2]CRO, Biostatistics, Potsdam, Germany

Background and Aims: Tandem control IQ is the second commercially available Hybrid-AID-System in Germany. Before commercialization, this study was performed to gain experience with the system. In total 50 patients were included in this trial, whereas 25 already using Basal IQ with the t:slim X2 pump, 25 were on any other therapy.

Methods: We present preliminary data of the start group. In this group 25 consecutive patients from our outpatient clinic at Children's Hospital AUF DER BULT in Hannover with any type of intensified insulin therapy (MDI or CSII) were offered to start AID therapy with Control IQ. All patients received training by a diabetes educator nurse experienced with AID therapy. All patients were AID naïve. Therapy data from glucose sensors and

Table1: demographic parameters and metabolic outcome

n=	Before (n=25)	After (n=18)	Significance (only pairs)
Age	12.4±3.6		
Sex (female) [n (%)]	12 (48)		
Diabetes Duration [y]	3.1±3.3		
BMI z-score	0.1±1.0		
Previous pump use [n (%)]	9 (36)		
Previous CGM use [n (%)]	25 (100)		
HbA1c [%]	7.1±1.1	7.0±0.8	n.s.
TDD Insulin [U/kgBW/d]	39.9±22.9	37.7±26.7	n.s.
TIR [%]	66.3±17.9	68.2±14.6	n.s.
Patients TIR >70% [n]	12 (48)	8 (44)	n.s.
TBR 54-<70 [%]	2.6±2.2	1.4±1.4	n.s.
TBR <54 [%]	1.3±3.7	0.4±0.7	0.01
Patients TBR <4% [n (%)]	17 (68)	16 (89)	n.s.
Episodes < 70 mg/dl	15.1±12.6	7.7±7.1	0.01
TAR 181-250 [%]	28.9±35.3	30.3±38.6	n.s.
TAR >250 [%]	7.9±8.7	8.9±5.8	n.s.
Mean [mg/dl]	153±27	158±21	n.s.
SD [mg/dl]	55±13	55±11	n.s.
CV	35.9±5.6	34.8±6.1	n.s.

questionnaire for patient related outcomes were obtained before pump update and 3 months after the update.

Results: 25 children and adolescents were recruited. For demographic data and metabolic outcomes see table 1. Time in range increased 3 months after switch. TBR hypoglycemic episodes and CV decreased both significantly. Other parameters showed only trends of improvement in this interim analysis of 18 patients.

Conclusions: After switch to a Hybrid-AID-System, even in a well-treated collective, patients still benefit from the new system as an improvement of metabolic control. Especially the reduction in hypoglycemia was a success for this population with a high amount of hypoglycemia at baseline.

EP041 / #812

Topic: ***AS01-Closed-loop System and Algorithm***

THE BIHORMONAL INTRAPERITONEAL ARTIFICIAL PANCREAS ACHIEVE FULLY CLOSED LOOP CONTROL IN ANESTHETIZED ANIMALS.

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Background and Aims: Fully automatic blood glucose (BG) control without meal announcement is a considerable challenge for Artificial Pancreas (AP) systems due to the slow subcutaneous (SC) insulin absorption and delayed effect on glucose homeostasis. In this paper we propose to exploit the faster absorption rate of the Intraperitoneal (IP) insulin as an alternative. In addition, single hormone APs are shown to be conservative in dealing with exercises and sudden drops in the BG. We use IP infusion of both insulin and glucagon to achieve a tight glycemic control without meal and exercise announcements.

Methods: A combination of nonlinear model predictive control (NMPC) and Zone MPC algorithms was designed. The penalty used for different BG is shown in Fig. 1.

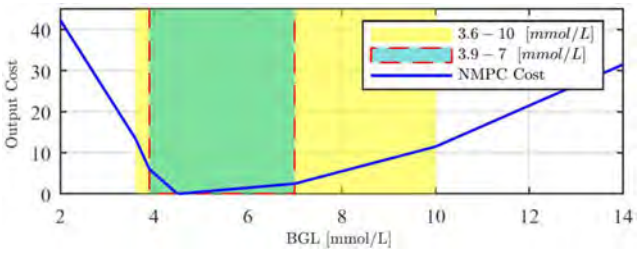

Fig. 1. Penalty used for different BG levels in the NMPC. The controller used a modified version of the model presented by Zazueta et al [1], in which the hepatic first-pass effect was included for insulin. A moving horizon estimator was employed to estimate states and meals. Meals and physical activity were simulated in the three anesthetized animals by manipulating the intravenous glucose infusion rates as shown in Fig. 2:

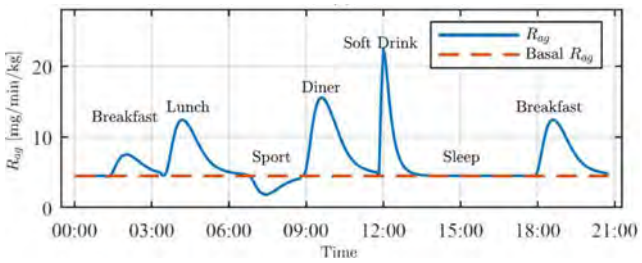

Fig. 2. Glucose infusion rate used in animal experiments.

Results: The designed AP kept the BG in the target zone (3.9-10 mmol/l) at 87%, 93% and 94% of the time for three experiments. This was achieved without informing the controller about the meals and exercise.

Conclusions: The preliminary results in three animal experiments indicate that a fully automated bi-hormonal IP AP achieves very good glycemic control.

[1] Zazueta et al, 2021. DOI: 10.1109/TBME.20213125839

EP042 / #818

Topic: ***AS01-Closed-loop System and Algorithm***

HOW DO PHYSICIANS RATE THE INDICATION FOR MODERN TECHNOLOGIES IN PEOPLE WITH DIABETES?

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Background and Aims: To assess the potential of modern technologies and digital applications, we asked diabetologists in Germany how they consider the indication for modern technologies for different groups of people with diabetes (PwD)?

Methods: In 2021, 305 diabetologists in Germany (48% female, average age 53.7 years) were asked via online survey how they assess the target group for modern technologies in diabetes ("In your estimation, what percentage of the following patient groups would benefit from the different therapies?").

Results: Children, adolescents with TD1: Continuous glucose monitoring (CGM) 93.1%); AID systems (AID) 71.3%; Insulin pumps (IP) 71.3%; Smart pens (SP) 45,4%. TD1 (adults): CGM 93,1%; AID 71,3%; ID 71,3%; SP 45,4%. Pregnant TD1: CGM 92,1%; AID 70,7%; ID 73,6%; SP 47,0%. TD2 (MDI) CGM 78,3%; AID 31,6%; ID 25,2%; SP 48,6%. TD2 (conventional insulin therapy) CGM 42,7%; AID 11,1%; ID 7,6%; SP 30,8%.

Conclusions: For the vast majority of PwD-TD1, the diabetologists surveyed would assess an indication for a CGM, and for over 70% also for an AID-System. For most PwD-TD2 (MDI), physicians also see an indication for CGM and AID-Systems. But there also seems to be some indication for CGM and surprisingly also for an AID-System for PwD-TD2 (conventional insulin therapy). Quite independently of the reimbursement situation, diabetologists see a very broad indication for modern diabetes technologies.

EP043 / #819

Topic: ***AS01-Closed-loop System and Algorithm***

CURRENT AND FUTURE IMPORTANCE OF AID-SYSTEMS FOR PEOPLE WITH DIABETES

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Background and Aims: How do people with diabetes view the current and future importance of AID-Ssystems?

Methods: People with diabetes (PwD) in Germany were asked via online surveys about their attitudes and assessment of AID-Systems (2.417 PwD; 47.5% female, 57.8% type 1 diabetes (T1D), 20.7% type 2 diabetes (T2D), 19.0% parents of children with diabetes; Ø 47.7 years).

Results: Overall, 63% of PwD currently rate AID-Systems as important, 88% in five years. Parents of children with type 1 diabetes (currently 74.5%; 5-year: 96.2%) and adults with TD1 (currently 62.8%; 5-year: 88.7%) consider this issue more central than adults with type 2 diabetes do (currently 51.3%; 5-year:75.9%). Respondents estimate that in 10 years, one in two PwD-TD1will be using a AID-System. Parents of children with diabetes are slightly more optimistic (mean 8.8 years), while PwD-TD2 are slightly more pessimistic (mean 10.6 years).68.1 of PwD believe that they will become more independent and empowered with AID-Systems, but 55.9 see an increased diabetes education effort. Only 26.5% of PwDs fear that they will have less contact with the diabetes team, that the therapy will become riskier (13.1%) or that the diabetes team will become superfluous (4.4%).

Conclusions: Most PwD have high expectations of AID-Systems and believe that this will soon become the new standard therapy for TD1. Above all, they hope that AID-Systems will increase their autonomy and empowerment. Possible risks of AID systems are not perceived as very important.

EP044 / #93

Topic: ***AS01-Closed-loop System and Algorithm***

TRANSITION OF PATIENTS WITH T1D FROM MDI AND SMBG DIRECTLY TO MINIMED™ 780G ADVANCED HYBRID CLOSED LOOP SYSTEM: RESULTS OF A TWO-CENTER, RANDOMIZED CONTROLLED STUDY

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Background and Aims: The aim of this study was to evaluate whether the MiniMed 780G advanced hybrid closed-loop (AHCL) system may be effective in adult individuals with T1D naïve to CSII and CGM technologies.

Methods: The trial was a two-center, randomized controlled, parallel group study (Clinicaltrials.gov registry: NCT04616391) evaluating individuals with T1DM aged 24-58 years and managed with MDI/SMBG. After 2 weeks run-in phase, participants were randomized to AHCL or MDI/SMBG group and followed up during 3 months.

Table 1. Primary and secondary glucose and clinical outcomes

Category	Treatment Arm		Control Arm		Estimated Difference (780G - MDI)	95% Confidence Interval	P value
	Baseline	780G	Baseline	MDI			
Number of subjects	20	20	21	17			
Body weight (kg)*	76.3 ± 14.7	75.6 ± 16.5	77.7 ± 14.4	77.8 ± 15.3	-2.9^	-12.5; 8.1	0.637
BMI (kg/m²)*	24.5 ± 3.3	24.3 ± 3.9	25.6 ± 2.6	25.6 ± 2.9	-1.7^	-3.5;1.2	0.244
HbA1c (%)*	7.05 ± 0.8	6.7 ± 0.4	7.4 ± 1.2	7.4 ± 0.8	-0.6	-0.9; -0.2	0.005
Average SG (mg/dL)*	139.9 ± 21.2	133.2 ± 8.9	151.0 ± 23.6	153.1 ± 25.3	-15.4	-26.5; -4.2	0.008
CV of SG (%)*	39.0 ± 7.1	30.6 ± 4.7	39.5 ± 4.7	40.7 ± 6.3	-9.4^	-12.9; -5.6	<0.001
SG < 54 mg/dL (%)*	2.9 ± 1.8	0.3 ± 0.4	2.7 ± 4.9	2.6 ± 3.9	-0.9^	-1.6; -0.3	0.010
SG < 70 mg/dL (%)*	8.7 ± 7.3	2.1 ± 1.7	7.5 ± 7.9	8.1 ± 7.1	-4.4^	-7.4; -2.1	<0.001
SG 70-180 mg/dL (%)*	69.3 ± 12.3	85.0 ± 6.3	62.8 ± 10.7	61.5 ± 11.2	21.5	15.7; 27.3	<0.001
SG > 180 mg/dL (%)*	22.0 ± 12.3	12.9 ± 5.8	29.8 ± 13.4	30.5 ± 14.2	-14.7	-21.4; -8.0	<0.001
SG > 250 mg/dL (%)*	5.2 ± 6.4	1.6 ± 1.6	7.6 ± 5.8	9.3 ± 8.3	-4.5^	-11.0; -2.0;	<0.001

* values are presented as mean ± SD;

^ ANCOVA analysis with adjustment for baseline value. Mean difference was presented;

^^ Wilcoxin rank-sum test was applied when ANCOVA assumption was not meet, and median difference was provided;

Results: 41 participants were recruited and 37 were randomized to either the AHCL (20) or the MDI/SMBG (17) group. All 37 participants (age 40.3 ± 8.0 years; duration of diabetes 17.3 ± 12.1 years; BMI 25.1 ± 3.1; HbA1c 7.2 ± 1.0) completed the study. TIR increased from 69.3 ± 12.3% at baseline to 85.0 ± 6.3% at EoS in the AHCL group, remaining unchanged in the control group: 62.8 ± 10.7% to 61.5 ± 11.2% (difference 21.5% [95% CI 15.7, 27.3%]; P < 0.001). All secondary glucose outcomes at the end of study favored the intervention group (Table 1). Notably, TBR <70 decreased from 8.7% ± 7.3 to 2.1% ± 1.7 in the AHCL group, and remained unchanged in the MDI/SMBG group (7.5% ± 7.9 to 8.1% ± 7.1) (difference - 4,4% [95% CI -7.4, -2.1%]; P < 0.001).

Conclusions: In this report, people with T1DM naïve to CSII and CGM technologies who switched directly to AHCL significantly and safely improved their glycemic control.

EP045 / #142

Topic: ***AS02-New Insulin Analogues***

ATOS: REAL-WORLD EFFECTIVENESS AND SAFETY OF INSULIN GLARGINE 300 U/ML IN INSULIN-NAÏVE PEOPLE WITH TYPE 2 DIABETES: AD-HOC ANALYSIS OF RUSSIAN POPULATION.

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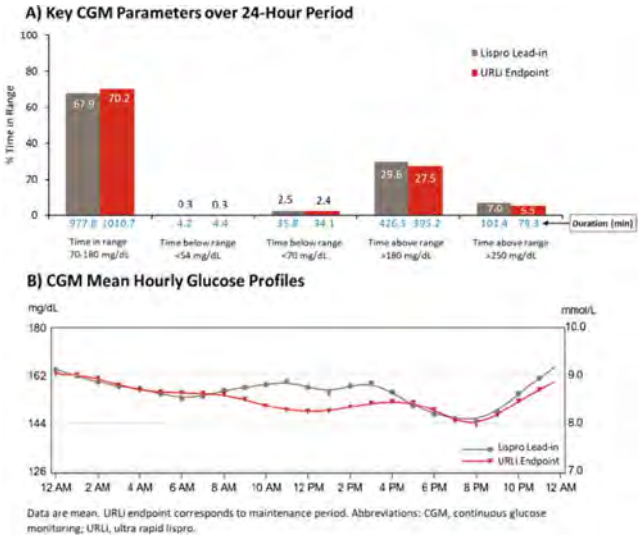
Background and Aims: Insulin glargine 300 U/mL (Gla-300) is a second-generation basal insulin analogue that has comparable glycemic control with lower risk of hypoglycemia compared with the first-generation analogue insulin glargine 100 U/mL (Gla-100) in adults with T2DM. Objective - to assess the real-world effectiveness and safety of Gla-300 based on prespecified analysis of population in Russian Federation.

Methods: ATOS (NCT03703869) was a 12-month, prospective observational multicentre study. Adults (≥18 years) with uncontrolled T2DM (HbA1c>7 and ≤11%) on ≥1 OAD and in whom the treating physician had decided to add Gla-300 were

recruited. This is an Ad-Hoc analysis for Russian Federation. Primary endpoint: Percentage of patients achieving predefined individualized HbA1c goal at Month 6. Secondary endpoints: HbA1c at Months 3 and 12; Change in HbA1c, FPG, SMBG at Months 3, 6 and 12 and safety. Descriptive statistics was used. The mean change from baseline in HbA1c, FPG, SMBG and insulin dose was assessed using a MMRM approach. A total of 4422 people with T2DM received Gla-300 and were eligible for assessment.

Results: 25.9% of patients achieved their predefined individualized HbA1c target at Month 6 (n = 381) and 53.3% achieved their HbA1c target at Month 12 (n = 784). Mean ± SD HbA1c decreased from 9.26 ± 0.93% at baseline to 8.17 ± 0.84%, 7.65 ± 0.74% and 7.23 ± 0.7% at Months 3, 6, and 12, respectively (LS mean change from baseline: -1.09, -1.61 and -2.02)

Conclusions: In a real-life setting in Russian Federation, initiation of Gla-300 in people with T2DM uncontrolled on OADs resulted in improved glycemic control with low rates of hypoglycemia and minimal weight change.



EP046 / #149

Topic: ***AS02-New Insulin Analogues***

ASSESSING TIME IN RANGE (TIR) WITH POSTPRANDIAL GLUCOSE (PPG)-FOCUSED TITRATION OF ULTRA RAPID LISPRO (URLI) IN PATIENTS (PTS) WITH TYPE 1 DIABETES (T1D)

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Background and Aims: To assess TIR (70–180 mg/dL) with PPG-focused titration of URLi in combination with degludec in T1D.

Methods: This was a Phase 2, single-group, open-label, exploratory study of 31 T1D pts on MDI therapy. All pts were treated with degludec and lispro for 11-day lead-in and then URLi for 35-day titration (glucose targets: PPG <20% increase or <140; fasting, 80–110; overnight excursion ≤±30 mg/dL) and 11-day endpoint maintenance period. Pts used InPen™ bolus calculator and Dexcom G6 CGM.

Results: Primary endpoint TIR with URLi during maintenance period was 70.2%. TIR and time below/above range were not significantly different with URLi (maintenance) vs lispro (lead-in) (Figure). HbA1c decreased from screening 7.1% to 6.8% (least squares mean [LSM] Δ: -0.36%, p < 0.001). Fructosamine and 1,5-anhydroglucitol improved (p < 0.001). Mean hourly glucose with CGM was reduced from 8 am–4 pm with URLi (Figure). Overall highest PPG excursion across meals was significantly reduced with URLi vs lispro (mean: 56.5 vs 72.4 mg/dL; p < 0.001). Insulin-to-carbohydrate ratio (U/X g) was reduced (more insulin given) at breakfast with URLi vs lispro (LSM: 9.0 vs 9.7 g; p = 0.002) and numerically decreased at other meals. With URLi vs lispro, total daily dose (TDD) was higher (mean: 50.2 vs 47.0 U; p = 0.046) with similar prandial/TDD ratio (mean: 52.1% vs 51.2%). There were no severe hypoglycemia events.

Conclusions: URLi in a basal-bolus regimen focusing on PPG targets demonstrated improved overall glycemic control and reduced PPG excursions without increased hypoglycemia in pts with T1D.

EP047 / #165

Topic: ***AS02-New Insulin Analogues***

EFFECTIVENESS AND SAFETY OF INSULIN GLARGINE 300 U/ML IN INSULIN-NAÏVE PATIENTS WITH TYPE 2 DIABETES (T2DM): POSTHOC ANALYSIS OF THE UKRAINIAN POPULATION FROM ATOS STUDY.

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Background and Aims: Insulin initiation in T2DM in Ukraine remaince late. Insulin glargine 300 U/mL (Gla-300) is a second-generation basal insulin analogue that allows achieving the target values of glycated hemoglobin (HbA1c) with low risk of hypoglycemia. The present subgroup analysis from ATOS study aimed to estimate the effictiveness and safety of Gla-300 in insulin-naïve T2DM patients from Ukraine. ATOS study (NCT03703869) Primary results were presented at ATTD 2021.

Methods: This 12-month prospective observational study in 20 cites included 198 T2DM adults who did not reach the target HbA1c levels with oral antidiabetics and were prescribed Gla-300. Statistical analysis was performed using Statistica 12.0 (Statsoft, USA).

Results: After 6 and 12 months of treatment, 22.2% and 37.9% of study participants had reached the predefined individualized HbA1c target. After 12 months of treatment the HbA1c of the study participants decreased, on average, by 2.10% (from 9,49 ± 1,05% to 7,51 ± 0,92%) and fasting plasma glucose (FPG) - by 4.10 mmol/L. The stricter the target, the fewer patients were able to achieve it. Hypoglycemia occurred in 2.02% of patients within 12 months of treatment; severe hypoglycemia was not reported. Of the 13 reported adverse events, only 1 case (asthenia) was associated with treatment.

Conclusions: Insulin therapy with Gla-300 significantly reduced HbA1c and FPG in insulin-naïve T2DM patients. No

serious treatment-related adverse events were detected, and the incidence of hypoglycemia was low. This subgroup analysis results might be interesting for Ukrainian HCP for bigger confidence in timely insulin initiation.

EP048 / #225

Topic: *AS02-New Insulin Analogues*

EFFECTIVENESS AND SAFETY OF INSULIN GLARGINE 300 U/ML (GLA-300) IN INSULIN NAÏVE PEOPLE WITH TYPE 2 DIABETES: ATOS STUDY SUBGROUP ANALYSIS BY BASELINE HBA1C

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Background and Aims: ATOS was a 12-month prospective observational study conducted in 18 countries outside US and Western Europe in insulin-naïve adults with type 2 diabetes, uncontrolled (HbA_{1c} >7-≤11%) on ≥1 oral antihyperglycemic drug. This subgroup analysis evaluated effectiveness and safety of Gla-300 in predefined baseline (BL) HbA_{1c} subgroups.

Methods: In this subgroup analysis participants were stratified by BL HbA_{1c}: <64 mmol/mol (<8%; N = 436), 64-75 mmol/mol (8-9%; N = 1348), 75-86 mmol/mol (9-10%; N = 1351) and ≥86 mmol/mol (≥10%; N = 1287). The primary endpoint was achievement of individualized HbA_{1c} target at 6 months.

Results: Mean age, BMI and duration of diabetes were similar across subgroups (Table). The physician-set individualized HbA_{1c} goal was less stringent in higher BL HbA_{1c} groups. HbA_{1c} target achievement improved over time and were higher in the subgroups with a lower BL HbA_{1c}; >50% of participants with BL HbA_{1c} <9% achieved their target at Month 12. On the other hand, greater reductions in HbA_{1c}, FPG and SMPG were observed in higher vs lower BL HbA_{1c} subgroups (Table). Increments in the Gla-300 dose were similar across subgroups. Overall, incidences and rates of reported hypoglycemia were low and similar between groups.

Conclusions: This subgroup analysis showed that initiation of Gla-300 was effective in reducing HbA_{1c} across BL HbA_{1c} subgroups with benefits of early insulin initiation observed for target achievement in those with lower BL values. Hypoglycemia incidence was low even in the high BL HbA_{1c} subgroups suggesting that further titration can be done with low risk of hypoglycemia, enabling more patients to reach their targets.

Table: Baseline characteristics and glycemic parameters and safety at Month 6 and Month 12 by baseline HbA_{1c} subgroups

Baseline HbA_{1c} subgroup	Baseline				Month 6				Month 12			
	<8%	≥8% - <9%	≥9% - <10%	≥10%	<8%	≥8% - <9%	≥9% - <10%	≥10%	<8%	≥8% - <9%	≥9% - <10%	≥10%
Age, years	57.8 (11.1)	57.4 (10.6)	58.3 (10.6)	55.6 (10.9)	–	–	–	–	–	–	–	–
Male, n (%)	214 (49.1)	668 (49.6)	652 (48.3)	597 (46.4)	–	–	–	–	–	–	–	–
BMI, kg/m²	29.6 (5.7)	29.2 (5.1)	29.6 (5.4)	29.2 (5.4)	–	–	–	–	–	–	–	–
Duration of diabetes, years	10.3 (7.6)	10.3 (6.2)	10.3 (6.1)	9.9 (6.1)	–	–	–	–	–	–	–	–
Any diabetes complication or comorbidity	332 (76.1%)	970 (72.0%)	980 (72.5%)	937 (72.8%)	–	–	–	–	–	–	–	–
HbA_{1c}, %	7.60 (0.23)	8.47 (0.30)	9.41 (0.30)	10.52 (0.36)	7.16 (0.80)	7.44 (0.83)	7.79 (0.93)	8.31 (1.22)	7.04 (0.85)	7.19 (0.78)	7.37 (0.90)	7.71 (1.14)
LS mean change from BL (SE)*					-0.48 (0.04)	-1.03 (0.02)	-1.62 (0.03)	-2.22 (0.04)	-0.60 (0.05)	-1.28 (0.02)	-2.02 (0.03)	-2.77 (0.03)
Individualized HbA_{1c} target achievement, n/N* (%)					161/361 (44.6)	402/1219 (33.0)	255/1226 (20.8)	172/1325 (15.3)	193/347 (55.6)	596/1170 (50.9)	516/1175 (44.1)	382/1056 (34.3)
95% CI:					39.4; 49.8	30.3; 35.7	18.6; 23.2	13.2; 17.5	50.2; 60.9	48.0; 53.8	41.2; 47.0	31.4; 37.2
FPG, mmol/L	9.40 (1.67)	10.11 (2.29)	11.08 (2.72)	12.47 (3.16)	6.87 (1.56)	7.24 (1.56)	7.52 (1.75)	8.13 (2.28)	6.88 (1.67)	6.85 (1.52)	7.00 (1.58)	7.30 (1.78)
LS mean change from BL (SE)*	–	–	–	–	-2.42 (0.09)	-2.85 (0.05)	-3.48 (0.05)	-4.32 (0.07)	-2.63 (0.09)	-3.21 (0.05)	-3.98 (0.05)	-5.15 (0.08)
Fasting SMPG, mmol/L	9.14 (1.98)	10.13 (2.13)	10.99 (2.31)	11.76 (2.94)	6.89 (1.25)	7.33 (1.47)	7.73 (1.55)	8.10 (1.77)	6.70 (1.22)	6.90 (1.22)	7.11 (1.39)	7.58 (1.62)
LS mean change from BL (SE)*	–	–	–	–	-2.31 (0.07)	-2.78 (0.05)	-3.39 (0.05)	-3.63 (0.06)	-2.54 (0.08)	-3.24 (0.04)	-3.79 (0.05)	-4.19 (0.06)
Glа-300 dose, U/kg	0.197 (0.075)	0.178 (0.068)	0.184 (0.066)	0.20 (0.097)	0.240 (0.108)	0.207 (0.112)	0.177 (0.112)	0.182 (0.120)	0.253 (0.112)	0.282 (0.117)	0.297 (0.117)	0.300 (0.131)
LS mean change from BL (SE)	–	–	–	–	0.074 (0.010)	0.089 (0.103)	0.068 (0.102)	0.079 (0.109)	0.088 (0.109)	0.109 (0.112)	0.106 (0.115)	0.097 (0.129)
Hypoglycemia events, % (event rate PPY)												
Documented symptomatic (≤3.9 mmol/L)	–	–	–	–	1.38 (0.042)	0.82 (0.028)	1.04 (0.033)	0.21 (0.016)	1.83 (0.027)	1.04 (0.025)	1.52 (0.028)	0.47 (0.015)
Documented symptomatic (<3.0 mmol/L)	–	–	–	–	0	0.15 (0.003)	0.15 (0.003)	0.09 (0.002)	0.23 (0.002)	0.30 (0.003)	0.22 (0.002)	0.08 (0.001)
Severe	–	–	–	–	0.23 (0.005)	0	0.30 (0.007)	0	0.23 (0.002)	0.07 (0.001)	0.30 (0.004)	0

Data are mean (SD) unless otherwise specified. *LS mean change assessed using mixed model for repeated measurements analysis. †All eligible participants with HbA_{1c} value not missing at the visit. BL, baseline; BMI, body mass index; CI, confidence interval; FPG, fasting plasma glucose; Gla-300, insulin glargine 300 U/mL; HbA_{1c}, glycated hemoglobin; LS, least squares; PPY, per participant year; SD, standard deviation; SE, standard error; SMPG, self-monitored plasma glucose

EP049 / #233

Topic: *AS02-New Insulin Analogues*

EFFECTIVENESS AND SAFETY OF INSULIN GLARGINE 300 U/ML (GLA-300) IN INSULIN-NAÏVE PEOPLE WITH TYPE 2 DIABETES AND RENAL IMPAIRMENT: A SUBGROUP ANALYSIS OF ATOS STUDY

A. Tirosh[1], N. Khan[2], H. Vargas-Uricoechea[3], M.A.N. Mabunay[4], M. Coudert[5], V. Pilorget[6], G. Galstyan[7]

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Background and Aims: ATOS, a 12-month prospective observational study conducted in 18 countries outside US and Western Europe in insulin-naïve adults with type 2 diabetes (T2D), showed improved glycemic control with low rates of hypoglycemia and minimal weight change. This subgroup analysis of the ATOS study evaluated the effectiveness and safety of Gla-300 in participants with T2D and a history of renal impairment (RI).

Methods: Participants were stratified by history of RI (≈70% microalbuminuria, with RI: N = 581; without RI: N = 3841). The primary endpoint was achievement of individualized HbA_{1c} target at 6 months.

Table: Baseline characteristics, glycemic parameters, and safety at Month 6 and 12 by history of renal impairment

	Baseline		Month 6		Month 12†	
	Renal impairment	No renal impairment	Renal impairment	No renal impairment	Renal impairment	No renal impairment
Age, Years	62.2 ± 10.3	56.4 ± 10.7				
Female, n (%)	329 (56.6)	1962 (51.1)				
BMI, Kg/m^2	30.7 ± 5.6	29.2 ± 5.2				
Duration of diabetes, years	12.7 ± 6.9	9.8 ± 6.6				
Any diabetes complication and comorbidity history, n (%)	580 (99.8)	2689 (66.7)	–	–	–	–
Microalbuminuria	404 (69.5)	0 (0)				
Macroalbuminuria	102 (17.6)	0 (0)				
Advanced kidney disease	68 (11.7)	0 (0)				
End stage renal failure	3 (0.5)	0 (0)				
HbA_{1c} target achievement, n (%)			141/514 (27.5)	840/3418 (24.6)	–	–
HbA_{1c} (%)	9.52 ± 0.97	9.17 ± 1.09	7.69 ± 1.06	7.76 ± 1.08	7.87 ± 0.88	7.17 ± 0.98
Change from baseline (95% CI)*	–	–	-1.90 (-1.99 to -1.41)	-1.50 (-1.54 to -1.47)	-1.84 (-1.91 to -1.26)	-2.48 (-2.51 to -2.05)
FPG (mmol/L)	11.06 ± 2.74	10.99 ± 2.99	7.66 ± 1.78	7.52 ± 1.91	7.25 ± 1.54	6.97 ± 1.62
Change from baseline (95% CI)*	–	–	-3.16 (-3.54 to -2.78)	-3.43 (-3.48 to -3.38)	-3.70 (-3.98 to -3.41)	-3.96 (-4.02 to -3.90)
SMPG (mmol/L)	10.62 ± 2.33	10.75 ± 2.59	7.78 ± 1.54	7.61 ± 1.61	7.28 ± 1.25	7.12 ± 1.48
Change from baseline (95% CI)*	–	–	-3.21 (-3.15 to -3.06)	-3.51 (-3.57 to -3.45)	-3.60 (-3.71 to -3.49)	-3.81 (-3.87 to -3.75)
Basal insulin dose (U/kg)	0.19 ± 0.10	0.18 ± 0.09	0.28 ± 0.12	0.27 ± 0.11	0.30 ± 0.11	0.29 ± 0.12
Change from baseline (95% CI)	–	–	0.10 (0.09 to 0.11)	0.09 (0.09 to 0.09)	0.12 (0.10 to 0.13)	0.10 (0.10 to 0.10)
Body weight (kg)	88.1 ± 17.5	80.1 ± 16.1	88.1 ± 16.7	80.9 ± 15.8	88.3 ± 16.4	80.9 ± 15.8
Change from baseline (95% CI)*	–	–	-0.2 (-0.6 to 0.2)	0.6 (-0.3 to 0.6)	-0.2 (-0.7 to 0.3)	-0.1 (-0.3 to 0.0)
Hypoglycemia incidence, % (event rate PPY)						
Documented symptomatic (≤3.9 mmol/L)	–	–	3.72 (0.068)	0.74 (0.021)	1.89 (0.035)	1.17 (0.033)
Documented symptomatic (<3.0 mmol/L)	–	–	0.34 (0.007)	0.08 (0.002)	0.34 (0.004)	0.16 (0.002)
Severe	–	–	0.52 (0.014)	0.05 (0.001)	0.52 (0.007)	0.08 (0.001)

Data shown are mean ± SD unless otherwise specified. Safety analyses were undertaken in the eligible population (RI: [N=581], non-RI: [N=3841]) those meeting the inclusion/exclusion criteria who started Gla-300 181 days from study start). Efficacy analyses were undertaken in the evaluable population (RI: [N=519]; non-RI: [N=3419]) of eligible patients with an HbA_{1c} assessment at Month 6, of whom RI: [N=389], non-RI: [N=3259] had an HbA_{1c} assessment at Month 12). Renal impairment subgroup is defined as "Yes" (as reported by the investigator) if the patient was diagnosed with renal impairment, nephropathy or chronic kidney disease; and "No" in other case. eGFR data was not available

*12-month period for hypoglycemia defined as from the first treatment administration to visit 3 (Month 6) or treatment discontinuation, whichever occurred first. †12-month period for hypoglycemia defined as from the first treatment administration to visit 4 (Month 12) or treatment discontinuation, whichever occurred first. ‡2 mean change from a MMRM approach

BMI, body mass index; CI, confidence interval; FPG, fasting plasma glucose; HbA_{1c}, glycated hemoglobin; LS, least squares; MMRM, mixed model for repeated measurements; PPY, per patient year; RI, renal impairment; SD, standard deviation; SMPG, self-monitored plasma glucose; U, units.

Results: Participants with RI were older (62.2 ± 10.3 vs 56.4 ± 10.7 years), had a longer duration of T2DM (12.7 ± 6.9 vs 9.8 ± 6.0 years) and more comorbidities than those without RI. Baseline HbA_{1c} was comparable between groups (9.3%). Physician-set individualized HbA_{1c} (%) goals at baseline in the RI vs non-RI groups were <7: 7.2 vs 14.6%; 7-<7.5: 60.4 vs 72.0%; 7.5-<8: 25.0 vs 9.8%; ≥8:7.4 vs 3.6%. HbA_{1c} target achievement at Month 6 was 27.5% (95% CI: 23.7-31.6) in RI group and 24.8% (95% CI: 23.4-26.3) in the non-RI group. There was no difference between groups in HbA_{1c} reductions from baseline to Month 6 (-1.50 vs. -1.50%) and 12 (-1.84 vs. -1.88%). The reported hypoglycemia incidence was low, although higher in the RI group (Table). Incidence of treatment-emergent adverse events was low in both RI (9.8%) and non-RI (5.9%) groups.

Conclusions: Initiation of Gla-300 is effective with low risk of hypoglycemia in people with T2D with and without RI.

Table. Mean change in glycemic parameters and mean daily insulin dose from baseline to Week 26

Parameters	Baseline, Mean (SD)	Change from baseline, LS mean (95% CI)	
		Week 12	Week 26
HbA_{1c}, mmol/mol	71.22 (8.44)	−7.27 (−8.46, −6.08)	−8.91 (−10.12, −7.70)
HbA_{1c}, %	8.67 (0.77)	−0.66 (−0.77, −0.56)	−0.82 (−0.93, −0.70)
FPG, mmol/L	9.08 (2.95)	−1.44 (−1.73, −1.14)	−1.66 (−1.95, −1.37)
	Baseline, Mean (SD)	Week 12, Mean (SD)	Week 26, Mean (SD)
Gla-300 daily dose, U/kg	0.352 (0.200)	0.473 (0.230)	0.501 (0.243)

CI, confidence interval; FPG, fasting plasma glucose; Gla-300, insulin glargine 300 U/mL; HbA1c, glycated hemoglobin; LS, least squares; SD, standard deviation.

Conclusions: In people with T2DM uncontrolled on previous BI, switching to Gla-300 with optimal titration was associated with improved glycemic control, low incidence of hypoglycemia and no specific safety concerns.

EP050 / #238

Topic: ***AS02-New Insulin Analogues***

EFFICACY AND SAFETY OF INSULIN GLARGINE 300 U/ML IN PEOPLE WITH TYPE 2 DIABETES MELLITUS UNCONTROLLED ON BASAL INSULINS: ARTEMIS-DM STUDY

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Background and Aims: The efficacy and safety of switching to insulin glargine 300 U/mL (Gla-300) in type 2 diabetes mellitus (T2DM) uncontrolled on basal insulin (BI) has been demonstrated in RCTs and real-world studies in the US and EU. However, similar data in wider geographic regions are limited. ARTEMIS-DM is a multicenter, interventional, single-arm, phase 4 study aimed to evaluate the impact of this switch in 14 countries across Asia, Middle East, Africa, and Latin America.

Methods: ARTEMIS-DM study enrolled adults with T2DM uncontrolled (HbA_{1c} 58–86 mmol/mol [7.5–10%]) on BI therapy. Primary endpoint was change in HbA_{1c} from baseline to 26 weeks.

Results: A total of 372 participants (50% male) were included, with mean (SD) age 60.9 (10.0) years and BMI 29.57 (5.43) kg/m^2. Majority of participants (62.6%) were <65 years and median diabetes duration was 12 years. A total of 222 (59.7%) participants had insulin glargine (100 U/mL) as previous BI. There was a decrease in mean HbA_{1c} and fasting plasma glucose (FPG) at Weeks 12 and 26 (Table). Any hypoglycemic event occurred in 20.4% of the participants; 9.4% of the participants experienced nocturnal hypoglycemia and one participant had severe hypoglycemia. With the recommended titration algorithm, the mean daily Gla-300 dose increased from 0.35 U/kg at baseline to 0.5 U/kg at Week 26.

EP051 / #239

Topic: ***AS02-New Insulin Analogues***

PATIENT PERSPECTIVES AND EXPERIENCES OF BASAL INSULIN (BI) TITRATION IN TYPE 2 DIABETES (T2D): A US CROSS-SECTIONAL SURVEY

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Background and Aims: Appropriate BI titration in T2D is crucial for glycemic target achievement, but many people with T2D remain uncontrolled and their perspectives and experiences regarding titration are not well understood. This survey aims to analyze perspectives and experiences of BI titration in people with T2D initiating BI.

Methods: Adults with T2D and ≥2 claims (≥30 days apart in the most recent 12-month period) in the Optum Research Database, who initiated a BI analogue between February and April 2021, were asked to complete a one-time, mailed survey.

Results: Characteristics of the 416 survey responders were: 51% male, 71% white, mean age 70 years, mean BMI 32 kg/m^2, 72%> 10 years T2D duration. Most responders (74%) had BI titration explained by their provider; 67% were very/extremely satisfied with the support received. One-fifth received no BI titration resources/training. Most responders documented BI dose (89%) and fasting blood glucose (FBG; 80%) daily. Only 35% met FBG targets; 58% had not and were still titrating and 7% had stopped using BI. Half (49%) experienced hypoglycemia during titration. Mean Diabetes Treatment Satisfaction Questionnaire total score was 28 (range 0–36; higher score indicates greater satisfaction). Only 6% were categorized as ''disengaged and overwhelmed'', 30% were categorized as ''becoming aware, but

struggling'', 39% as ''taking action'' and 26% as ''maintaining behaviors and pushing further'' by the Patient Activation Measure score.

Conclusions: While many people with T2D initiating BI had received titration education/support, only one-third reached FBG target, suggesting novel strategies to achieve effective BI titration are needed.

EP052 / #240

Topic: *AS02-New Insulin Analogues*

REAL-WORLD EFFECTIVENESS AND SAFETY OF INSULIN GLARGINE 300 U/ML (GLA-300) IN OLDER ADULTS (≥70 YEARS) WITH TYPE 2 DIABETES (T2D): ATOS STUDY SUBGROUP ANALYSIS

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Background and Aims: ATOS was a 12-month prospective observational study in 18 countries outside US and Western Europe in insulin-naïve adults with T2D, uncontrolled (HbA_{1c} >7–≤11%) on ≥1 oral anti-hyperglycemic drugs. This subgroup analysis compared effectiveness and safety of Gla-300 in older (≥70 years; N = 514) and younger (<70 years; N = 3908) adult populations.

Methods: Participants included in ATOS study were stratified by age: older (≥70 years; N = 514) and younger (<70 years; N = 3908) adults. The primary endpoint was achievement of individualized HbA_{1c} target at 6 months.

Results: People aged ≥70 years had a longer duration of T2D and more comorbidities than those aged <70 years. Physician-set individualized HbA_{1c} (%) goals at baseline in the <70 vs ≥70 years groups were <7: 14.6 vs 6.2%; 7–<7.5: 72.9 vs 52.1%; 7.5–<8: 9.3 vs 30.9%; ≥8: 3.2 vs 10.7%. HbA_{1c} target achievement was higher in the older population than in the <70 years age group: Month 6 (32.3% vs 24.2%) and Month 12 (53.2% vs 43.4%). HbA_{1c} reductions from baseline to Month 6 (-1.48 vs -1.51%) and Month 12 (-1.76 vs -1.89%) were similar in both groups. A very low rate of hypoglycemia was reported, although numerically higher in ≥70 years group. Increases in the Gla-300 dose were similar across the groups. Consistent results were observed in subgroups of ≥65 and <65 years.

Conclusions: Initiation of Gla-300 in the older adults is effective in achieving their pre-defined HbA_{1c} goals with low risk of hypoglycemia in both older and younger adults with T2D.

Table: Baseline characteristics, glycemic parameters, and safety at Month 6 and 12 by age groups

	Baseline		Month 6*		Month 12*	
	Age <70 years	Age ≥70 years	Age <70 years	Age ≥70 years	Age <70 years	Age ≥70 years
Age, Years	55.0 ± 9.4	74.0 ± 4.0				
Female, n (%)	1972 (50.5)	319 (62.1)				
BMI, Kg/m²	29.4 ± 5.4	28.9 ± 5.0				
Duration of diabetes, Years	9.7 ± 5.9	14.1 ± 7.4	–	–	–	–
Any diabetes complication and comorbidity history, n (%)	2771 (70.9)	448 (87.2)				
HbA_{1c} target achievement, n (%)			841/3470 (24.2)	149/461 (32.3)	1438/3314 (43.4)	231/434 (53.2)
95% CI			22.8 to 25.7	28.1 to 36.8	41.7 to 45.1	48.4 to 58.0
HbA_{1c} <7.5%, n (%)			1454 (41.9)	169 (36.7)	2145 (64.7)	255 (58.8)
HbA_{1c} <8%, n (%)			2262 (65.2)	304 (65.9)	2709 (81.7)	346 (79.7)
HbA_{1c} (%)	9.28 ± 1.00	9.20 ± 0.94	7.78 ± 1.08	7.73 ± 0.87	7.37 ± 0.97	7.45 ± 0.89
Change from baseline (95% CI)†	–		-1.51 (-1.54 to -1.47)	-1.48 (-1.56 to -1.40)	-1.89 (-1.92 to -1.86)	-1.76 (-1.84 to -1.67)
FPG (mmol/L)	10.97 ± 2.99	11.18 ± 2.75	7.52 ± 1.92	7.63 ± 1.65	6.98 ± 1.63	7.25 ± 1.75
Change from baseline (95% CI)†	–		-3.40 (-3.47 to -3.34)	-3.52 (-3.69 to -3.35)	-3.94 (-4.00 to -3.89)	-3.92 (-4.09 to -3.75)
SMPG (mmol/L)	10.76 ± 2.59	10.77 ± 2.29	7.63 ± 1.64	7.67 ± 1.45	7.12 ± 1.43	7.25 ± 1.43
Change from baseline (95% CI)†			-3.10 (-3.16 to -3.03)	-3.07 (-3.23 to -2.92)	-3.62 (-3.68 to -3.57)	-3.51 (-3.67 to -3.35)
Basal insulin dose (U/kg)	0.19 ± 0.09	0.18 ± 0.09	0.27 ± 0.12	0.27 ± 0.12	0.29 ± 0.12	0.29 ± 0.12
Change from baseline (95% CI)	–		0.08 (0.08 to 0.09)	0.09 (0.08 to 0.10)	0.10 (0.10 to 0.11)	0.11 (0.10 to 0.10)
Body weight (kg)	81.2 ± 16.4	76.8 ± 15.0	81.7 ± 15.6	78.1 ± 14.3	81.7 ± 15.3	78.5 ± 14.2
Change from baseline (95% CI)†			-0.1 (-0.2 to 0.1)	0.4 (0.1 to 0.7)	-0.2 (-0.4 to -0.1)	0.5 (0.1 to 0.9)
Hypoglycemia incidence, % (event rate PPY)						
Documented symptomatic (≤3.9 mmol/L)	–		0.82 (0.027)	1.17 (0.031)	1.13 (0.020)	2.33 (0.031)
Documented symptomatic (<3.0 mmol/L)	–		0.13 (0.003)	0.00 (0.000)	0.15 (0.002)	0.58 (0.006)
Severe	–		0.08 (0.002)	0.39 (0.012)	0.10 (0.001)	0.39 (0.006)

Data shown are mean ± SD unless otherwise specified. Safety analyses (hypoglycemia) were undertaken in the eligible population (<70 years: [N=3908]; ≥70 years: [N=514] those meeting the inclusion/exclusion criteria and started Gla-300 ±31 days from study start). Efficacy analyses were undertaken in the evaluable population (<70 years: [N=3470]; ≥70 years: [N=461]; all eligible patients with an HbA_{1c} assessment at Month 6, of whom <70 years: [N=3314]; ≥70 years: [N=434] had an HbA_{1c} assessment at Month 12)

*6-month period for hypoglycemia defined as from the first treatment administration to visit 3 (Month 6) or treatment discontinuation, whichever occurred first. *12-month period for hypoglycemia defined as from the first treatment administration to visit 4 (Month 12) or treatment discontinuation, whichever occurred first. †LS mean change from a MMRM approach

BMI, body mass index; CI, confidence interval; FPG, fasting plasma glucose; HbA_{1c}, glycated hemoglobin; LS, least-square; MMRM, mixed model for repeated measurements PPY, per patient-year; SD, standard deviation; SMPG, self-monitored plasma glucose

EP053 / #355

Topic: *AS02-New Insulin Analogues*

RELATIVE CONTRIBUTION OF FASTING PLASMA AND POSTPRANDIAL GLUCOSE TO HBA1C AND TIR IN PEOPLE WITH T1D ON BASAL-BOLUS INSULIN THERAPY

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Background and Aims: Fasting plasma glucose (FPG) and postprandial glucose (PPG) contribution to HbA1c and time in range (%TIR) in people with type-2 diabetes on basal-bolus therapy with Lispro were published. We extended this analysis to people with type-1 diabetes (PwT1D) using data from phase-3 trial PRONTO-T1D. PwT1D received 26 weeks of mealtime ultra-rapid lispro (URLi; N = 451), postmeal URLi (N = 329) or mealtime Lispro (N = 442) and had continuous glucose monitoring (CGM) in a substudy.

Methods: Multivariate regression model quantified contribution of FPG and PPG change to change in HbA1c and %TIR. Relative contribution (RC) of PPG to FPG was determined. %TIR was derived using 10-point self-monitored blood glucose (SMBG) and CGM data. Results of mealtime groups are shown.

Results: On URLi, a 1mmol/L reduction in FPG and PPG was associated with 0.11% ± 0.02% (mean±standard error) and 0.09% ± 0.01% reduction in HbA1c, respectively, $p < 0.0001$, with RC of PPG to FPG of 82%. On Lispro, a 1mmol/L reduction in FPG and PPG was associated with reduction in HbA1c of 0.12% ± 0.02% and 0.07% ± 0.02%, respectively, $p < 0.0001$, with RC from PPG to FPG of 58%. On URLi, a 1mmol/L reduction in FPG and PPG was associated with increase in SMBG-derived %TIR of 10.0% ± 0.53% and 8.6% ± 0.47%, respectively, $p < 0.0001$. On Lispro, a 1mmol/L reduction in FPG and PPG, was associated with increase %TIR of 9.8% ± 0.56% and 8.6% ± 0.52%, respectively, $p < 0.0001$. CGM effects were similar, but FPG and PPG differed.

Conclusions: Changes in FPG and PPG significantly impacted HbA1c and %TIR in PwT1D, reinforcing the need to manage FPG and PPG for optimal glycemic control.

EP054 / #584

Topic: *AS02-New Insulin Analogues*

EFFECTIVENESS AND SAFETY OF INSULIN GLARGINE 300 U/ML (GLA-300) IN INSULIN-NAÏVE PEOPLE WITH TYPE 2 DIABETES (T2DM): A SUB ANALYSIS OF ATOS STUDY

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Background and Aims: Real-world studies have shown regional differences in clinical benefits of basal insulin therapy. The present subanalysis of the ATOS study aimed to evaluate effectiveness and safety of Gla-300 in participants with T2DM enrolled in the Gulf region.

Methods: ATOS was a 12-month, prospective, observational study in 4422 insulin-naïve adults with T2DM, uncontrolled (HbA1c >7–≤11%) on more than one oral antidiabetic drug (OAD). This subgroup analysis included participants from the Gulf region (Kuwait, Saudi Arabia, and United Arab Emirates). The primary endpoint was achievement of individualized HbA1c target at 6 months.

Results: A total of 412 eligible participants were from Gulf region. Mean age, BMI, and T2DM duration were 52.2 years, 30.3 kg/m2, and 10.7 years, respectively. History of diabetes complications and comorbidity was reported in 66.5% of participants. Predefined individualized HbA1c targets were achieved by 13.8% of patients at Month 6 and 37.2% at Month 12, with a mean HbA1c reduction of -1.29% and -1.76%, respectively. Documented symptomatic hypoglycemia with blood glucose ≤70 mg/dL was reported by only one patient. There was no reporting of severe hypoglycemia or adverse events resulting in death. Patient-reported outcomes (DTSQ and EQ-5D-3L) indicated improvement in patient satisfaction and a decrease in perceived frequency of hypoglycemia and hyperglycemia.

Conclusions: In the present subanalysis of the ATOS study, Gla-300 was associated with improved glycemic control and low hypoglycemia events. Results show that Gla-300 offers favorable therapeutic options for people with T2DM uncontrolled on OADs in the Gulf region in a real-life setting. This study was sponsored by Sanofi.

EP055 / #696

Topic: ***AS02-New Insulin Analogues***

100 YEARS WITH INSULIN. IMPLEMENTATION OF ANALOGS AND TECHNOLOGY IN OUR ENVIRONMENT

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Background and Aims: Since 2003 have been several ultrafast analogs and slow insulins that have been arriving on the market, especially in the last decade. In parallel, the use of blood glucose meters / monitors and even insulin pumps has become widespread.

Methods: To evaluate the clinical experience in the incorporation of different insulin analogues and technology in our current practice Methods: DM1 patients older than 6 months from the start of follow-up in specialty consultations at our center.Assessment of age,sex,age of debut,HbA1c,type of technology used. Descriptive study IBM SPSS Stastistics 19.0.

Results: 71 children (35♂), mean age 9.8 a [2-17]. HbA1c (DCA): 7.9% [6.1-9.2], debut time 3.9a [0.8-10.1]MDI, 6 insulin pumps. 98% use some non-capillary glucose monitoring or control system (1 patient refuses), either type continuous monitoring for age <4th or linked to CSII or flash type. Of the 6 pumps, they use lispro(4/6),aspartic(1/6) and another glulisine(1/6) MDIs,NPH 0/65,detemir12/65(85% are <6 years),U100-10/65,U300-35/65 liraglutide 8/65.The indication has been for age,comfort,morning/night dissociated doses,variability control and switch due to poor previous basal adjustment.Actrapid0/65,lispro30/65(1 U200 off labell per dose),aspartic 10/65,ultrafast (15/65) and glulisine 10/65.68/71 patients(100% of >4th) are on inhaled glucagon.Previous severe hypoglycemia with previous loss of consciousness in <5% of cases (0.03 patient/year cases).ISCI offered to 70% of families. 80% initial rejection rat.

Conclusions: We assume that this study may have some shortcomings due to the size of the sample, but our study demonstrates the implementation of the most modern analogs in the office, of measurement technology, but the need to advance in the use of insulin pumps.

EP056 / #737

Topic: ***AS02-New Insulin Analogues***

OPEN-SOURCE AUTOMATED INSULIN DELIVERY WITH INSULIN LISPRO COMPARED TO ULTRA-RAPID INSULIN IN A MAN WITH TYPE 1 DIABETES MELLITUS: A CASE REPORT

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Background and Aims: Rapid-acting insulin analogues still insufficiently reduce postprandial glucose excursion after meals. The development of new ultra-rapid insulin analogues aims to mimic physiological insulin secretion even better and to improve postprandial glucose control.

Methods: We report on a 33-year-old man with type 1 diabetes mellitus (diabetes duration 28 years, BMI 25.1 kg/m^2) using an Android Artificial Pancreas System (AAPS, version 2.8.2) in combination with a DANA RS insulin pump (Sooil, South Korea) and a Dexcom G6 sensor (Dexcom, USA) with insulin lispro and ultra-rapid insulin lispro (URLi, both Eli-Lilly) for 3 months each. Data was collected retrospectively from the electronic medical record and the Nightscout documentation.

Results: When using insulin lispro, mean glucose was 7 ± 2.4 mmol/L (127 ± 43 mg/dl), HbA1c was 45mmol/mol (6.3%), and time in (<70%), below (<5%), and above (>25%) the glucose target range (3.9-10.0 mmol/L) was 83.4%, 5.3%, and 11.3%, respectively. Mean glucose of 6.4 ± 1.9 mmol/L (115 ± 35 mg/dl), HbA1c of 42 mmol/mol (6.0%), and time in, below, and above the glucose target range of 90.0%, 5.7%, and 4.3%, respectively, was observed with URLi. Total daily insulin was 41.6 ± 7.3 units (insulin lispro) and 30.7 ± 7.6 units (URLi). Mean carbohydrate intake per day during both periods was 277 ± 65.9 g (insulin lispro) and 225.8 ± 53.4 g (URLi).

Conclusions: We observed improved glycaemic control while using URLi, in particular the percentage of time in target range increased, while the time above target range decreased. This is most likely attributed to improved postprandial control with URLi, even in the setting of well controlled type 1 diabetes managed with AAPS.

EP057 / #753

Topic: ***AS02-New Insulin Analogues***

EFFICACY AND SAFETY OF GLA-300 VERSUS IDEG/ASP IN PEOPLE WITH TYPE 2 DIABETES (PWT2D): A SYSTEMATIC LITERATURE REVIEW AND INDIRECT TREATMENT COMPARISON (ITC)

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Background and Aims: This analysis compared the efficacy and safety of insulin glargine 300 U/mL (Gla-300) with premixed insulin degludec/insulin aspart (IDeg/Asp) in insulin naïve PWT2D inadequately controlled on oral antidiabetic drugs (OADs), using the Bucher ITC method.

Methods: MEDLINE®, Embase®, and CENTRAL databases were searched (from inception to April 23, 2021) for randomized controlled trials (RCTs) evaluating once-daily Gla-300 or IDeg/Asp in insulin naïve PWT2D. Changes in HbA_{1c}, body weight, final insulin dose, and hypoglycemia incidences were assessed at 26 weeks.

Results: Four RCTs involving 2,304 PWT2D were eligible for ITC analysis (Gla-300 vs Gla-100, n = 2; IDeg/Asp vs Gla-100, n = 2). Mean baseline HbA_{1c} was similar across trials, but BMI was heterogeneous (ranging from 25.1 to 33.0 kg/m^2). No significant differences were observed between Gla-300 and IDeg/Asp in HbA_{1c} change (mean difference [MD]: 0.10%; 95% confidence interval [CI]: −0.20, 0.39; $p = 0.5$) or final insulin dose (MD: 0.03 U/kg; 95% CI: −0.05, 0.12; $p = 0.4$). Body weight gain (MD: −1.31 kg; 95% CI: −1.97, −0.65; $p = 0.0001$), any hypoglycemia (odds ratio [OR]: 0.62; 95% CI: 0.41, 0.93; $p = 0.02$) and confirmed hypoglycemia (plasma glucose [PG] <3.0–3.1 mmol/L) incidence (OR: 0.47; 95% CI: 0.25, 0.87; $p = 0.02$) were significantly lower with Gla-300 vs IDeg/Asp. No significant differences were observed for confirmed (PG <3.9 mmol/L) or severe hypoglycemia.

Conclusions: Insulin naïve PWT2D inadequately controlled on OADs commencing Gla-300 may achieve similar glycemic improvements with less weight gain and lower risk of clinically significant hypoglycemia (PG <3.1 mmol/L) compared with IDeg/Asp.

EP058 / #778

Topic: ***AS02-New Insulin Analogues***

USE OF AN ULTRA-RAPID ACTING INSULIN ANALOG WITH CONTROL-IQ: A CASE REORT

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Background and Aims: Newer insulin analogs with a faster onset of action have recently been approved for the management of type 1 diabetes (T1D), however their impact on glycemic control in hybrid closed-loop systems designed for analogs with different pharmacokinetic profiles has not been determined.

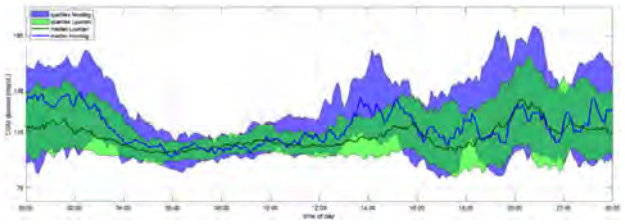
Methods: Data from a 19-year-old with T1D using a Tandem t:slimX2 pump with Control-IQ technology and a Dexcom G6 CGM were compared while using Lyumjev (13 weeks) followed by Novolog (4 weeks).

Results: Average total daily insulin and carbohydrate intake were similar with both insulin analogs (48.6 units vs. 46.9 units; 43 g vs. 34 g). TIR was higher and TBR was lower with use of Lyumjev (Table) with fewer average daily boluses (5.9 vs. 6.7). Average CGM with Lyumjev was 113 mg/dL compared to 121 mg/dL with Novolog, and the daily CGM profile on Lyumjev was notably tighter (Figure). Table

Conclusions: The use of an ultra-rapid acting insulin with Control-IQ improved glycemic control in a well-controlled patient following a low carbohydrate diet without modifications to the control algorithm.

TIR data (CGM)

	Lyumjev	Novolog
% <54 mg/dL	0% [0-0.7]	0% [0 – 0.7]
% <70 mg/dL	2.4% [0.7-5.5]	4.9% [3.3 – 8.5]
% 70-140 mg/dL	79.2% ± 9.6%	68.8% ± 9.5%
% 70-180 mg/dL	90.9% ± 6.9%	84.9% ± 6.0%
% >180 mg/dL	3.7% [0 – 8.1]	9.7% [5.5 – 13.2]
% >250 mg/dL	0% [0 – 0]	1.7% [0 – 4.5]



EP059 / #87

Topic: ***AS02-New Insulin Analogues***

EVALUATION OF PATIENT REPORTED SATISFACTION AND CLINICAL EFFICACY OF INSULIN GLARGINE 300 U/ML VERSUS 100 U/ML IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: To analyze patient reported satisfaction and clinical effectiveness of concentrated insulin glargine 300 U/mL (Gla-300) among patients with type 1 diabetes (T1D) using Intermittent-scanning continuous glucose monitoring'' (iscCGM) system.

Methods: In this single arm, single centre prospective study, conducted among 86 patients with T1D (aged 14-40 years), who

were treated with Glargine 100 U/mL (Gla-100) and switched to Gla-300 at day 1 (baseline). In addition to demographic data, clinical parameters, markers of glycemic control were also collected. All patients completed the Arabic version of the diabetes treatment satisfaction (DTSQ) questionnaire at baseline and at 12 weeks. All the observed data on baseline (Gla-100) and 12 weeks (Gla-300) were compared and analyzed.

Results: Ambulatory glucose profile (AGP) markers, i.e., mean time in range (TIR), mean time above range (TAR) mean time below range (TBR), mean glucose level, hemoglobin A1c (HbA1c) and total daily dose of insulin (TDDI) were shown a markable but, insignificant improvement after 12 weeks of Gla-300 treatment. Compared to Gla-100, patients treated with Gla-300 experienced insignificant improvement in the current treatment satisfactions. In addition, patients on 12 weeks of Gla-300 treatment showed a statistically insignificant improvement in convenient finding treatment recently, flexible finding treatment recently, satisfied with understanding diabetes, recommend the current treatment and satisfied to continue the current treatment compared to Gla-100.

Conclusions: Both Gla-100 and Gla-300 showed statistically comparable results on clinical measures of glycemic control and patient-reported satisfaction.

Table: Comparisons of glucose management and patient-reported outcomes

	G1 (reference) (N=77)	G2 (N=116)	G3 (N=94)	G4 (N=300)	G5 (N=200)
Percentage of HbA1c ≤ 7%, by model [a]	53.3%	32.1%	28.1%	30.4%	39.1%
0	-	**	**	***	*
1	-	**	**	***	*
2	-	**	***	***	*
3	-	***	***	***	*
4	-	***	***	***	*
Episodes of hypoglycemia during the past 3 days, by model [a]	1.0 (0, 3.0)	1.0 (0, 2.0)	1.0 (0, 2.0)	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)
0	-	NS	NS	NS	*
1	-	NS	NS	NS	*
2	-	NS	NS	NS	*
3	-	NS	NS	NS	*
4	-	NS	NS	NS	NS
Hypoglycemia Fear Survey-II Total score, by model [b]	31.0 (20.0, 42.5)	31.0 (19.3, 48.8)	32.0 (21.0, 42.0)	31.0 (22.0, 44.0)	31.0 (21.0, 44.0)
0	-	NS	NS	NS	NS
1	-	NS	NS	NS	NS
2	-	NS	NS	NS	NS
3	-	NS	NS	NS	NS
4	-	NS	NS	NS	NS
Diabetes Distress Scale score, by model [b]	2.00 (1.50, 2.71)	1.91 (1.47, 2.88)	1.91 (1.35, 2.66)	1.94 (1.41, 2.69)	2.00 (1.47, 2.63)
0	-	NS	NS	NS	NS
1	-	NS	NS	NS	NS
2	-	NS	NS	NS	NS
3	-	NS	NS	NS	NS
4	-	NS	NS	NS	NS

Data were presented as percentage or median (IQR).
[a] Logistic regression models were applied. [b] linear regression models were applied. Model 0: no adjustment; model 1: adjusting for sex; model 2: adjusting for age; model 3: adjusting for sex and age; model 4: adjusting for sex, age and insurance status.
NS: not significant from the reference group. *: P < 0.05; **: P < 0.01; ***: P < 0.001.

EP060 / #100

Topic: ***AS03-Artificial Pancreas***

COMPARISON OF GLUCOSE MANAGEMENT AND PATIENT-REPORTED OUTCOMES BETWEEN AUTOMATED INSULIN DELIVERY SYSTEM AND OTHER TREATMENT MODALITIES IN ADULTS LIVING WITH TYPE 1 DIABETES

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Background and Aims: There is no real-world study comparing automated insulin delivery (AID) system with other main therapeutic options: [capillary blood glucose (CBG)+multiple daily insulin injection (MDI), continuous glucose monitoring (CGM)+MDI, CBG+pump and CGM+pump] in people living with type 1 diabetes (PWT1D). We aim to compare AID with the other options' glucose management and patient-reported outcomes among adult PWT1D.

Methods: Cross-sectional study using data from the BETTER registry, a registry recruiting PWT1D in Quebec, Canada. Inclusion criteria: type 1 diabetes, aged ≥18 y/o, using MDI or pump,and not pregnant. Among 787 eligible participants (65.1% female), median (Q1-Q3) age was 43.0 years (32.0, 56.0) with 23.0 years (11.0, 35.0) of diabetes. About 77 used AID (Group 1), 116 CBG+MDI (G2), 94 CBG+pump (G3), 300 CGM+MDI (G4) and 200 CGM+pump (G5). Regression models were used to assess the difference between G1 and the other groups.

Results: AID users had the highest proportion of attaining hemoglobin A1c ≤ 7%: G1 (53.3%) vs. G2 (32.1%) vs. G3 (28.1%) vs. G4 (30.4%) vs. G5 (39.1%). The abovementioned differences between G1 and each of the other groups were statistically significant, even after adjusting for age, sex and insurance status (Table). No difference between groups were found for reported hypoglycemic episodes (<4.0 mmol/L), Diabetes Distress Scale score or Hypoglycemia Fear Survey-II score after adjustment.

Conclusions: In a real-world setting, AID is the treatment modality associated with the most optimal glucose outcomes.

EP061 / #124

Topic: ***AS03-Artificial Pancreas***

ADVANCED HYBRID CLOSED LOOP SYSTEM MINIMED 780G IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES: DOES PREVIOUS PUMP EXPERIENCE IMPACT THE GLYCEMIC CONTROL?

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Background and Aims: The aim of the study was to evaluate glycemic control between Multiple Daily Injection (MDI) and Insulin Pump (IP) therapy in children and adolescents switching to Advanced Hybrid Closed Loop (AHCL) System MiniMed 780G (Medtronic, Northridge, US).

Methods: Children and adolescents (aged 7-18 years) with T1D, who initiated AHCL system were analyzed int two groups: MDI Group, participants with previous MDI therapy and IP Group, participants with previous Insulin pump therapy (open loop system with or without sensor). The primary outcome of the study was group change in the time spent in the target in range (TIR) of 70-180 mg/dl and HbA1c from baseline (MDI + CGM, 1 week) to study phase (AHCL, 12 weeks).

Results: A total of 98 patients were analyzed: 53 patients (age 11.6 ± 1.9 years) in MDI group and 45 patients (age 12.9 ± 2.2 years) in IP group. HbA1c in the MDI group decreased from

8.6 ± 1.3% (69 ± 13.1 mmol/mol) at baseline to 6.7 ± 0.9% (54 ± 9.8 mmol/mol) at the end of the study (p = 0.001), compared to the IP group for which HbA1c decreased from 7.7 ± 1.5% (70 ± 14.2 mmol/mol) to 6.6 ± 1.1% (53 ± 12.0 mmol/mol), (p = 0.001), respectively). No significant difference of HbA1c and TIRs between groups was found at the end of the study. No DKA events and severe hypoglycemia in both groups was observed during the study.

Conclusions: Previous pump experience is not needed to improve glycemic control when switching to AHCL system, like MiniMed 780G. Children and Adolescents with T1D previously treated with MDI can achieve similar results with those previously treated with IP therapy.

EP062 / #190

Topic: ***AS03-Artificial Pancreas***

FEASIBILITY OF A CLINICAL TOOL TO SUPPORT CLINICIANS IN CARING FOR PERSONS WITH DIABETES USING AUTOMATED INSULIN DELIVERY

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Background and Aims: Clinicians face challenges implementing new AID technologies in their clinical practice. The aim of this study was to test the feasibility of a clinical tool (Figure) to assist clinicians in providing care for people with diabetes using the t:slim X2 Control-IQ, a new AID system.

Methods: Diabetes clinicians were recruited to use the Tool during clinical encounters with Control-IQ users. Clinicians completed the system usability scale (SUS) to assess satisfaction and usability of the Tool, ranked their confidence in provided care to Control-IQ users on a 1-10 scale, and reported additional feedback on helpful aspects of the Tool and whether it changed their clinical practice.

Figure 1. Control-IQ Clinic Tool, available at http://BDCPantherDiabetes.org

The PANTHER Program Control-IQ clinic tool consists of: 1)Introduction: Brief summary of Control IQ system and instructions for using the tool. 2)Dashboard Report Assessment: assessing time in range, system use and insulin delivery. 3)CGM Hourly and Timeline Assessment: assessing glucose patterns and bolus behaviors; education on bolusing, hypoglycemia management and infusion set changes. 4)Device settings and education: Information on which insulin pump settings can be adjusted and optimizing control IQ device settings. 5)Electronic Heath Record (EHR) Note: Template language that can be copy and pasted into an EHR note. 6)After Visit Summary: Summary handout of key education for Control-IQ users to take home after clinic visit

Results: Twenty-eight clinicians from 9 clinical centers in the United States completed a total of 89 clinical encounters using the Tool. SUS scores were in the 90-95th percentile for usability and clinician confidence in providing care increased from 7.6 (6.7, 8.5) at baseline to 9.00 (8.6, 9.2) after using the Tool (p < 0.001). Seventy-five percent of clinicians reported overall satisfaction with the tool and 90% indicated they would recommend the tool to colleagues. Ninety percent of participants affirmed that use of the Tool changed their clinical practice and indicated that the tool's systematic guidance to data assessment and clinical recommendations increased their confidence in providing care.

Conclusions: The Control IQ clinical tool was feasible and acceptable to clinicians. Practical tools that can support clinicians at the point of care may help to bolster clinician confidence in providing care amidst a rapidly evolving landscape of diabetes technologies.

EP063 / #241

Topic: ***AS03-Artificial Pancreas***

RETROSPECTIVE REAL-LIFE STUDY ON THE IMPROVEMENT OF GLUCOSE CONTROL OVER 6 MONTHS AFTER SWITCHING FROM AN OPEN TO A CLOSED-LOOP IN TYPE 1 DIABETIC PATIENTS

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Background and Aims: Glucose control in type 1 diabetic patients (T1D) can be suboptimal under open-loop (OL) despite the use of alarm thresholds (Préau Y. Sensors 2021). We aimed to evaluate the benefits at 6 months of switching to closed-loop (CL).

Methods: Ambulatory glucose profile parameters were collected retrospectively in 21 T1D (age 43 ± 17 years, BMI 26 ± 4, duration of diabetes 20 ± 10 years, 16 women) over the last 3 months (M0) of OL (FreeStyle Libre1 or Dexcom platinum G4) and of 6-month CL (minimed 780G Medtronic system), then expressed as 24-hr averages. Data are means ± standard deviation or medians [Q1;Q3] and statistics were performed using paired t-test or Wilcoxon for matched-pairs.

Results: After 6 months on CL, TIR 70-180 mg/dL increased (77 ± 6 vs. 58 ± 12%, p < 0.0001), time in hyperglycemia TAR 181-250 mg/dl and TAR >250 mg/dL decreased (15 [13;21] vs. 25 [23;27]%, p < 0.0001; 3 [1;4] vs. 11 [5;15]%, p < 0.0001; respectively) as well as mean interstitial glucose concentration (142 ± 12 vs. 166 ± 23 mg/dL, p < 0.0001), glucose management indicator (6.7 ± 0.3 vs. 7.3 ± 0.5%, p < 0.0001), glucose CV% (34 ± 3 vs 39 ± 6, p = 0.0017) and blood HbA1c (6.8 ± 0.7 vs 7.7 ± 1.0, p < 0.0001). No change was observed for the times in hypoglycemia (TBR 69-54 mg/dL: 2 [1;3] vs. 3 [1;5]%; TBR <54 mg/dL: 0.0 [0;1] vs. 0.5 [0.2;2.3]%).

Conclusions: After 6 months of switch to CL the TIR was very significantly improved (+19 points) and the time in

hyperglycemia significantly reduced, in agreement with the literature (Brown S.A. NEJM 2019, Amadou C. Diabetes Care 2021, DuBose S. DTT 2021), without an increase in the time spent in hypoglycemia.

EP064 / #253

Topic: ***AS03-Artificial Pancreas***

GLUCAGON PHARMACOKINETICS IN A PIG MODEL

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Background and Aims: There is increasing evidence supporting the use of low-dose glucagon in addition to insulin in artificial pancreases for patients with diabetes mellitus type 1. By delivering both hormones intraperitoneally one could mimic normal physiology. However, our knowledge of the pharmacological properties of glucagon after intraperitoneal administration is limited. This study aims to compare the pharmacokinetics of glucagon after intraperitoneal, subcutaneous and intravenous administration and the pharmacodynamic effects of glucagon on glucose metabolism after intraperitoneal and subcutaneous administration in a pig model.

Methods: 12 pigs were included. 1.5 μg/kg glucagon was administered intraperitoneally, subcutaneously and intravenously in a randomised order. Samples for plasma glucagon and arterial blood glucose were collected every 2-10 minutes for 150 minutes.

Results: The bioavailability of glucagon is significantly lower after intraperitoneal compared to subcutaneous administration, amounting to (mean (95 per cent confidence interval)) 3 (2-5) and 22 (6-38) per cent, respectively. The effects on glucose metabolism are equivalent.

Conclusions: Despite having lower bioavailability, intraperitoneally administered glucagon exerts the same effects on glucose metabolism as subcutaneously delivered glucagon. We regard this as evidence of a large first-pass metabolism of glucagon in the liver, which, in theory, could favour the intraperitoneal route for an artificial pancreas.

EP065 / #260

Topic: ***AS03-Artificial Pancreas***

DEVELOPMENT OF A "COGNITIVE AWARENESS ARTIFICIAL PANCREAS ENHANCEMENT" (CAPE) TO HELP ADOLESCENTS WITH T1D OPTIMIZE THEIR USE OF ARTIFICIAL PANCREAS SYSTEMS

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Background and Aims: Background and Aims: Artificial pancreas (AP) systems can improve glycemic control in adolescents and young adults (AYA) with T1D. Harnessing inputs related to physiological, cognitive, behavioral, and emotional states may improve the use of AP by lending information on situational awareness of the user related to their diabetes self-management. These data can be used to design and implement smart ''nudges'' to promote the user toward better diabetes self-management behaviors.

Methods: Methods: A multidisciplinary team selected putative inputs for a ''cognitive awareness'' AP enhancement based on theoretical importance in determining situational awareness, practicality of collection, and privacy concerns. Selected inputs included diabetes-related decisions and behaviors (boluses, meals, insulin pump screen views), heart rate, sleep, exercise, and subjective assessments of motivation, mood, stress, and social support. Data were collected passively by smart devices (cell phone, watch) and by survey (figure).

Results: Results: A total of 10 AYA using a Control-IQ AP system collected data for 14 days each by wearing a smart watch, carrying their smart phone, responding to brief state assessment surveys throughout day and using the AP system as part of routine diabetes care. Data will synthesized into complex hierarchical models to determine optimal timing of ''nudge'' interventions to impact diabetes self-management.

Conclusions: Conclusion: A future ''cognitively aware'' system will be predicated on physiological, cognitive, and emotional data that can predict optimal times to intervene with the AP user. Future studies will determine optimal timing of smart ''nudge'' interventions and the efficacy of this approach to improving diabetes self-management in AYA with T1D.

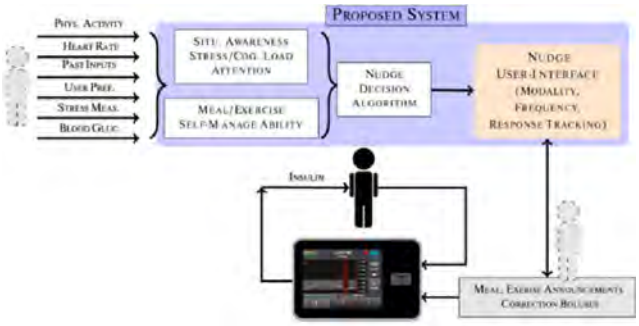

Figure: The CAPE project utilizes physiological, cognitive, behavioral, and emotional inputs to develop smart "nudges" to improve diabetes self-management in adolescents with T1D using artificial pancreas systems.

EP066 / #290

Topic: ***AS03-Artificial Pancreas***

SERACCESS® - A NOVEL INTRAVENOUS AUTOMATED INSULIN DELIVERY SYSTEM. A FEASIBILITY STUDY CHARACTERIZING THE AUTOMATED GLUCOSE MEASUREMENT (AGM)

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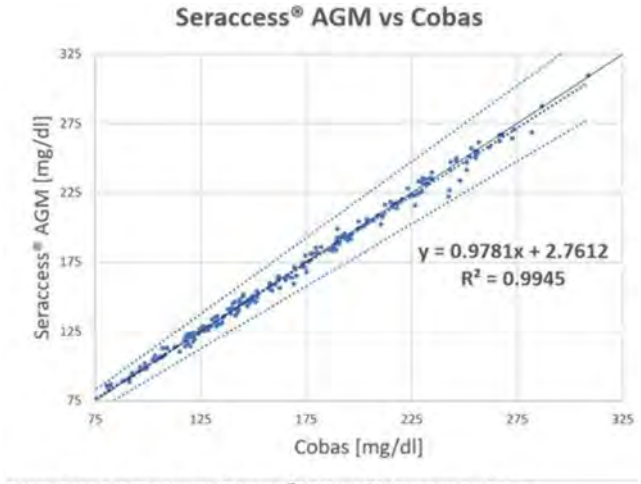
Background and Aims: We are developing an innovative blood glucose control technology based on intravenous blood

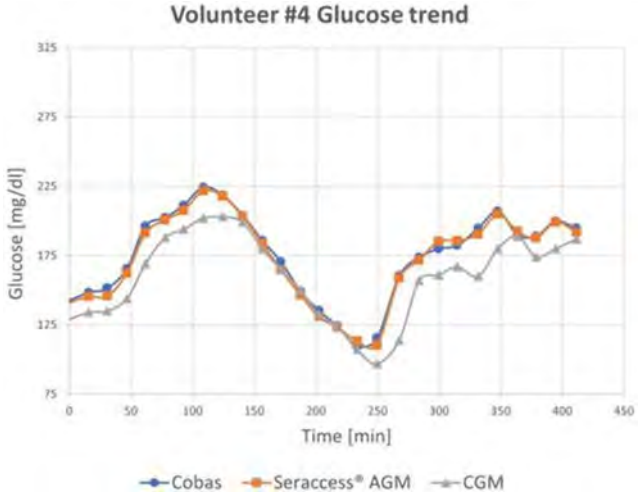


Values of one diabetic volunteer: Seraccess® AGM and CGM compared to Cobas.

sampling and insulin delivery. Compared to current subcutaneous technologies, the intravenous pathway enables more accurate measurements and removes the time lag between interstitial and blood compartments. A wearable device extracts plasma out of blood, photometrically measures glucose by using the hexokinase reaction and calculates the insulin dosage. Here, we present data of a feasibility study of the new AGM in a clinical environment. Volunteers with diabetes type-1 using a CGM were included, which enabled us to additionally compare the glucose values in venous samples with the sensor results.

Methods: The feasibility study contained eight 6-hour measurement sessions. Blood samples were collected via a catheter (PVC) every 15-20 minutes and CGM values were recorded. The glucose level in each sample was measured with the new AGM and with a Roche Cobas for reference.

Results: The blood glucose measurement accuracy was evaluated by the MARD, which was 2.3%. 196 out of 196 measurements (100%) were in the ±10% error interval. The corresponding MARD of the CGM values was 7.8%.



Conclusions: The results show the good accuracy of the new device compared to the reference method. Because intravenous sampling eliminates the lag between venous and interstitial compartments, it reduces the overall delay, leading to higher performance.

The new method is an effective technique to be used in automated insulin delivery systems: combined with closed-loop computation of the insulin quantity.

EP067 / #301

Topic: ***AS03-Artificial Pancreas***

SLEEP AND FEAR OF HYPOGLYCEMIA IN PARENTS OF YOUTH WITH TYPE 1 DIABETES FOLLOWING IMPLEMENTATION OF HYBRID CLOSED-LOOP TECHNOLOGY

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Background and Aims: Parents of youth with type 1 diabetes (T1D) frequently have fear of hypoglycemia (FOH), especially during the night, and are often not meeting the recommendations for sleep duration. Hybrid Closed-Loop (HCL) technologies positively impact glycemic control and quality of life. The aims of this analysis were to test for associations between parent FOH and sleep measures and to evaluate change in parent FOH over time, following initiation of HCL technology.

Methods: Parents (age 42.0 [IQR 38.0, 47.5] yrs, 82.1% female) of 39 youth with T1D (age 11.1 ± 3.6 yrs, 53.8% male, T1D duration 1.1 [IQR 0.3, 2.9] yrs) starting on Tandem's Control-IQ (CIQ) HCL system wore actigraphy watches for objective sleep data and completed the Hypoglycemia Fear Survey (HFS). Mixed effects models were used to test associations between HFS scores and actigraphy measures and to evaluate change in HFS scores over time.

Results: No significant associations were observed between actigraphy sleep measures and HFS total and subscales. However, significant decreases in Parent HFS scores were observed from Baseline to 3 and 6 months (Table).

Conclusions: Significant improvements in parental FOH were seen over 3-6 months of CIQ use, suggesting that HCL technology positively impacts FOH in parents of youth with T1D. Additionally, the improvement was maintained through 6 months, indicating sustained effects on FOH. Further research is needed to determine the impact of long-term HCL system use on parental FOH and the relationship with sleep.

Table: Parent HFS Total and Subscale Scores

	Baseline Mean ± SE	Month 3 Mean ± SE	Baseline-Month 3 p-value	Month 6 Mean ± SE	Baseline-Month 6 p-value
Total	43.3 ± 2.2	36.4 ± 2.2	**0.01**	34.7 ± 2.4	**0.002**
Worry	20.8 ± 1.3	15.9 ± 1.3	**0.01**	15.2 ± 1.5	**0.005**
Worry-helpless/low BG	17.6 ± 1.1	13.2 ± 1.1	**0.002**	13.3 ± 1.2	**0.005**
Worry-negative social consequences	3.15 ± 0.4	2.65 ± 0.4	0.61	1.9 ± 0.5	0.08
Behavior	22.5 ± 1.2	20.6 ± 1.2	0.10	19.5 ± 1.3	**0.01**
Behavior-maintain high BG	4.2 ± 0.5	4.1 ± 0.5	0.98	3.5 ± 0.5	0.26

*Statistics reported are least-squares means and SE; p-values represent the change in scores between timepoints

EP068 / #308

Topic: ***AS03-Artificial Pancreas***

CONTROLLED DELIVERY OF VEGF USING AN IMPLANTABLE HYDROGEL LOADED SOFT ROBOTIC DRUG DELIVERY SYSTEM TO PREVASCULARISE AN IMPLANT SITE FOR ISLET TRANSPLANTATION

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Background and Aims: Over 60% of islets transplanted in macrodevices are lost immediately post transplantation due to hypoxia from inadequate early vascularisation. Our approach is to stabilise and extend the half-life of VEGF *in vivo* by electrostatically interacting it with a carboxymethylcellulose-sodium alginate (CMC-SA) based hydrogel and loading into the soft robotic drug delivery (SRDD) system, which will be actuated to release a predetermined amount of VEGF with the aim to prevascularise an implant site for islet transplantation.

Methods: Animal protocols were carried out in accordance with the Italian Ministry of Health (Authorisation number 719/2020-R). SRDD systems were filled with CMC-SA based hydrogel without (N = 8) or with VEGF (N = 9) and implanted subcutaneously in the dorsal region of female Sprague Dawley rats. The SRDD system was connected to a vascular access button implanted at the neck of the rats to facilitate once daily actuation for 7 days by the external system. SRDD systems and surrounding tissue were explanted *en bloc* at euthanasia with samples stained with CD31 (neovessel density) and αSMA (vessel maturity and stability) for histological analysis of angiogenesis.

Results: Preliminary results suggest a trend towards increased number and length density of CD31+ and αSMA+ neovessels with a decrease in radial diffusion distance in CD31+ and αSMA+ tissue samples in the VEGF treated group compared to the no VEGF controls.

Conclusions: Histological analysis is still ongoing, but controlled delivery of VEGF by the SRDD system appears to stimulate angiogenesis at the implant site for future islet transplantation.

EP069 / #363

Topic: ***AS03-Artificial Pancreas***

COLLAGEN AND ENDOTHELIAL CELL CO-CULTURE IMPROVES BETA-CELL FUNCTION AND SUPPORTS PANCREATIC ECM IN HYPOXIC CONDITIONS

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Background and Aims: Pancreatic islet transplantation is a promising therapeutic advancement in the treatment of type 1 diabetes; however, a major obstacle remains in supporting cell function in the hypoxic post-transplant conditions. Advancements in islet transplantation research has shown that encapsulation of the islets within a hydrogel functionalized with extracellular matrix (ECM) proteins can support cell survival and function. The goal of this study was to assess how pancreatic ECM proteins are affected by post-transplant-like hypoxic conditions in an effort to improve tissue-engineered strategies to support transplant efficacy.

Methods: We investigated the expression of pancreatic ECM proteins in human native tissue, including basement membrane proteins, proteoglycans, and fibril-forming proteins. We used the EndoC-βH3 pseudo-islet system for our *in vitro* hypoxia model and identified that the ECM proteins were affected differently by the hypoxic conditions. We further encapsulated the pseudo-islets within a collagen type 1 (COL1) hydrogel with endothelial cells to support β-cell function and relevant ECM expression.

Results: The COL1 hydrogel improved function of β-cells under hypoxic conditions while also mitigating the impact on proteoglycans and fibril-forming protein expression. The incorporation of endothelial cells into the hydrogel further improved the β-cell response as well as the expression of relevant ECM proteins.

Conclusions: COL1 hydrogels supported with endothelial cells can serve as initial source of ECM proteins to allow cell engraftment while preserving cell functionality post-transplantation.

EP070 / #370

Topic: ***AS03-Artificial Pancreas***

A SHORT-TERM EVALUATION OF CHILDREN WITH DIABETES USING MEDTRONIC 780G SYSTEM- A SINGLE CENTER EXPERIENCE FROM TURKEY

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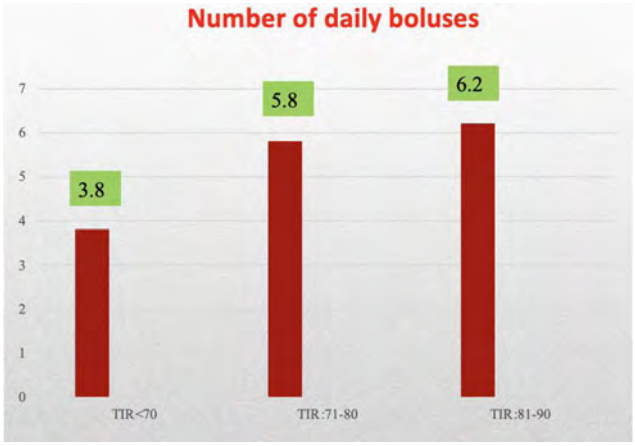
Background and Aims: The MiniMed™ 780G has been used in Turkey since January 2021. We aimed to evaluate its impact on achieving treatment goals and the parameters affecting the time in range(TIR).

Methods: Two separate analyzes were performed. First one included comparison in children who transitioned from Medtronic 640G system to the Medtronic 780Gsystem. The second



one included the first 3 month-period analysis regarding frequency of achievement of glycemic goals, and factors related with TIR children using Medtronic 780G system, regardless their previous treatment.

Results: First cohort included the children(n:25, age:10.5 ± 2.5 years) those who have at least 3 month-period data.TIR(70-180 mg/dl) increased from 75.5 ± 10 % at baseline to 80 ± 6.2% (p:0.008), while TAR (>180mg/dl) reduced from 17.9 ± 7.7% at baseline to 15 ± 4.8 % (p:0.022). No differences in TBR(<70mg/dl) and CV were noticed. Second cohort included the children(n:33, age: 12.1 ± 3.2years) under 780G-system for at least 3-months. In this group, the success rate of achieving three targets (TIR >70%, TBR <4% and GMI <7%) is 81%.Number of calibrations and ratio of bolus/TDD had positively correlated with TIR, whereas TDD, ratio of basal insulin, ratio of autocorrection were negatively correlated with TIR. The number of boluses around 4-6 positively affects the TIR rate (Figure1).

Conclusions: MiniMed™ 780G has enabled the majority of children with Type 1 diabetes to reach CGM metric targets. As the bolus insulin rate increases, TIR increases, while high basal insulin rate and high autocorrection rate negatively affect the TIR rate. Optimal bolus number may be recommended as 6/day.

EP071 / #384

Topic: ***AS03-Artificial Pancreas***

NIDOGEN-1 IMPROVES BETA-CELL FUNCTIONALITY AND SURVIVAL UNDER POST-TRANSPLANTATION CONDITIONS

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Background and Aims: Islet transplantation is a promising treatment option for diabetes mellitus type I (T1D); however, 50 % of transplanted islets fail within short term due to ischemic conditions at the transplantation site. Therefore, new strategies to support islet survival post-transplantation are required to improve the efficacy of islet transplantation. In this study, we investigated the effect of the basement membrane protein Nidogen-1 (NID1) on human β-cells under hypoxic conditions.

Methods: We created a glucose-responsive pseudo-islets from the human β-cell line EndoC-βH3. We supplemented these pseudo-islets with different concentrations of NID1 and cultured them under normoxic (20% O_2) and hypoxic (1% O_2) conditions for 72h. Subsequently, we investigated NID1-treated and control islets using immunofluorescence staining, Raman microspectroscopy, DigiWest and glucose stimulated insulin secretion (GSIS) assays.

Results: We discovered that NID1 at 30 μg/mL significantly improves glucose-responsiveness under normoxic conditions. NID1-treatment significantly improved survival of pseudo-islets under hypoxic conditions while preserving glucose-responsiveness. Binding and blocking assays confirmed that NID1 acts on β-cells via the integrin $\alpha v\beta 3$ through Wnt and MAPK pathway signaling.

Conclusions: Our data proposes that NID1 improves the survival of human β-cells under post-transplantation conditions and is therefore a promising protein to be used in islet transplantation.

EP072 / #546

Topic: ***AS03-Artificial Pancreas***

GLYCEMIC OUTCOMES WITH OPEN-SOURCE AUTOMATED INSULIN DELIVERY SYSTEMS AFTER 12 MONTHS OF USE IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: Open-source automated insulin delivery (AID) systems, also known as do-it-yourself artificial pancreas system (DIY APS), have been self-building and supported by online communities of patients with type 1 diabetes (T1D). This approacht represents an alternative to commercial AID in order to improve glycemic control. The aim of the study was to evaluate retrospectively glycemic outcomes with the use of DIY APS in adults with T1D.

Methods: Subjects with T1D started using open-source AID systems (AndroidAPS with Insight insulin pump and Dexcom G6 or FreeStyle Libre 2 CGM and Loop with Minimed Paradigm and Dexcom G6). Glycemic outcomes at baseline on open-loop and after 12 months on DIY APS were analyzed.

Results: 23 users open-source AID systems (22 AndroidAPS and 1 Loop) were included (age 38.4 ± 10 years, 56.5% females, diabetes duration 20.8 ± 10.6 years and capillary HbA1c 6.6 ± 0.5%). 18 patients previous insulin pump users with a use 3.5 ± 4 years, 5 previously treated with multidose and CGM use 2.6 ± 2.1 years. Glucose Management Indicator (GMI) decreased from 6,6 ± 0.6% to 6 ± 0.5% ($p < 0.001$) and time in range (TIR) 70–180 mg/dL increased from 69.9 ± 11.5% at baseline to 87.5 ± 7.8% at 12 months ($p < 0.001$). Time in hyperglycemia >180 and >250mg/dL were reduced from 23.5 ± 11,5 to 9.6 ± 7.5% and from 5,8 ± 4% to 2.1 ± 3.2, respectively ($p < 0.001$). Time in hypoglycemia <70 mg/dL decreased from 5 ± 3.6% to 2.8 ± 2.1% ($p = 0.006$). At year, improvements in coefficient of variation from 35.7 ± 6% to 30.3 ± 6.2% ($p = 0.001$) and sensor glucose from 144.7 ± 18.3% to 127 ± 14% ($p < 0.001$).

Conclusions: Open-source AID systems achieves a sustained improvement in glycaemic control and glycemic variability in adults with T1D.

EP073 / #550

Topic: *AS03-Artificial Pancreas*

THE DBLG1 SYSTEM CAN IMPROVE BLOOD SUGAR CONTROL IN PEOPLE WITH POORLY CONTROLLED TYPE 1 DIABETES, ESPECIALLY WHEN THE INITIAL IMBALANCE IS HIGH.

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Background and Aims: In type 1 diabetes (T1DM), despite technological advances, results on glycaemic control or quality of life remain poor. Improvements could be achieved with system that automatically calculates doses and controls the pump such as DBLG1-system which is evaluated in our study.

Methods: 140 T1D patients treated with insulin pumps and poorly balanced (HbA1c >8%) were recruited in early 2020 in 9 French diabetes centres. They were randomised to receive three months of automated insulin delivery by the DBLG1 system and a Dana pump (CL) or to continue their usual treatment (OL), with a randomisation ratio of 4 DBLG1/1 conventional treatment. The COVID crisis prematurely terminated the study. We present the results of the 99 patients treated for at least 14 days with CGM data for at least 75% of the time (88 CL/11 OL).

Results: After adjustment for initial HBA1c and centres, patients treated with CL spent on average 12 min less per 24h in hypoglycaemia <70 mg/dl than patients treated with OL ($p < 0.01$). They spent 13.6% more time in the 70-180 target range ($p < 0.001$) per 24 hours, i.e. almost 3.5 hours, and 3 hours less in hyperglycaemia >180 mg/dl ($p < 0.0007$). The benefit was mainly nocturnal. There was a linear relationship between the time in hypo- or normoglycaemic targets at baseline and the amount of improvement achieved by the system ($p < 0.001$).

Conclusions: In T1DM patients poorly controlled by insulin pumps, the DBLG1 system significantly improves the time spent in hypo- and normoglycaemia. The greater the initial imbalance, the greater the improvement.

EP074 / #552

Topic: *AS03-Artificial Pancreas*

IMPACT OF DELAYED PRANDIAL INSULIN BOLUSES ON GLUCOSE CONTROL IN PATIENTS ON ADVANCED TECHNOLOGIES.

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Background and Aims: Advanced technologies (Hybrid Closed Loop Systems (HCLS) and Sensor Augmented Pump (SAP)) significantly improve blood glucose control in patients with type 1 diabetes. However, the optimization of their performances requires patient's compliance to proper pre-meal insulin bolus administration. We explored how timely patients on HCLS or SAP inject the pre-meal bolus and whether delayed boluses may affect blood glucose control.

Methods: Two diabetologists (RT, RDA) independently reviewed two-week CGM and pump reports of 96 patients on HCLS and 28 on SAP recruited consecutively, 58 men and 66 women, age 40 ± 16 years, GMI 7.0 ± 0.4%. Delayed boluses were assigned when a prandial bolus was preceded on CGM by a steep increase in blood glucose clearly indicating a postprandial response. Two-week CGM metrics were evaluated in relation to the number of delayed boluses by Pearson correlation

Results: At least one delayed bolus was identified in all patients, with a mean total number over two weeks of 9.4 ± 4.9 delayed boluses. The number of delayed boluses was directly associated with GMI ($r = 0.245$, $p = 0.006$), Coefficient of variation ($r = 0.236$, $p = 0.008$), TAR >250 ($r = 0.307$, $p < 0.001$), TAR >180 ($r = 0.168$, $p = 0.059$), TBR <70 ($r = 0.121$, $p = 0.176$), TBR <54 ($r = 0.174$, $p = 0.051$), and inversely associated with TIR ($r = -0.320$, $p < 0.001$).

Conclusions: Delayed insulin boluses in patients on advanced technologies are very common (on average 1 out of 5 meals) and are associated with a significant worsening of blood glucose control. Adequate attention should be given to the timing of bolus injection also in patients on advanced technologies.

EP075 / #614

Topic: *AS03-Artificial Pancreas*

GLUCOMETRIC ANALYSIS IN A COHORT OF PEDIATRIC TYPE 1 PATIENTS USING DIFFERENT LEVELS OF DIABETES TECHNOLOGY FROM A SINGLE PEDIATRIC CENTER

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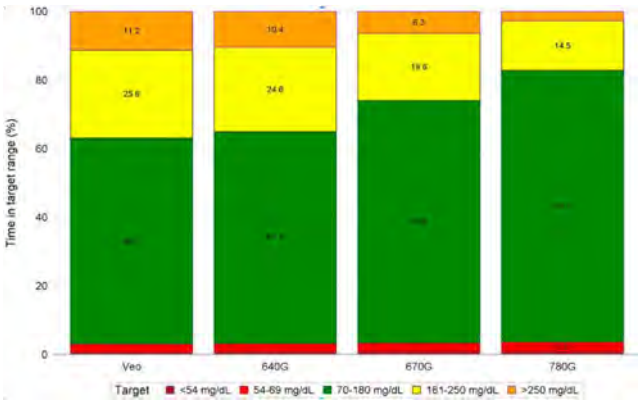
Background and Aims: Outcomes for metabolic control in T1D pediatric patients depend heavily on treatment and technology. These include predictive and low glucose suspend, advanced and hybrid closed-loop systems. The aim was to investigate patient outcomes using four different devices.

Methods: 188 pediatric patients (mean age: 15, median T1D diagnosis: 10 years) were followed at the Pediatric Diabetology Unit at San Raffaele Hospital. The devices analyzed included Paradigm Veo, Minimed 640G, Minimed 670G, and Minimed 780G.

Results: Sensor usage showed remarkable outcomes between Veo and Minimed. Significant differences were seen comparing 780G and 670G (+8.5%; 95% CI: 4.7%-12.3%; $P<0.001$). TBR remained stable. TIR showed improvements especially after switching to 670G, (estimated changes between 640G and 670G: +15.1%; 95% CI: 12.2%-17.9%; $P<0.001$ and +7.7%; 95% CI: 5.2%-10.2%; $P<0.001$). TITR (70-140 mg/dL) remained constant. TIR, TAR showed similar values when using Veo or 640G and decreased after switching to 670G. Of note, after switching to 780G, all targets averaged in range. Average blood glucose levels decreased after switching to 670G (estimated changes from 640G and 670G are -24; 95% CI: -29–20; $P<0.001$ and -15; 95% CI: -19–11; $P<0.001$). 780G showed a 66% reduction of exits from auto-mode with respect to 670G, (RR: 0.3; 95% CI 0.2-0.4; $P<0.001$).

Conclusions: The introduction of technology and automatic insulin delivery can significantly reduce expositions to low values and can steadily ameliorate glucometrics. In particular, children and adolescents using the 780G can achieve >60% of TITR and this represents new frontiers for pediatric diabetes management.



EP076 / #622

Topic: ***AS03-Artificial Pancreas***

EARLY CHANGES IN BLOOD GLUCOSE CONTROL AFTER STARTING AUTO-MODE WITH DIFFERENT HYBRID CLOSED LOOP SYSTEMS.

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Background and Aims: Wide real-life datasets show that currently available closed loop systems (HCLS) significantly improve blood glucose control. No studies compared performances of different HCLS in the same clinical setting. We compared early trends in CGM metrics after initiation of three different HCLS in adults with type 1 diabetes.

Methods: Two-week CGM metrics were collected before and 1 and 3 months after starting auto-mode with Medtronic 780G ($n=38$), Tandem Control I-Q ($n=25$), or DBLG1 ($n=20$) systems in type 1 diabetes patients attending the diabetes outpatient clinic of a university hospital. All patients were provided with technical and clinical training and non-aggressive profiles were generally set. Data were analyzed by two-factor repeated measure GLM using as within factor time (baseline, 1 month, 3 months) and as between factor the type of system.

Results: TIR_70-180 significantly increased in the patients on Medtronic 780G (baseline $67\pm10\%$, 1-month $72\pm8\%$, 3-month $70\pm9\%$; $p=0.005$) and Tandem Control I-Q (baseline $60\pm16\%$, 1-month $75\pm10\%$, 3-month $75\pm10\%$; $p<0.001$), and decreased in the patients on DBLG1 (baseline $66\pm13\%$, 1-month $66\pm11\%$, 3-month $62\pm12\%$; $p=0.182$) with a significant interaction time*system ($p<0.001$). TAR >180 and TAR >250 significantly decreased in the patients on 780G and Control I-Q ($p<0.05$). The coefficient of variation significantly decreased with Control I-Q ($p=0.017$). TBR <54 and TBR <70 did not change significantly with any system.

Conclusions: Current HCLS may differ for time required to achieve glucose targets. This may depend on the inadequate use of more aggressive/individualized settings and should be considered when handling patients' expectations during the early phase of HCLS implementation.

EP077 / #623

Topic: ***AS03-Artificial Pancreas***

REINFORCEMENT LEARNING FOR LONG-TERM ADAPTATION OF AN ARTIFICIAL PANCREAS

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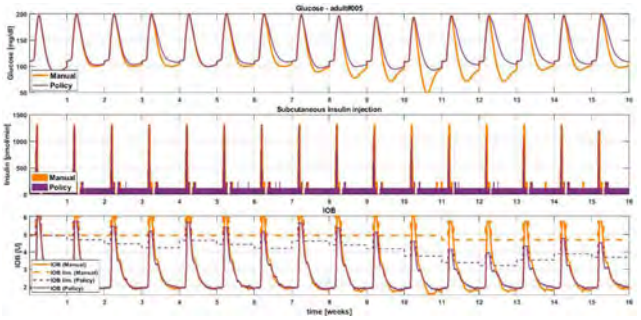
Background and Aims: Previous clinical trials and in-silico work show that insulin sensitivity variation in diabetic patients can compromise the performance of closed loop glycemic control. Generating adaptive controllers is key to overcome this issue.

Methods: In this work, a Q-learning based long-term adaptation technique for the previously introduced Automatic Regulation of Glucose (ARG) algorithm [1] is presented. The presented configuration modifies only one parameter in the controller (the insulin-on-board limit) instead of replacing it entirely, avoiding the "black box" issue associated with Reinforcement Learning. The resulting policy is evaluated *in-silico* using the UVA/Padovas's virtual patient cohort and compared against a manual rule-based strategy.

Results: In-silico results shows that the RL agent manages to regulate insulin infusion when the patients sensitivity changes. Particularly, when sensitivity increases, episodes of hypoglycemia are avoided without significantly increasing time in hyperglycemia, while the manual scheme does not achieve similar results. The llustrative example in the figure shows that severe hypoglycemic episodes ocurr when using manual scheme but are succesfully avoided by the long-term adaptation of the controller.



It is also worth noting that insulin infusion is reduced showing that the RL strategy improves insulin infusion profile, as well as overall glycemic excursion.

Evolution over time for Adult#05 using the ARG algorithm with the RL agent (purple thinner) and with manual scheme (orange thicker). At bottom: IOB (solid line) and IOB limit (dashed line).

Conclusions: Reinforcement learning for long-term adaptation shows great promise as it modifies insulin infusion, increasing overall performance and succesfully avoiding hypoglycemia when patient's sensitivity changes.

EP078 / #700

Topic: ***AS03-Artificial Pancreas***

HEALTHCARE NEEDS OF ADULTS WITH TYPE 1 DIABETES CONSIDERING, IN TRANSFER TO OR USING DO-IT-YOURSELF CLOSED LOOP SYSTEMS.

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Background and Aims: This study investigated the healthcare needs of adults with type 1 diabetes considering, in transfer to or using Do-It-Yourself Closed Loop (DIYCL) systems.

Methods: $N = 21$ adults with type 1 diabetes ($n = 7$ considering, $n = 4$ in transfer to, $n = 10$ using DIYCL) participated in qualitative, semi-structured interviews. Age and diabetes duration ($M \pm SD$) were 35.7 ± 11.4 and 19.1 ± 13.6 years ($n = 9$ female, $n = 1$ non-binary). HbA_{1c} was 48.0 ± 7.7 mmol/mol. All used sensors (11 flash, 10 real-time), 17 used insulin pumps. Topics included barriers/facilitators, healthcare needs and (ideal) image of future diabetes care. Individual and thematic content analyses were performed (open, axial and selective coding).

Results: Barriers towards DIYCL included absence of professional guidance and information abundance. Facilitators included (online) peer support and clear step-by-step instructions. Whereas those considering or in transfer tended to prefer close monitoring, most users preferred independence from their diabetes team. Participants expressed a need for personalized diabetes care and freedom of choice. Legal and practical barriers to the integration of DIYCL in diabetes care were acknowledged, including technical complexity, limited reimbursement and lack of manufacturer support. Overall, DIYCL systems were expected to subsist despite the development of commercial systems. Participants hoped for increased support and technological assistance by healthcare professionals during DIYCL orientation and start.

Conclusions: DIYCL healthcare needs differed according to the experience level of the person with diabetes and their diabetes team. Further investigation of healthcare professionals' needs considering DIYCL is necessary (interviews ongoing).

EP079 / #749

Topic: ***AS03-Artificial Pancreas***

ISLETRX, ALGINATE MICROENCAPSULATED PLURIPOTENT STEM CELLS-DERIVED PURIFIED ISLET-LIKE CLUSTERS EXHIBIT LONG TERM THERAPEUTIC FUNCTION IN IMMUNOCOMPETENT MICE

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Background and Aims: hPSC-derived islet-like clusters (ILCs) produced by the known differentiation protocols contain various cell populations, which may not be necessary for islet function, and even may impair the efficacy or the safety of the transplanted cells for future clinical treatment of diabetes. To alleviate this problem, we identified cell surface markers for the purpose of improving the purity and support the long term therapeutic function of hPSC-derived ILCs cells in immunocompetent mice.

Methods: Several antibodies for SC-ILCs purification were identified. Follwoing validation, integrin-alpha1 (CD49A) was found to bind the insulin-producing cells that express Nkx6.1, a transcription factor essential for the formation and function of mature β-cells. Another antibody, against CD26 (DPP4), was found to bind only insulin-producing cells that do not express Nkx6.1. Relevant sorting strategies were implied and purified ILCs were tested for their capacity to normalize glycemia in C57 STZ-treated mice following microencapsulation and IP implantation.

Results: The ILC fraction enriched in $CD49A^+$ cells rapidly reduced glycemia when implanted in diabetic mice. However, CD49A-enriched exhibted similar results to non-purified ILC cells. Only when applying first CD26 depletion, followed by enrichment for $CD49A^+$ cells, the $CD26^-/CD49A^+$ enriched ILC cells exhibited improved function and maintained prolonged (>6 months) normoglycemia in immunocompetent C57 mice.

Conclusions: We established a highly effceint purifiacation protocol and delivery method using aliginate microcapsules IP, demosnstrating the feasibility of functional enrichment to improve the prolonged therapeutic activity of hPSC-derived ILCs for the treatment of insulin depndent diabetes. Follwoing these POC results, IsletRx is now progressing towards IND-enabling submission.

EP080 / #759

Topic: ***AS03-Artificial Pancreas***

LAST ADVANCES OF THE ARG ARTIFICIAL PANCREAS PROJECT

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Background and Aims: After the artificial pancreas (AP) trials performed in 2016-7 with DiAs system, during the COVID-19 pandemic the first outpatient clinical trial was carried out in Argentina. The main objective was to evaluate the feasibility of running full closed-loop (FCL) algorithms in an own and free platform developed from open-source resources.

Methods: The ARG project (Automatic Regulation of Glucose) aims at developing a robust AP algorithm prioritizing patient autonomy. The evolution of the project phases is summarized in the figure. The last step towards this objective was the implementation of a FCL algorithm in our InsuMate platform and its evaluation in an outpatient setting. Five adults with DMT1 completed one week of study, consisting in 3 days of open-loop (OL) followed by 3 days of FCL (i.e., without CHO counting and without delivering meal priming insulin boluses). Accu-Chek pumps and Dexcom G6 CGMs were used.

Results: When analyzing the full duration of the trial, the time in range increased in FCL control vs. OL, while the time above range decreased, as did the mean BG. On the other hand, the time below range and the time in severe hypoglycemia remain similar across methods, both achieving the ADA recommended values. The FCL showed greater improvement by the end of the trial, particularly for daytime metrics. InsuMate properly operated in FCL for an average of 95.4% of time.

Conclusions: It can be concluded from this experience that the outpatient automatic regulation of glucose levels using the ARG algorithm and Insumate platform is feasible, safe, and effective.

ARG PROJECT	*Phase 1*	*Phase 2*	*Phase 3*
N:	5	5	5
Place	Hospital Italiano de Buenos Aires	Hospital Italiano de Buenos Aires	Hotel
Hours in CL	36	36	72
Hours in OL	36	36	72
Algorithm	UVA	ARG	ARG
Platform	DIAS	DIAS	Insumate

EP081 / #769

Topic: ***AS03-Artificial Pancreas***

HYBRID CLOSED LOOP SYSTEM IMPROVES METABOLIC CONTROL AND GROWTH PARAMETERS IN A PATIENT WITH MAURIAC SYNDROME: A CASE REPORT

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Background and Aims: Mauriac syndrome (MS) is a rare complication of poorly controlled type 1 diabetes (T1D) and is characterized by growth failure, delayed puberty, Cushingoid features, hepatomegaly, and elevated transaminases. Little is known about whether hybrid closed-loop (HCL) systems can improve glycemic control in patients with documented non-compliance and poorly controlled T1D with MS.

Methods: CGM, HbA1c, AST, ALT, GGT, testosterone, and growth data from a male teenager with poorly controlled T1D and features of MS including hepatomegaly and growth failure were compared before and after treatment with a HCL system (Tandem t:slimX2 with Control-IQ).

Results: Patient's glycemic control, weight gain, linear growth, pubertal development, and hepatomegaly improved significantly following the transition from multiple daily injections (MDI) to HCL therapy (Table and Figure). His TIR increased from 21% to 46% and his growth velocity increased from 0-1.2 cm/yr to 11.8 cm/yr. Despite ongoing non-compliance and frequent missed boluses for meals, no episodes of DKA while using HCL have occurred. Figures and Tables

Conclusions: Use of a HCL system improved glycemic control and reversed the clinical signs of MS in a pediatric patient with poorly controlled T1D.

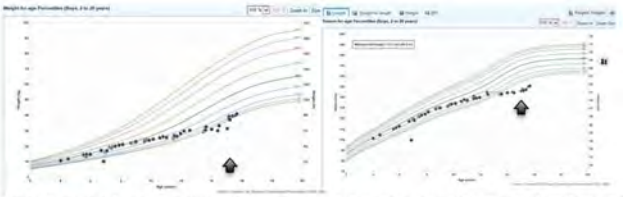

Figure 1: Weight for age and Stature for age curves. Arrow heads indicate the start of hybrid close loop system.

	2019 (MDI)	2021 (HCL)
HbA1C	>14 %	9.2 %
ALT U/L	92	27
AST U/L	92	32
GGT U/L	104	33
IGF-1 ng/mL (nl: 158-814)	82	181
Testosterone ng/dL	6	52

Table 1: Biochemical data in a patient with Mauriac syndrome on MDI vs. HCL

EP082 / #222

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

EVALUATION OF AN INSULIN-CARBOHYDRATE-RATIO ADJUSTMENT ALGORITHM PERFORMED ON REAL PATIENTS DATASETS

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Background and Aims: Better insulin dose adjustment depends directly from precise carb evaluation and using the right insulin-carb ratios (ICR). As SAGE study shows, many people with type 1 diabetes (pT1D) do not know how to readjust their calculation parameters and need to wait for a medical visit. Helping them to keep those parameters adjusted continuously on their bolus calculator application is essential for maintaining a good glucose control.

Methods: We used two datasets from previous studies conducted in our medical center to evaluate the performance of an algorithm that intends to converge to the optimal patient's ratio. The algorithm being programmed for SMBGs and CGMs, GLUCAL dataset included 24 adults followed for two months, while FLK datasets included 15 children followed for around 30 days.

Results: The algorithm was evaluated in 32 subjects, for an average period of 43 days. For simulation purpose, the algorithm was initiated at the random value of 1 U/10g, and succeeded in less than 9 days to converge to the ICR defined by the practitioner. In cases where the algorithm converged to a different value, our sub-analysis showed that the patient had persistent post-meal hypoglycemia or hyperglycemia.

Conclusions: Our data indicates that our algorithm can retrieve and maintain itself around the optimal ratios, and in cases where the reference ratios given by the practitioner needed an adjustment, our algorithm succeeded to compensate it. The addition of this algorithm to our application DiappyMed can increase post-meal glucose control thanks to a more precise insulin dose adjustment.

EP083 / #229

Topic: *AS04-Clinical Decision Support Systems/Advisors*

NOVEL AI-BASED ALGORITHM TO DETECT AND RECONSTRUCT MEAL REAL TIME USING CGM DATA

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Background and Aims: In self-management systems, the meal management remains a major issue. Patients still need to input manually the information regarding each meal so that the system can provide relevant bolus-dose recommendations. But meal reports are often incomplete or missing because of the complexity of inputting manually such information in an app. There is a need for a real-time meal-detection and reconstruction algorithm so that the system does not have to rely on manual inputs from patients. Hillo has been working on a novel AI-based real-time meal detection algorithm based on CGM data only.

Methods: The meal detection algorithm was built and tested using a data-set from the CDDIAB observational study. the first 14 days of data from all patients are used to train one model. Then its performance is assessed on the test set comprising the remaining data available. Different metrics are computed: Precision, Sensitivity, f1 (f-score: the harmonic mean of the precision and the sensitivity), ROC curve, AUC (Area Under the ROC curve), MDT (Mean Detection Time). A meal detected 45 minutes after it really occurred is considered as a false positive. Meal detection algorithms are then evaluated using AUC, f1 and MDT.

Results:

AUC (%)	Precision	Sensitivity	f1	MDT (min)
88±4.5	0.50±0.10	0.56±0.09	0.53±0.08	21±2.5

Conclusions: Preliminary work shows the feasibility of a meal detection system based only on real-life CGM data with very promising results, which could be improved using a more accurate data-set. Indeed, missing or inaccurate meals in the test-set introduce a bias in the evaluation of false positives.

EP084 / #252

Topic: *AS04-Clinical Decision Support Systems/Advisors*

MACHINE LEARNING METHOD TO PREDICT AND MITIGATE REAL-TIME BLOOD GLUCOSE PREDICTION UNCERTAINTY

P. Soulé[1], L. De La Brosse[1], P. Calmels[1], T. Camalon[1], M. Rehn[1], N. Caleca[1], S. Bidet[1], J. Place[2], E. Renard[3]

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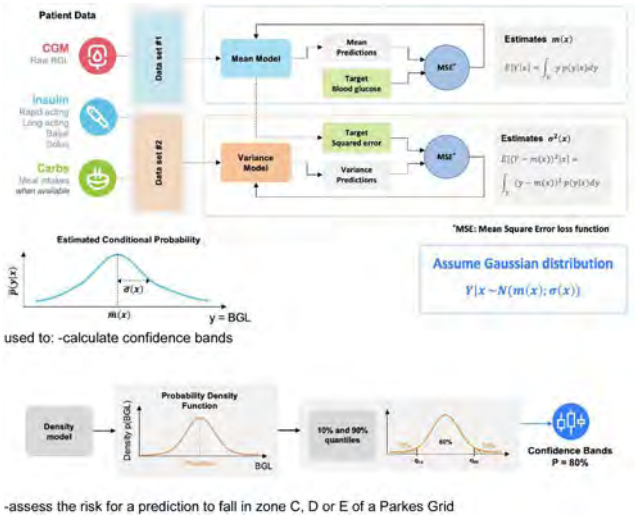
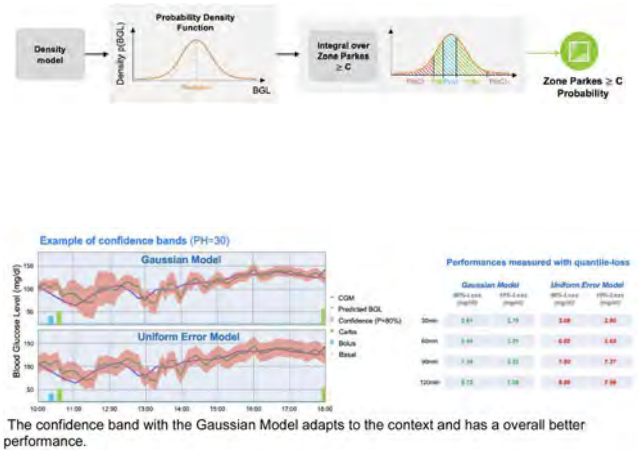
Background and Aims: Hillo has developed a Machine Learning (ML) method to predict future blood glucose levels (BGL) with a very good accuracy, but for large prediction horizons the error can lead to bad decisions for the patient. It is necessary to anticipate and mitigate these errors in real time to give a confidence index in the prediction and filter out the riskiest ones.

Methods: We have developed a ML method to model the uncertainty around a predicted value. When a prediction is performed, only part of the information that may impact BGL is known (past CGM readings, insulin injections and meal intakes). Future unknown inputs and external disturbance to the system can be modeled as a random noise around an expected value. A BGL predictor and a ML variance estimator are trained consecutively, using the same data, to estimate the probability of having a blood glucose value at a target time, conditioned to our known information at prediction time, thus we build a consistent conditional probability distribution estimator:

Results: Performances are compared with a Uniform Error Model computed from the marginal error distribution





The confidence band with the Gaussian Model adapts to the context and has a overall better performance.

The density model methodology can be improved by using a different distribution-model and by adding a calibration step.

Conclusions: We showed a method to anticipate and mitigate risky stuations.

EP085 / #275

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

TYPE 1 DIABETES RISK CALCULATOR FOR CLINICAL RESEARCHERS AND CLINICIANS

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Background and Aims: Assessing the risk of clinical T1D is critical for the identification of individuals who may be candidates for prevention treatments. Furthermore, screening for T1D risk reduces the risk of diabetic ketoacidosis (DKA) at onset. Prediction models that use demographic (e.g., age, race/ethnicity, etc.), immunologic (e.g., islet autoantibodies), genetic and/or metabolic (e.g., glucose, C-peptide, etc.) data have been developed that are highly accurate at T1D prediction. However, until now these models remained inaccessible to clinical researchers, clinicians and families. Here, we aimed to build a tool to estimate an individual's T1D risk in an accurate, user-friendly manner.

Methods: Based on highly accurate T1D predictive models that we previously generated with data from The Environmental Determinants of Diabetes in the Young (TEDDY) (n = 7998) and TrialNet studies (n = 952) (ROC-AUC at 3-year horizon, respectively, 0.95 and 0. 86), we built a web application on a R shiny framework and an application programming interface (API) using the Plumber package.

Results: The resulting web application tool and API allows the user to enter known data (e.g., age, race/ethnicity, family history, autoantibodies, glucose, C-peptide, genetic risk score, etc.) and the desired future horizon time on a user-friendly interface. The system returns T1D risk estimation at the selected future horizon time.

Conclusions: The development of easily accessible tools that researchers, clinicians and families can use to accurately estimate T1D risk will be instrumental in the risk/benefit assessment for T1D prevention treatments and reduction of DKA at T1D diagnosis.

EP086 / #328

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

IDENTIFICATION OF BEHAVIOURAL PATTERNS AND CGM DERIVED METRICS FOR OPTIMISING GLYCAEMIC CONTROL IN PEOPLE WITH T2D ON ORAL SEMAGLUTIDE: A TRIAL PROTOCOL

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Background and Aims: People with type 2 diabetes (T2D) receiving oral antidiabetics (OADs) have varying degrees of adherence to treatment, leading to suboptimal treatment. A decision support system (DSS), providing personalised guidance on OAD administration based on continuous glucose monitoring (CGM), may potentially aid the patient and increase the treatment effect. Oral semaglutide is a new, promising OAD, however no studies have collected CGM and other high temporal data from people with T2D on oral semaglutide. Thus, the objective is to investigate interstitial glucose profiles from people on oral semaglutide to identify behavioural patterns and glucose metrics suitable for optimising glycaemic control.

Methods: A 12 weeks prospective non-interventional study with 20 participants will be conducted at Steno Diabetes Center North Denmark, Aalborg University Hospital, Denmark. The

participants must be ≥18 years, have T2D, a HbA1c level between 7-9%, and be treated with either metformin or metformin and oral semaglutide. All participants will receive both metformin and oral semaglutide in the dosage required to reach their glycaemic target. CGM, activity, sleep, medication events, and meals are collected during the trial period. A DSS, based on glucose level prediction, is developed using machine learning.

Results: A high temporal data set on behavioural patterns, CGM, and adherence, that can be used to develop a DSS.

Conclusions: A DSS to support OAD administration could potentially lead to increased bioavailability of the drug and better glycaemic control. This work was supported by a research grant from the Danish Diabetes Academy, which is funded by the Novo Nordisk Foundation, grant number NNF17SA0031406.

EP087 / #334

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

IMPACT OF A DIGITAL THERAPEUTIC PLATFORM ON WEIGHT LOSS AND DIABETES SELF-MANAGEMENT

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Background and Aims: Diabetes and obesity have increased incidence and morbidity and are recognized as epidemic by the World Health Organization. To compound matters, evidence suggests that weight loss is more difficult in persons with diabetes. Clinical guidelines emphasize the importance of weight loss to avoid complications such as cardiovascular disease. Digital therapeutics are designed to help users develop active roles in managing health. Dario, a digital therapeutic platform, may assist patient self-monitoring to optimize outcomes in obesity and diabetes.

Methods: A retrospective study was performed on 715 Dario active members who started with a baseline BMI of ≥30 kg/m^2 (51% male; 48% female; 80% with type 2 diabetes) and who recorded weight measurements for at least 12 months. Weight measurements and blood glucose readings were observed over 12 months.

Results: Nearly two-thirds of the population improved their weight, with an average reduction of 7.4% ($p < 0.05$) and an average reduction in BMI of 2.8 kg/m^2. Over 30 percent achieved weight loss of 5% or greater over 12 months. The subset of 237 users who started with a BMI of ≥35 kg/m^2 achieved weight loss of 5% over 12 months ($p < 0.05$). The subgroup of 108 users that started at high-risk blood glucose levels (average blood glucose >180 mg/dL) reduced their weight by 4.9%, average blood glucose by 16.1%, and high readings ratio by 38% over 12 months ($p < 0.05$).

Conclusions: This observational study demonstrates the potential for digital platforms to durably improve diabetes and weight self-management among users who had started with BMI of ≥30 kg/m^2

EP088 / #389

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

ONLINE-ESTIMATION OF INSULIN SENSITIVITY TO INFORM INSULIN DOSING IN TYPE 1 DIABETES AFTER MODERATE- AND HIGH-INTENSITY EXERCISE

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Background and Aims: Estimate insulin sensitivity (IS) from continuous glucose monitoring (CGM) data after exercise of varying duration and intensity for insulin bolus adjustment.

Methods: We generated in-silico CGM data of 25 virtual patients for three types of exercise: short moderate-intensity, prolonged moderate-intensity with glycogen depletion, and high-intensity exercise. The activity was performed in the afternoon in a full day simulation containing three meals and corresponding insulin treatment, at 60% VO_2^{max} for 90 and 180 min, and at 85% VO_2^{max} for 45 min, respectively. From the glucose measurements, we estimated IS using an unscented Kalman filter and reduced the meal bolus proportionally to the rise in IS compared to baseline. Similarly, we adjusted the basal bolus after exercise according to estimated overnight IS in MDI therapy.

Results: For all types of exercise, we successfully estimate baseline IS and the exercise-driven, prolonged rise in IS. There is a tracking delay at the onset of the activity, since the estimation algorithm is not informed about exercise. This delay is most pronounced for high-intensity exercise, where blood glucose (BG) increases during the activity, whereas BG levels are dropping during moderate-intensity exercise. In all considered scenarios, adjusting insulin treatment proportionally to estimated insulin sensitivity improves glycemic control and elevates overnight glucose levels, which can lower the risk of nocturnal hypoglycemia.

Conclusions: We demonstrate the feasibility of estimating exercise-driven changes in IS from CGM data for a wide range of exercise scenarios. Corresponding bolus adjustments after the activity can lead to an improvement in BG outcome.

EP089 / #427

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

GLUCAGON AWARENESS AND UTILIZATION IN CHILDREN WITH TYPE 1 DIABETES

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Background and Aims: Hypoglycemia is one of the most severe and life threatening complications of insulin therapy for patients with diabetes. The risk of severe hypoglycemia is higher in children with type 1 diabetes when compared to the general diabetes patients. Glucagon is usually distributed as ''Emergency Kits'' and often stored in patients' homes and schools to be used in case of severe hypoglycemic episodes.

Methods: 1. To evaluate the experience of the patients with diabetes and their caregivers of utilizing the glucagon emergency kit by filling out or completing a one page survey 2. To use this survey as a reminder for patients to ask about the glucagon emergency kit availability, refills, and explore any educational needs regarding its utilization.

Results: In this study, thirty-four patients and their families have participated. Of the thirty-four patients, thirty families (88%) had at least one kit of Glucagon rescue medication. Only four patients (12%) have used it in the past. Upon verification, nine families (26%) realized that the medication had an expired shelf life and a renewal of the prescription was submitted. Eight families (24%) expressed a need to review the demonstration of its use.

Conclusions: Hypoglycemia risk reduction depends on patient education and self-empowerment. If the patient's hypoglycemic episode is not severe, utilizing simple glucose intake orally is often done without any need to use the emergency kit. Thus, the emergency kit may expire in shelf life, get lost, or not be properly utilized when needed due to lack of experience of the patient or care-givers in using it.

EP090 / #472

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

THE MY FRIEND DIABETES CARBOHYDRATE BOLUS CALCULATOR: USER EXPERIENCES

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[1]Koç University, School Of Medicine, istanbul, Turkey, [2]Koc University Hospital, Pediatric Endocrinology And Diabetes, Istanbul, Turkey

Background and Aims: Meal management in T1D has barriers such as not knowing the carbohydrate values of foods, miscalculated doses, not fully understanding the mathematics of T1D. ''My Friend Diabetes Carbohydrate Bolus Calculator'' mobile app was developed as a hybrid version of nutrition apps and insulin titration apps to calculate meal's carbohydrates and the matching bolus dose(figure1). A nutrition database was created based on weights and equivalent carbohydrate ingredients of foods, which served with practical units such as a tablespoon, pieces, glasses. The app calculates the bolus dose according to glucose value, carbohydrates(grams), insulin sensitivity, and Carbs/insulin ratio.We investigated the possible benefits of the app through an online survey.

Methods: In an online survey, the effects of the app on carbohydrate counting, diabetes management, and the usability of the app were examined with a 5-point Likert scale of 17 questions.

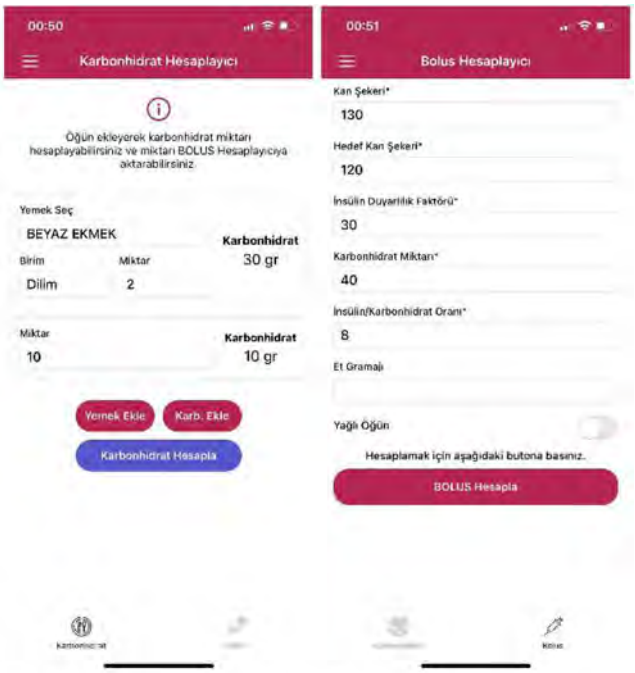

Figure1: My Friend Diabetes Carbohydrate-Bolus Calculator: Carbohydrate calculator(on left) and Bolus Calculator(on right).

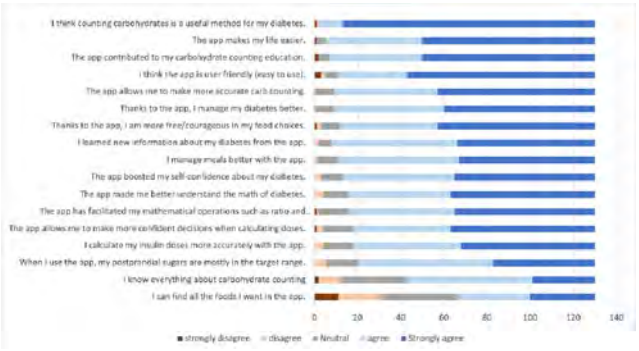

Figure2: 5-point Likert questions about the app.

Results: Of 165 people who fully participated in the survey, 58 had T1D (35.2%), 107 had relatives with T1D (64.8%), 87 participants (52.7%) were female, and the mean duration of diabetes was 4.72 years. 130 participants used the app. Participants showed agreement that the app improved the users' meal management, diabetes management, carbohydrate and dose calculations(N = 130,Mean = 4.38,SD = 0.57). They are more confident in the dose calculation, freer in the food choices, and more confident in diabetes care because of the app(N = 130,Mean 4.46, SD = 0.57)(figure2).

Conclusions: People with T1D benefit from the ''My Friend Diabetes Carbohydrate-Bolus Calculator'' mobile app. Diabetes teams can reach more people through mobile apps and improve their clinical outcomes.

EP091 / #541

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

TRANSLATION FROM PUMP TO PEN IN TYPE 2 DIABETES: THE EFFECT OF BIOAVAILABILITY

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Background and Aims: Artificial pancreas (AP) systems may offer an alternative to standard of care titration in type 2 diabetes (T2D). Preliminary simulations show that short-term AP treatment can safely identify an efficient daily dose of long-acting insulin for pen-based treatment. However, these initial simulations do not incorporate the difference in bioavailability between rapid- and long-acting insulin. Pump studies in T2D populations have shown a 20% reduction in insulin need compared to pen-based treatment. In simulation, we investigate how the bioavailability of insulin analogues affect the translation from pump to pen.

Methods: We simulate a virtual clinic of 100 insulin-naïve people with T2D using an extended, stochastic version of the integrated glucose insulin (IGI) model. After three weeks of AP treatment, we translate the insulin infusion rate, unit-to-unit, into a daily injection of long-acting insulin. In a series of simulations, we scale the bioavailability of long-acting insulin with a factor between 0.8 and 1.2 compared to rapid-acting insulin.

Results: Before the switch to pen-based treatment, the average pre-breakfast glucose level is 7.7 ± 1.3 mmol/L. After stabilizing on pen-based treatment, the rapid- to fast-acting insulin

bioavailability ratios of 1:1.2, 1:1, and 1:0.8 result in an average pre-breakfast glucose level of 7.3 ± 1.2 mmol/L, 8.0 ± 1.3 mmol/L, and 8.6 ± 1.4 mmol/L, respectively.

Conclusions: For the investigated bioavailability ratios, our results indicate no hypoglycemia risk associated with a unit-to-unit translation from pump to pen. However, to achieve comparable treatment outcomes after the pump to pen switch, the bioavailability ratio is key to successful dose conversion.

EP092 / #561

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

DEAPP (DIABETESEDUCATIONAPPLICATION) CHILDREN'S TYPE 1 DIABETES STRUCTURED EDUCATION PROGRAM POST PILOT OUTCOME DATA 2018-20

J. Greening[1], *S. Lockwood-Lee*[2], *L. Paxman-Clarke*[3]

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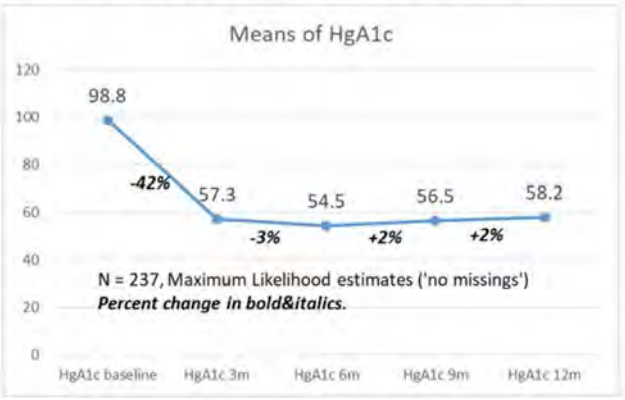
Background and Aims: Diagnosis of type 1 diabetes is the critical period to embed knowledge and understanding of diabetes. Deapp overcomes this, Triangulating: quality assured structured education, interactive education and learning resources using flipped learning. We tested the Deapp program promoted self-learning , engagement and management of diabetes.

Methods: 5 units and subgroup analysis deapp vs control, were compared.Hypoglycaemia awareness (Clarke) ; fear of hypoglycaemia; problems associated in diabetes 20 (PAID-20) & kaufmann competency. HbA1c trajectory,user surveys and length of inpatient stay

Results: N = 237 (55 excluded (no baseline Hba1c) analysed N = 193 (77%) showing reduced HbA1c baseline to 3 months: 98.9 - 57.3 mmol/l (M difference = 46.02, p < .001) and no significant change from 3-12 months. Qualitative questionnaires (n = 59 (24.9%) low scores (all 4 questionnaires and survey.

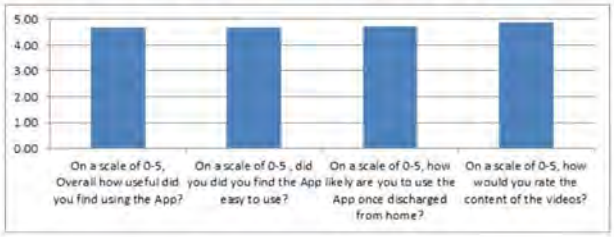
Table 1: mean Hba1c and % change of the mean (0-12 months).



Subgroup-deapp vs control: n = 32 (n = 17 control, n = 15 deapp) control mean hba1c : 52% (109mmol/l -53mmol)fall in hbA1c (18 months) control vs 48% deapp(101mmol/l- 52mmol/l). Clarke scores 0.3 (control) -1.4 (deapp). Fear of hypoglycaemia 8 (control)- 10 (deapp). PAID-20 16 (control) -22 (deapp). Kaufmann 35 (control) -39 (67% post-deapp). Bed stay = 3 days(control)vs 2 days (Deapp):

Conclusions: Deapp is able deliver structured education using flipped learning Deapp achieved at least parity of glycaemic control to existing education programs HbA1c trajectory acheived target hba1c of <58 mmol/l by 3 months and remained unchanged up-to 12 months. Subgroup showed similar hba1c

Table 2. The opinions about the app from a subsample of parents (n=59).



Question	M	SD
Overall how useful did you find using the App?	4.68	1.08
Did you did you find the App easy to use?	4.71	.99
How likely are you to use the App once discharged home?	4.25	1.22
How would you rate the content of the videos?	4.75	.77

Note: The parents used a scale from 0 (not at all) to 5 (very much) to indicate their response

Standardise diabetes scores (n=59 (60% of the pilot)

Measure	Site	Average	Range
Kauffman competency (scoring 0-8) as a measure of self-competency of management	Other 4 pilot sites	4.1	range 2-6
	Nottingham	4	range 3-5
Paid "problem areas in diabetes"	Other 4 pilot sites	10.29	range 5-14
	Nottingham	10	range 7-13
Clarke hypo scores	Other 4 pilot sites	<4	range 0-3
	Nottingham	<4	range 0-2

Interpretation: although numbers are small at this stage deapp demonstrated at least parity with traditional education and low qualitative scoring (By default: centre Nottingham didn't obtain qualitative outcomes so has worked as a de-facto control group)

trajectory deapp vs control at 18 months. 5 Sites and subgroup (control vs deapp) saw high quality life scores, high patient satisfaction & reduced inpatient bedstay for deapp

EP093 / #565

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

FACTORS AFFECTING DECISIONAL CONFLICT OF SELF-MANAGEMENT WITH TYPE 2 DIABETES MELLITUS IN CHINA

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Background and Aims: To examine the level of decisional conflict of self-management and explore the influencing factors related to decisional conflict of decisional conflict in type 2 diabetes mellitus.

Methods: Totally 200 patients with type 2 diabetes mellitus in China participated in this study. The Decisional Conflict Scale (DCS), Medical Outcomes Study Social Support Scale, MOS-SSS) and Diabetes Distress Scale (DDS) were administered and demographic and professional data were collected after obtaining informed consent. Multiple linear regression was used to model the relationship between the influencing factors (i.e., social support, diabetes distress and social-demographic characteristics) and decisional conflict of self-management.

Results: The level of decision conflict in self-management is moderate (Mean = 31.85, standard deviation = 21.93), and the level of the effective decision subscale is high (Mean = 37.88, standard deviation = 29.36). In multiple linear regression equations, whether the patient has received education about diabetes, doctor-related distress, and relationship-related distress may affect the level of decisional conflict of self-management.

Conclusions: Self-management decision conflict in type 2 diabetes mellitus need to pay attention to. More studies are needed to explore the influencing factors of self-management decision conflict.

EP094 / #569

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

CLINICAL VALIDATION OF GLUCLAS, A SOFTWARE FOR ASSISTING CLINICIANS IN GLUCOSE CLAMP EXPERIMENTS

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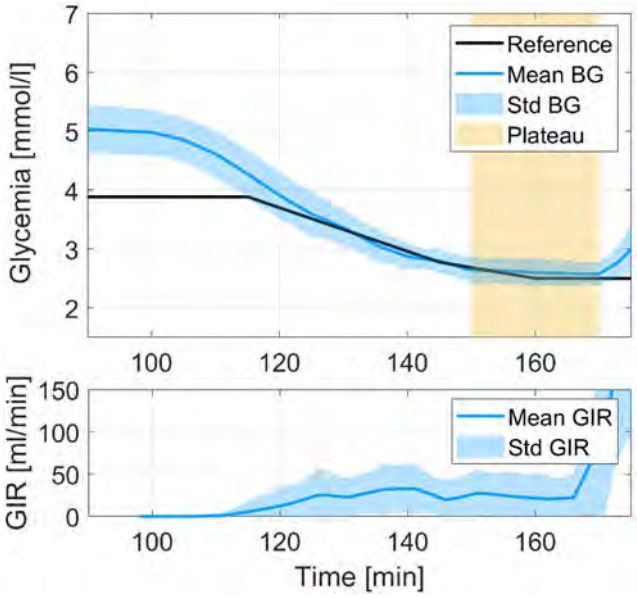
Background and Aims: Glucose clamp (GC) is a widely used technique for assessing various aspects of glucose metabolism. Using a continuous intravenous (iv) insulin infusion and an iv variable glucose infusion, blood glucose (BG) levels are clamped at a pre-defined target. Most commonly, glucose infusion rate (GIR) is manually adjusted by the clinician – a non-trivial task that depends on individual expertise. In this work, we report the clinical validation of Gluclas, an open-source software for the suggestion of GIR modulation in GC experiments.



Methods: Gluclas is based on a PID control algorithm, which suggests GIR modulation based on BG measurements provided by users. The software was tested in 31 non-diabetic subjects undergoing a hypoglycemic clamp. These experiments required to maintain a glycemic plateau of 2.5 mmol/l for 20 min, starting at a pre-defined time. Performance was evaluated by computing the average value and the coefficient of variation (CV) of glycemia at target BG, both reported in terms of mean ± standard deviation.

Results: The average glycemic value during the plateau was 2.61 ± 0.18 mmol/l, i.e., a mean relative deviation of +4.4% from target. The CV during the plateau was 4.06 ± 2.16 %, which is lower than 2/3 of previously reported hypoglycemic clamp achievements (systematic review by Fabricius et al. (2021) reporting an average CV of 10 ± 9 %).

Conclusions: Gluclas provided effective suggestions to ensure high-quality and convenient hypoglycemic clamp experiments, achieving CV comparable to, if not lower than, that reported in current literature.

EP095 / #597

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

USE OF DIAPPYMED® APP FOR CARB&BOLUS COUNTING RESULTS IN IMPROVED POST-MEAL GLUCOSE CONTROL IN PATIENTS WITH TYPE 1 DIABETES IN A RANDOMIZED CONTROL STUDY

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Background and Aims: The accurate estimation of carbohydrates (CHO) is essential for computing meal insulin doses and achieving targeted post-meal glucose level in patients with type 1 diabetes (pT1D). We developed a smartphone application that automatically computes CHO content of declared food intakes and needed insulin dose according to patient's CHO/insulin ratio. We assessed the outcomes of its use in free-life on post-meal glucose control in a randomised control study.

Methods: Thirty adult pT1D, under basal-bolus insulin regimen and SMBG, were randomised in a two-month cross-over study. APP or PATIENT estimations of meal CHO were used for computing meal boluses during two 1-month periods in random order. Computed CHO amounts, injected insulin doses and 2-hour post-prandial blood glucose (PPG) levels were recorded for each meal.

Results: Twenty-for patients (age 43 ± 15, HbA1c 7.5 ± 0.6 %) completed the study. Number of APP vs. PATIENT study days and meals were respectively 30.6 ± 2.6 vs. 31.3 ± 4.3 and 80.8 ± 17.4 vs. 86.8 ± 19.8. Percentage of PPG values in 80-180mg/dl range (primary study endpoint) was higher with GLUCAL: 53.8 ± 13.1 vs. 48.1 ± 12.5 ($p = 0.0002$), thanks to reduced %PPG >180mg/dl: 32.3 ± 11.6 vs. 38.3 ± 11.3 ($p = 0.0010$), while %PPG <80mg/dl were similar: 13.9 ± 6.9 vs. 13.6 ± 5.7 ($p = 0.7875$). Post-meal carb and bolus corrections actions were reduced by 9% during APP phase.

Conclusions: Our data supports the benefits of using DiappyMed (ex-GLUCAL) application to improve post-meal glucose control in T1D patients through better adjusted insulin doses which reduce PPG values >180mg/dl without increasing hypoglycaemia. The addition of other features to facilitate carb estimations and adjust dosage parameters can improve these results.

EP096 / #605

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

IMPACT OF DIGITAL THERAPEUTICS ON HBA1C AND DRUG COMPLIANCE IN T2DM PATIENT OF CENTRAL INDIA

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Background and Aims: Regular follow-up or intervention improves outcomes in T2DM. Patients need to be monitored and intervened regularly to get better outcomes. Day-to-day clinical practice does not allow very close follow-up of patients. Digital therapeutics help in creating a bridge between patients and doctors. This is now emerging as a tool to improve patient outcomes.

Methods: 46 patients, randomized into two groups 23 in the Digital therapeutics arm and 23 in the control arm. Monitored for 2 months. We put Those in the Digital therapeutics arm on Zyla platform. It also monitored patients for, HBA1C, Drug Compliance, and perceived stress score. Inclusion Criterion: Known Diabetic, ability to use the digital platform. Exclusion criterion: history of mental illness,

Results: out of 23 patients, the Digital Therapeutics arm shows a better reduction in average HBA1C -2.0 vs = 1.4, also we see reduced anxiety scores and a better Morisky green score as compared to the control arm.

Conclusions: Digital therapeutics if used correctly improves the lives of patients and also can lead to a reduction in HBA1C as seen in our study. also, this sort of intervention can lead to improvement in drug compliance as well. We should present this sort of technology to reduce the burden on the troubled healthcare system in India.

EP097 / #618

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

LONG-TERM COST-EFFECTIVENESS USING THE SMART INSULIN PEN CAP INSULCLOCK® IN RELATION TO THE STANDARD-OF-CARE TREATMENT IN TYPE 1 DIABETES POPULATION IN SPAIN

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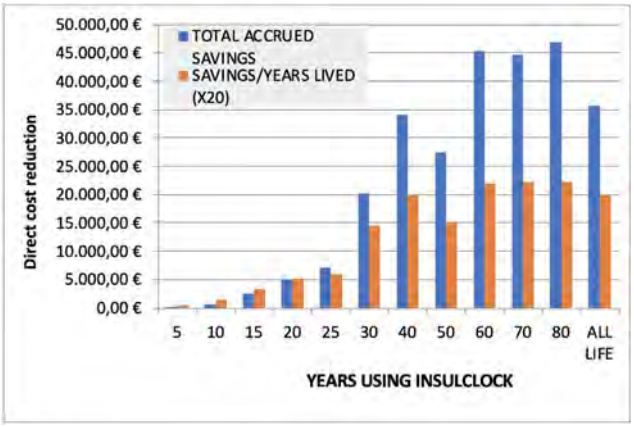
Background and Aims: *Insulclock®* system includes an insulin pen smart cap and app designed to improve treatment adherence and diabetes self-management results, integrating insulin doses and CGM information. Previous RCTs showed an improvement in glycemic levels, adherence, and satisfaction in T1DM patients. Healthcare payers ask for evidence to support the value of new technologies in diabetes management. This analysis assessed the cost-effectiveness of the *Insulclock®* system compared to standard-of-care (Soc) from the Spanish National Health System perspective.

Methods: A microsimulation model was developed projecting the occurrence of complications, and mortality over patients' lifetimes based on DCCT RCT data. The clinical impact of the Insulclock® device and app were obtained from a RCT with 21 T1DM participants using basal-bolus insulin therapy and CGM. The use of app information and alerts was associated with an 8% increase in TIR ($P = 0.026$). Change in TIR translated into an -0.55% HbA1c difference. Unitary costs (€, year 2021) were derived from literature and the Spanish official tariffs for healthcare services. A 3% annual discount rate was considered.

Results: *Insulclock®* system resulted in a dominant option, providing more effectiveness (1.6 additional life years and 0.3



retinopathy, 0.01 nephropathy ESKD, 0.1 neuropathy (amputations) and 0.1 CV avoided complications/patient) and less total cost (up to €-35.658 /patient) compared to SoC. The average saving per year of life is 996 EUR.

Conclusions: The continued use of the *Insulclock*® system in the Spanish T1DM population would derive clinical benefits and cost savings for the health system.

EP098 / #626

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

TELEPIED ASSESSMENT OF DIABETIC FOOT ULCER CARE VIA TELEMEDICINE VERSUS CONVENTIONAL FOLLOW-UP

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Background and Aims: The diabetic foot is a major public health problem worldwide. It is associated with poorer survival and functional outcomes with a high recurrence rate. The diabetic foot is one of the leading causes of lower limb amputations. Approximately 50% of non-traumatic amputations were performed in patients with diabetes. In 2013 the health insurance fund recorded 33,661 diabetic foot-related stays for 20,586 patients **Objectives:** To study whether the total number of hospital days for healing a new foot wound in a patient living with diabetes is lower in the Télépied experimental group than in the usual care control group.

Methods: -Monocentric, controlled, open-label, parallel-arm study in diabetic patients with a new foot wound or recurrence of an existing healed wound. **Primary Outcome:** Comparison of the total number of hospital days over 1 year or until a diabetic foot wound is completely healed between the Télépied group and the "usual care" group.

Results: In the standard follow-up group (N = 82 patients), the average number of hospital days for foot ulcers in a patient living with diabetes (DFU) at one year of follow-up was 14.64 days [9.97; 19.29].In the telemonitoring group (N = 87 patients), the mean number of days of hospitalisation related to DFU at one year of follow-up was 7.36 days [2.83; 11.89]. The adjusted difference in mean is 7.27 days [0.77; 13.77], p-value = 0.0286).

Conclusions: Telemedicine follow-up with the intervention of a referral nurse significantly reduces the number of days of hospitalisation for healing of a foot wound in patients with diabetes.

EP099 / #661

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

RECONCILING THE INTERNATIONAL CONSENSUS REPORTS FOR TYPE 1 AND LADA.

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Background and Aims: In 2020, Buzzetti et. al. released "Management of Latent Autoimmune Diabetes in Adults: A Consensus Statement From an International Expert Panel" and in 2021, Holt et. al. released "The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)". We review these works and present a framework for merging them into one comprehensive guide for the diagnosis and treatment of Type 1, LADA, and Type 2 Diabetes. In doing so we take the strengths of both reports and remove contradictions between them. This gives clinicians a clear guide on diagnosis and treatment, regardless of the rate of progression of the disease.

Methods: Our analysis involved two parts. First, we reviewed the proposed flow diagrams and recommendations for the diagnosis of Type 1 and LADA in the two works. Determining common ground we then merged them to form a simple step-by-step guide for diagnosis. The second part involved the same process for the recommended treatments, again, merging the two reports to build on the strengths of both.

Results: The final result is one flow diagram from initial presentation of symptoms, through to long term treatment options and a proposed cadence of diagnostic reviews. The guide covers Type 1, LADA, and Type 2 diabetes allowing, for the first time, consistency in diagnosis and treatment.

Conclusions: We conclude that while both reports are milestone works in themselves, together they provide a complete picture for diabetes diagnosis and management.

EP100 / #69

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

USING A FASTING PLASMA GLUCOSE SIMULATOR TO OPTIMIZE BASAL INSULIN (DEGLUDEC) TITRATION IN INSULIN-NAÏVE TYPE 2 DIABETES PATIENTS

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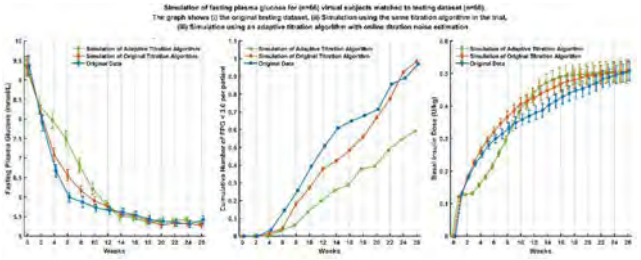
Background and Aims: Type 2 diabetes (T2D) patients are switched to basal insulin when other therapies fail to achieve satisfactory glycemic control. Fasting plasma glucose (FPG) levels are commonly used in insulin titration rules aimed at achieving tight glycemic control without undue hypoglycemic risk. Comparing titration rules and iterating on novel designs is a lengthy, expensive, and potentially risky process. We propose a novel simulation platform that predicts glycemic outcomes from FPG-based titration rules. Using the platform, we then show how an adaptive titration algorithm could improve level-2 hypoglycemia (<3.0 mmol/L) exposure while maintaining glycemic control.

Methods: A simple linear fasting glucose model with multiplicative titration noise (capturing metabolic and sensor variability) is fitted and validated on a dataset (daily FPG and insulin) of 220 insulin-naive T2D for 26 weeks (NCT01006291, training: n = 154, testing: n = 66). Validation is obtained by re-simulating the clinical trial data of the testing set. Using this platform, we simulated the outcomes of an adaptive basal titration algorithm using matched testing set avatars.

Results: Model parameters were estimated with good precision: CV <100%. In the testing dataset, matched avatars predicted the trial outcomes (Figure). Online estimation of the



titration noise for each avatar enables an adaptive basal titration algorithm that lowers the hypoglycemia exposure two-fold (0.98 [0.0–21.0] *vs.* 0.59 [0.0–5]) (Mean [Min–Max]) while achieving the same glycemic control (Figure).

Conclusions: This FPG simulator predicts the performance of FPG-driven insulin basal titration rules for T2D. Titration rule matching subject-specific titration noise may improve glycemic outcomes in T2D patients.

EP101 / #762

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

CARDIOVASCULAR RISK ASSESSMENT IN PEOPLE LIVING WITH TYPE 1 DIABETES FROM THE RENACED-DT1 MEXICAN REGISTRY

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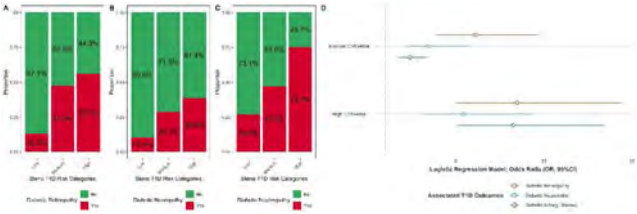
Background and Aims: Cardiovascular (CV) disease is the main cause of morbidity and mortality in individuals living with type 1 diabetes (T1D). CV risk assessment in this population is often limited. Our objective was to classify Mexican individuals registered in the RENACED-DT1 national registry according to their CV risk using the Steno-T1D Score and to associate microvascular complications

Parameter	Total Population (n=1718)	Low-Risk (n=1476)	Middle-Risk (n=149)	High-Risk (n=94)	P-value
Age (years)	35 (18-36.1)	22 (17-30)	48 (41-55)	54 (45-64.5)	<0.001
Male sex (%)	692 (38.5)	601 (40.7)	51 (34.2)	40 (42.5)	<0.001
BMI (kg/m2)	22.9 (20.3-25.9)	22.5 (19.7-22.4)	24.7 (23.3-28.3)	24.2 (22.2-28.2)	<0.001
Diabetes duration (years)	11.7 (6.8-18.9)	10.3 (6.5-16.4)	20.5 (12.6-29.4)	30.7 (22.4-40.6)	<0.001
Insulin dose (mg/kg/day)	0.69 (0.39-0.89)	0.66 (0.40-0.91)	0.54 (0.41-0.78)	0.50 (0.33-0.73)	<0.001
HbA1c (%)	8.3 (7.2-10.1)	8.3 (7.1-10.1)	8.4 (7.2-9.9)	8.4 (7.5-9.9)	0.4269
Albumin-to-Creatinine Ratio (mg/mg)	6.53 (3.6-47.0)	5.57 (3.5-22.8)	18 (3.7-97.3)	144 (28-442)	<0.001
Microalbuminuria (%)	365 (21.2)	302 (20.4)	41 (27.5)	22 (23.4)	<0.001
Macroalbuminuria (%)	104 (6.1)	44 (2.3)	26 (17.4)	44 (46.8)	<0.001
eGFR (mL·min^{-1}·1.73 m^{-2})	113.3 (31.6)	120.8 (25.6)	86.7 (26.1)	56.9 (32.8)	<0.001
Systolic blood pressure (mmHg)	110 (100-120)	110 (100-118)	120 (110-130)	120 (115-140)	<0.001
Diastolic blood pressure (mmHg)	70 (60-76)	69 (60-75)	70 (64.5-80)	70 (65.5-85)	<0.001
Total Cholesterol (mg/dl)	173 (149-199)	170 (147-197)	176 (152-202)	187 (160-216)	<0.001
HDL-C (mg/dl)	49 (40-59)	48 (40-58)	53 (40-65)	54 (44-62)	<0.001
LDL-C (mg/dl)	99 (80.3-120)	98.6 (80-120)	98 (83-119)	102 (82-127)	<0.001
Hospitalization (%)	173 (10.1)	148 (10.2)	16 (10.7)	9 (9.6)	0.5785
Mild-or-Moderate Hypoglycemia (%)	151 (8.8)	123 (8.3)	20 (13.4)	8 (8.5)	0.7323
Severe-Hypoglycemia (%)	120 (6.9)	84 (5.7)	16 (10.7)	20 (21.3)	<0.001

Table 1: Descriptive characteristics of the RENACED-DT1 stratified by the Steno T1 Risk Categories.



Methods: We included subjects with T1D. Patients who had prior CVD events were excluded. The Steno-T1D Score was estimated using the online calculator (https://steno.shinyapps.io/T1RiskEngine/). Risk categorization was based on NICE guidelines in low, middle and high risk. Association of Steno-T1D Score with microvascular complications was assessed using logistic regression models.

Results: We estimated the Steno-T1D score in 1718 patients living with T1D registered by 49 physicians across the country. 85.9% were classified as low-risk, 8.7% as middle-risk and 5.5% as high-risk. Descriptive characteristics are presented in table 1. Most of the clinical, biochemical and chronic diabetic complications showed an adverse profile as the CV risk increased. Patients with high-risk CV had the highest probability for diabetic retinopathy (OR 8.49, 95% CI 5.00-14.42), neuropathy (OR 5.43, 95% CI 3.14-9.41) and chronic kidney disease (OR 8.27, 95% CI 5.09-13.43) (Figure 1).

Conclusions: The Steno T1D Risk Engine cardiovascular risk categories are associated with metabolic and microvascular complications in Mexicans living with T1D. Routine CV risk assessment and treatment of risk factors for developing macrovascular disease in individuals with T1D is essential in order to decrease the burden caused due to these complications.

EP102 / #788

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

HYPOGLYCEMIA (TIME BELOW RANGE) IN PERSONS WITH RELATIVELY WELL CONTROLLED DIABETES (7% TO 8% HBA1C) ON SULPHONYLUREA THERAPY BY AMBULATORY GLUCOSE PROFILE

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Background and Aims: SU is conventionally used as a powerful glucose lowering agent and is notoriously known to increase the risk of hypoglycaemia. Introducing continous

glucose monitoring (CGM/AGP) in patients on SU therapy can help clinicians to optimize diabetes treatment along with nutrition which can reduce the risk of hypoglycaemia. This paper is an attempt to assess the risk of hypoglycaemia (TBR) in patients of diabetes who are on SUs with fairly controlled diabetes (HbA1c between 7 to 8) using AGP.

Methods: A retrospective analysis was done at our diabetes care centre. 300 persons with type 2 diabetes on AGP and on SU therapy were studied. Only those patients with HbA1c between 7- 8%, indicating fairly controlled diabetes were included.

Results: It was observed that no hypoglycaemia was present in 44% of the patients as per AGP data. 32% patients had hypoglycaemia with less than 5% TBR. 24% patients had hypoglycaemia with TBR more than 5%, out of which only 20% reported symptoms of hypoglycaemia.

Conclusions: Judicious use of sulphonylureas does not increase the risk of hypoglycaemia (time below range) in type 2 diabetics as is traditionally believed.

EP103 / #806

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

RISK STRATIFICATION USING INDIAN DIABETES RISK SCORE IN PEOPLE ATTENDING A DEDICATED DIABETES CLINIC

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Conquer Diabetes, Diabetes, Mumbai, India

Background and Aims: Madras Diabetes Research Foundation developed Indian Diabetes Risk Score (IDRS)

Methods: IDRS was prospectively used to categorise 97 people for low, moderate, and high risk for a score of <30, 30-60 and >60, respectively

Results: There were two people with an IDRS of <30, 57 with a moderate IDRS (30-60) and 38 who had a high IDRS of ≥60. Mean age (years) was 42 (SD ±15, 95% CI 44 to 50). The mean IDRS was 60 (SD ±15, 95% CI 57 to 60). The mean RBS (mg/dL) and waist circumference (WS) (cm) were 177 (SD ±49, 95% CI 167 to 187) and 37 (SD ±6.3, 95% CI 36 to 38). There was a significant correlation between RBS and WS ($r = 0.29$, $p = 0.0036$, 95% CI 0.098 to 0.46). 82.4% (n = 80) were prediabetic (RBS 140-200 mg/dL) and 17.5% (n = 17) were diabetics (RBS >200 mg/dL). Women (n = 55) 62.7 (SD ±14.4, 95% CI 58.8 to 66.6) had higher mean IDRS score than men (n = 42), 56.1 (SD ±14.1, 95% CI 51.7 to 60.5); $p = 0.028$. Age significantly correlated with the IDRS ($p < 0.0001$, $r = 0.42$), irrespective of diabetes ($p = 0.029$, $r = 0.52$), or prediabetes ($p = 0.0003$, $r = 0.39$). There was a significant difference in the mean age in the low (20.5 ± 3.5), moderate (44.25 ± 14.9) and high-risk groups (51.6 ± 12.7), ($p = 0.0019$).

Conclusions: IDRS is a simple, cost-effective tool, useful to stratify patients based on the risk factors. This enables to deliver precise diabetes treatment and utilise effective decision making for judicious lifestyle and pharmacological management of diabetes.

EP104 / #119

Topic: ***AS05-Glucose Sensors***

USE OF DIABETES TECHNOLOGY IN ELDERLY PATIENT WITH TYPE 1 DIABETES

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Background and Aims: The use of diabetes technology in older adults with type 1 diabetes (T1D) is currently not well documented. In this population, more flexible glucose targets have been proposed. The aim was to perform a real-life assessment of frequency, results and barriers of technology use in elderly patients.

Methods: Elderly patients (age ≥65 years) with T1D, using any diabetes technology device were evaluated. A retrospective descriptive analysis of parameters reflecting the use of technology was performed. Reasons for discontinuation or refusal of therapy were collected.

Results: 47 patients were included (age: 70 ± 5 years (65 - 87), 49% (n = 23) females, diabetes duration 28 ± 14 years).

A significant difference was found between HbA1c before the start of the device and HbA1c in the last visit (HbA1c 7.8 ± 1.3% vs HbA1c 7.4 ± 0.9 %; $p = 0.043$). 32 patients (68%) had a time in range 70-180 mg/dl >50%. 18 patients (38%) had a time in range 70-180 mg/dl >70%. 8 patients (17%) had a time <70 mg/dl <1%. Out of 47 subjects, 5 refused to initiate the prescribed device and 1 discontinued its use. Reasons for refusal were: alarm fatigue, lack of improvement or inability to understand the system. Two subjects initiated first flash/continuous glucose monitoring, and afterwards, closed-loop systems.

Conclusions: The use of technology in the elderly patients achieved an adequate glycaemic control, although control of hypoglycaemia frequency remains a challenge. Some of these patients were reticent or had difficulties to use diabetes technology.

Table 1. Outcomes of use of diabetes technology in elderly subjects.

Duration of use of device (years)	2.3 ± 1.9
Diabetes technology option:	
MDI + Flash glucose monitoring n (%)	26 (62)
MDI + Continuous glucose monitoring n (%)	10 (24)
Closed-loop system n (%)	3 (7)
Pump Therapy + Flash glucose monitoring n (%)	1 (2)
Pump Therapy + SMBG n (%)	2 (5)
Glycaemic outcomes	
GMI (%)	7 ± 0.6
Time 70-180 mg/dl (%)	65 ± 17
Time >180 mg/dl (%)	30 ± 16
Time >250 mg/dl (%)	8 ± 11
Time <70 mg/dl (%)	3 ± 3.3
Time <54 mg/dl (%)	0.5 ± 1.4
Mean glucose of sensor glucose (mg/dl)	160 ± 28
SD of sensor glucose (mg/dl)	55 ± 17
CV of sensor glucose (%)	33 ± 6
Sensor use (%)	91 ± 15

N = 42 (Glycaemic outcomes n = 37). Data are expressed as mean ± standard deviation, unless otherwise indicated.

EP105 / #136

Topic: ***AS05-Glucose Sensors***

LONGITUDINAL RELATIONSHIP BETWEEN TIME IN RANGE AND HBA1C IN A REAL-WORLD CLINICAL PRACTICE SETTING

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Background and Aims: Guidelines suggest every 10% increase in time in range (TIR) corresponds to an average decrease in glycated hemoglobin (HbA1c) of 0.5%. To facilitate adoption of Continuous Glucose Monitoring (CGM) metrics by practitioners, our objective was to estimate the real-world association between TIR and HbA1c, measured at the time of TIR and at subsequent routine clinic visits.

Methods: A retrospective sample of CGM-experienced adults (≥18 years old) with Type 1 diabetes (T1D) from the Barbara Davis Center for Diabetes with available ambulatory glucose profiles and at least two laboratory-measured HbA1c values (i.e., same visit as TIR [70-180mg/dL] and subsequent routine visits) were analyzed at the patient-visit level between 2018 and 2020. Longitudinal mixed-models were used to estimate subject-specific associations between TIR and HbA1c, adjusting for relevant characteristics.

Results: Among 542 adults with T1D and 2,017 visits, mean (SD) age was 38 (16) years, HbA1c at first visit was 7.5% (1.4), number of visits was 3.6 (2.9), and duration between visits was 4.9 (5.1) months. For each 10% increase in TIR, there were statistically significant changes in HbA1c of -0.34% (95% CI: -0.37%, -0.31%) when TIR and HbA1c were measured near the same visit and -0.20% (95% CI: -0.24%, -0.16%) when HbA1c was measured at subsequent routine visits, respectively.

Conclusions: Although HbA1c reduction was lower compared to guideline suggestions, this real-world data showed meaningful associations between TIR and HbA1c which were sustained at subsequent follow-up visits. To gain confidence in using TIR for glycemic control assessment, practitioners should assess TIR and HbA1c across multiple visits.

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Topic: ***AS05-Glucose Sensors***

THE IMPACT OF CONTINUOUS GLUCOSE MONITORING DATA LOSS ON GLYCEMIC OUTCOMES – IS 70% OF DATA SAMPLING OVER 14 DAYS ENOUGH?

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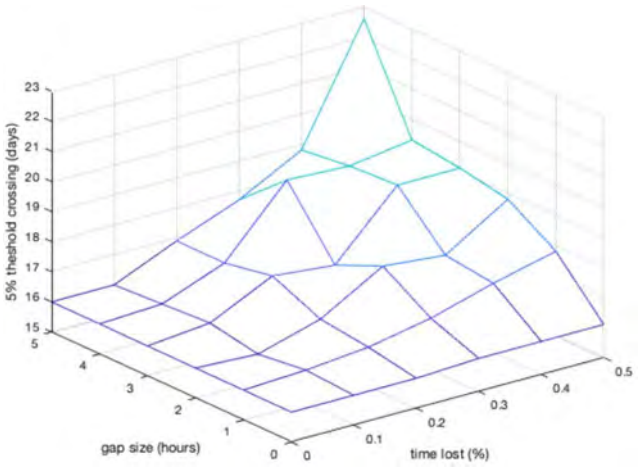
Background and Aims: To investigate the impact of data loss on optimal duration of continuous glucose monitoring (CGM) for time-in-target range (TIR).

Methods: In this single center, real-life study, Dexcom G6 CGM data up to 90 days were collected for 291 adults (≥ 18 years) with type 1 diabetes of ≥2 years attending Barbara Davis Center for Diabetes Adult Clinic. Pregnancy and patients on closed-loop systems were excluded. Random data loss was generated by creating data gaps (1-5 hours) and removing CGM values until the desired percentage of data loss (10-50%) is achieved. For CGM TIR (70-180 mg/dL), days required to cross 5% threshold of median absolute percentage error (MdAPE) by random data loss and data gaps were calculated.



Results: Five percent threshold for crossing MdAPE remained constant at 16 days for random data loss up to 50% (Figure 1). However, data loss by eliminating larger gaps, the MdAPE crossing threshold increases with the percentage of data loss and with longer gaps. For example, 5 hour of gaps with 50% of data loss would require 23 days of CGM data. Figure 1: 3D diagram represents days of CGM data require to cross 5% threshold of MdAPE for % time-in-range. 16 days of CGM data is sufficient up to 50% of random data loss or larger gaps (5 hours) with 20% of data loss.

Conclusions: International consensus recommendation for 70% CGM data adequacy is sufficient to report time in range (70-180mg/dl) with two weeks of data without large data gaps.

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Topic: ***AS05-Glucose Sensors***

THE ASSOCIATION BETWEEN BODY MASS INDEX (BMI) AND TIME IN RANGE AMONG YOUNG ADULTS WITH TYPE 1 DIABETES: DATA FROM THE T1D EXCHANGE QI COLLABORATIVE

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Background and Aims: Background: Obesity in type 1 diabetes (T1D) is known to be associated with higher blood glucose levels and diabetes-related complications. Blood glucose (BG) control is increasingly being determined by Time in Range (TIR), a parameter derived from continuous glucose monitors (CGMs), corresponding to the percentage of time BG range is between 70-180 mg/dL. The primary objective of the U.S.-based multi-center study was to determine if body mass index (BMI) is associated with TIR.

Methods: Methods: Electronic health record data from the T1D Exchange Quality Improvement (T1DX-QI) Collaborative for young adults (18-35 years) from 2018-2020 was analyzed. People with complete information on TIR, recorded as a 2-week average, BMI, sex, race/ethnicity and insurance status were included in this analysis. Patients were classified as overweight and obese if they had a BMI (kg/m^2) of 25 to <30 and ≥30, respectively.

Results: Results: This analysis included 1,126 young adults, with T1D. ADA recommended TIR ≥70% was met by 18% of the study population, whereas 82% did not meet TIR ≥70% goal. People with TIR <70% were more likely to be overweight (28%) and obese (11%) than those with TIR ≥70% (23% and 6%; respectively; $p < 0.001$). (Table 1)

Conclusions: Conclusion: In this large population-based analysis of young adults with T1D, we found that overweight and obese people, publicly insured and those of Hispanic race/ethnicity, were more likely to have present a decreased average TIR.

Table 1: Patient characteristics by the percentage of time in target blood glucose range (N=1,126).

	TIR <70% N=926	TIR ≥70% N=200	P-value
Age, yrs Mean (SD)	21 (2)	20 (2)	<0.001
Sex - n (%) Male	446 (48)	105 (53)	0.30
Race - n (%)			0.11
White	688 (74)	164 (82)	
Black	33 (4)	6 (3)	
Hispanic	105 (11)	13 (6)	
Asian/Other	100 (11)	17 (9)	
Insurance - n (%)			0.21
Private	742 (80)	168 (84)	
Public	162 (17)	27 (14)	
BMI Category			<0.001
Normal	572 (61)	141 (71)	
Overweight	256 (28)	47 (23)	
Obese	98 (11)	12 (6)	
A1c, % Mean (SD)	8.9 (2)	7.2 (2)	<0.001

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Topic: ***AS05-Glucose Sensors***

REDUCTIONS IN HBA1C IN TYPE 1 AND TYPE 2 DIABETES WITH FLASH GLUCOSE MONITORING ARE SUSTAINED FROM 3-24 MONTHS: A META-ANALYSIS OF REAL-WORLD OBSERVATIONAL STUDIES

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Background and Aims: Real-world evidence (RWE) confirm that use of the FreeStyle Libre system is associated with reductions in HbA1c for adults and children with type 1 diabetes (T1DM) or type 2 diabetes (T2DM). The aims of this current meta-analysis are to investigate changes in HbA1c from 3 months to 24 months and to identify patterns of change in HbA1c for users of the FreeStyle Libre system for people living with T1DM or T2DM.

Methods: A bibliographic search up to December 2020, identified 74 studies reporting data on change in HbA1c in 30,522 participants with type 1 (n = 28,107) or type 2 diabetes (n = 2415) using the FreeStyle Libre system, including observations on children, adolescents and adults. Meta-analysis was performed using a random effects model.

Results: Reductions in HbA1c at 3 months were similar for adults with T1DM (-0.53%, 95% CI -0.69 to -0.38) or with T2DM (-0.45%, 95% CI -0.57 to -0.33), continuing through 4.5-7.5 months in T1DM (-0.42%, 95% CI -0.58 to -0.27) and in T2DM (-0.59%, 95% CI -0.80 to -0.39). Meta-regression analysis shows that higher starting HbA1c is correlated with greater reductions in HbA1c in T1DM and in T2DM. These patterns of change in HbA1c were sustained for 24 months in T1DM and for 12 months in T2DM.

Conclusions: Meta-regression analysis of RWE confirms that using the FreeStyle Libre system is associated with significant reductions in HbA1c for adults with T1DM or with T2DM. Reductions are greater for people with higher baseline HbA1c and are sustained for 3-24 months.

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Topic: ***AS05-Glucose Sensors***

EVALUATION OF THE ACCURACY OF CONTINUOUS GLUCOSE MONITORING WITHOUT CALIBRATIONS IN DIABETIC PATIENTS ON INTERMITTENT HEMODIALYSIS

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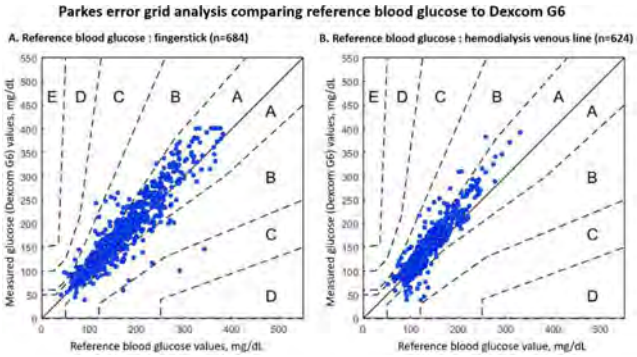
Background and Aims: Continuous glucose monitoring (CGM) improves glycemic control in diabetic patients, but its reliability on hemodialysis is poorly understood and potentially affected by interstitial and intravascular volume variations, chronic uremia, and metabolic acidosis. Studies are needed to assess factory calibrated CGM accuracy.

Methods: We assessed the DexcomG6 accuracy using blood glucose measurements (BGM) from venous line during hemodialysis sessions (iSTAT System, Abbott Laboratories, Chicago, IL, USA) and capillary blood tests at home (ContourNext Ascencia DiabetesCare glucometer, Basel, Switzerland) over 10 days.



Results: Twenty diabetic patients completed the protocol: mean age 61.2years, BMI 31.5kg/m^2, 6 women, 17 insulin treated and 12 daily glucometer users. Three CGMs failed between 5 and 7 days. The MARD (mean absolute relative difference) of DexcomG6 calculated on fingerstick BGM (n = 684) was 13.8% and venous BGM (n = 624) was 14.4%; 98.7% and 100% of values were in A/B zones of the Parkes error grid, respectively. Glucose measurements were overestimated with DexcomG6 compared to BGM in over 70% of values. Throughout 181 cumulative days of glucose monitoring with DexcomG6, the median time in range (70-180mg/dL) is 38.5% (IQR: 29.3-57.9), with 28.7% (7.8-40.6) of the time >250mg/dL and a mean coefficient of variation of 35.6 ± 9.5%. HbA1c, known to be underestimated in this population, was correlated with the glycemic management indicator (correlation coefficient 0.701, p = 0.0006) but significantly lower: GMI 8.2 ± 1.0% versus HbA1C 7.7 ± 1.3% (p = 0.02).

Conclusions: The overall performance of the DexcomG6 in diabetic patients on hemodialysis appears reasonably accurate and clinically relevant for use in practice by patients and health professionals to improve diabetes management.

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Topic: ***AS05-Glucose Sensors***

BETTER GLYCEMIC CONTROL AND HIGHER USE OF ADVANCED DIABETES TECHNOLOGY IN AGE GROUP 0-17 YRS COMPARED TO 18-25 YRS WITH TYPE 1 DIABETES

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Background and Aims: The development of diabetes technology is rapid and needs both education and resources to be successfully implemented in diabetes care management. The aims were to identify factors associated with glucose control and costs.

Methods: In an observational study we evaluated the use of advanced diabetes technology, resource utilization, glycemic control, and costs. The study population was all T1D individuals in the Region Halland in Sweden. The study cohort was followed for 7 years (2013-2019).

Results: Children aged 0-17 years have significantly better glucose control than young adults aged 18-25 years. The mean HbA1c difference between children and young adults was 8 mmol/mol. Significant difference was noted from 6 months after diabetes diagnoses and onwards. Co-morbidities such as ADHD, anxiety, depression, and eating disorders were associated with higher HbA1c. All groups, irrelevant of age and co-morbidity, had positive effect on glucose control after a visit to a dietitian or psychologist. Differences were found between the age groups in terms of more advanced diabetes technology and more frequent visits to a physician in children.

Conclusions: More frequent visits to physicians, dietitians, and psychologists are linked to improved glucose control. Increased resources including access to more advanced technology are required in young adults. A young adult diabetes team could be implemented to mitigate this inequality between age groups found in our study. Increased resources and strategies to improve glucose control, will likely lead to numerous positive effects, reduction of the burden of disease, and reduction of long-term costs in T1D.

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Topic: ***AS05-Glucose Sensors***

PATIENT CHARACTERISTICS AND GLUCOSE CONTROL IN TYPE 3C DIABETES

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Background and Aims: Diabetes mellitus secondary to pancreatic diseases is classified as pancreatogenic diabetes or type 3c diabetes mellitus (DM3c). Chronic pancreatitis is the most commonly identified cause. The other main causes are tumors of the pancreas, hemochromatosis, and surgery of the pancreas. Its prevalence is around 8% of the entire universe of diagnosed diabetes. In our country, National Health System has recently approved financing of continuous glucose monitoring devices for this type of diabetes. The aim of this study is to describe the main characteristics of our type 3c diabetes patients who use glucose monitoring devices. Also, we collected data of their ambulatory glucose profiles in order to determine if there are differences in their glucose control or need of insulin.

Methods: This is a retrospective, descriptive observational study from 29 October 2021 to 12 November 2021 (14 days). 16 patients were included (8 men), diagnosed with type 3c diabetes. We described the cause of diabetes, weight, age and insulin dosage and regimen. Ambulatory glucose profile report was collected based on data obtained from LibreView continuous glucose monitoring system (14 day period).

Results: Patients were divided in 3 groups (pancreatectomy, chronic pancreatitis and others). There are no differences by groups in TIR, TBR, TAR, GMI, number of hypoglicemias or CV. TBR was extremely low in this patients. Patients with pancreatic surgery needed the less insulin/kg than the other groups.

Conclusions: Glucose monitoring of patients with DM3c helps to reduce hypoglycemias. Pancreatic surgery group insulin needs is the lowest, maybe because of lower-degree of insulin resistance than others.

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Topic: ***AS05-Glucose Sensors***

VARIATION OF TIME IN RANGE

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Background and Aims: Knowledge of variation in time in range (TIR) is important in clinical practice to interpret observed individual changes and to dimension intervention studies. Our aim is to present data for variation in TIR.

Methods: Glucose data for eight weeks was downloaded for 166 patients with type 1 diabetes who performed intermittently scanned glucose monitoring (isCGM) with Abbott Freestyle Libre. Glucose data was calculated for four periods of two weeks and for two periods of four weeks.

Results: 140 patients (84%) used multiple daily injections and 26 (16%) used continuous insulin infusion. TIR calculated from the first two weeks was 52.2 ± 17.1 % and 53.7 ± 16.4 % from the last two weeks (difference 1.5%, standard deviation of the difference 10.4%, p = 0.07). It follows that 78 patients are needed in each arm of a parallel study to detect a difference of 5 percent point with a type I error 5 % and type II error 15 %. The within patient standard deviation for TIR was 6.3 % corresponding to a 95% prediction limit for the difference between two TIR values of ±17.6 % when calculated from two weeks. If TIR was calculated from periods of four weeks the 95 % prediction limits was ±13.2 %.

Conclusions: The 95 % prediction limit of TIR is huge for patients using isCGM. It is difficult to draw firm conclusions when individual TIR from two or four weeks are compared. This may not be valid for users of insulin pumps with hybrid closed loop.

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Topic: ***AS05-Glucose Sensors***

FIRST DATA FROM THE AMBULATORY GLUCOSE PROFILE OF PATIENTS WITH TYPE 1 DIABETES AT A TERTIARY HOSPITAL: A RETROSPECTIVE STUDY.

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Background and Aims: Flash glucose monitoring (FGM) improves glycemic control of patients with T1D. Our aim was to describe the AGP and its evolution during the time of use of this system.

Methods: 766 patients with T1D from the Endocrinology Department of a tertiary hospital were included, using FGM Freestyle Libre®2 (FSL2), from 2019 to the present. Current, 6, 12 months ago and initial data were described, consulting the LibreView platform. A not normal distribution of data was determined with the Kolmogorov-Smirnov test, so results were represented according to the median (p25-p75), and were compared using the U-Mann Whitney and Friedman test (statistical significance $p < 0.05$).

Results: 54.2% were women. Current AGP: percentage of time FSL2 is active (Active time) 94%(88-97%), GMI 7.00(6.60-7.40), CV 36.00%(31.70-40.60%), TIR 64%(52-75%), TBR 3%(1-7%), TAR 30%(20-43%). AGP 6 months ago: Active time 98%(93-100%), GMI 6.90(6.60-7.40), CV 36.70%(32.10-41.00%), TIR 66%(54-75%), TBR 4%(2-7%), TAR 28%(19-40%). AGP 12 months ago: Active time 98%(90-100%), GMI 6.90(6.60-7.40), CV 36.80%(32.90-40.75%), TIR 64.50%(54-75%), TBR 4%(2-8%), TAR 29%(18-40.50%). Initial AGP: Active time 52%(43-66%), GMI 6,90(6,50-7,40), CV 37,50%(32,60-42,20%), TIR 63%(53-73%), TBR 5%(2-9%), TAR 30%(18-40%). Statistically significant differences were observed between current and initial AGP in CV, TIR and TBR. When dividing the patients according to the active time (>90% vs <90%), there was a significant improvement of the AGP metrics, except TBR.

Conclusions: FSL2 improved TIR, CV and TBR after 6 to 12 months of use. A longer active time leads to a better AGP, except TBR, which can be explained by the alarms in hypoglycemia, regardless of its use.

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Topic: ***AS05-Glucose Sensors***

EFFECTIVENESS OF THE FREESTYLE LIBRE 2 FLASH GLUCOSE MONITORING SYSTEM ON DIABETES-SELF-MANAGEMENT PRACTICES AND GLYCEMIC PARAMETERS AMONG PATIENTS WITH TYPE 1 DIABETES USING INSULIN PUMP

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Background and Aims: To determine the effectiveness of Freestyle Libre 2 (FSL2) Flash Glucose Monitoring System (FGMS) on diabetes-self-management practices and glycemic parameters among patients with type 1 diabetes (T1D) using Insulin Pump (IP).

Methods: This prospective study was performed among 47 patients with T1D who self-tested their glucose levels by the conventional finger-prick method. Data related to glycemic profile i.e mean time in range (TIR), mean time above range (TAR) mean time below range (TBR), mean glucose level, HbA1), TDDI were collected at baseline and at the end of the study. Diabetes Self-Management (DSM) responses were collected from all participants at the baseline and at 12 weeks of the study.

Results: The mean TIR was 59.8 ± 12.6, TAR was 32.7 ± 11.6, TBR was 7.5 ± 4.3%. The mean glycemic variability SD was 63.2 ± 12.5 mg/dL, and the (CV) was 41.3 ± 11.4%). At baseline, the A1c level was 8.3%, and at 12 weeks, it dropped to 7.9%. The mean glucose level was 198 mg/dL at baseline, and it declined to 185 mg/dL at 12 weeks. The baseline glucose monitoring frequency through BGM was 2.4/day; however, after the employed the FSL 2, a higher degree of frequency of glucose monitoring was evident at 12 weeks as 8.2/day. A significant improvements were observed in the DSM subscales at 12 weeks, which includes glucose management ($P < 0.001$), dietary control ($P = 0.048$), physical activity ($P = 0.046$), health care use ($P = 0.024$), self-care ($P < 0.001$) compared to baseline.

Conclusions: Using FSL2 was found to raise the patients' DSM levels and improved the metabolic control.

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Topic: ***AS05-Glucose Sensors***

BARRIERS TO CONTINUOUS GLUCOSE MONITOR USE IN YOUTH WITH TYPE 1 DIABETES

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Background and Aims: Adolescents with type 1 diabetes (T1D) have the lowest continuous glucose monitor (CGM) use amongst all age groups. Therefore, we sought to assess barriers to CGM use.

Methods: Surveys were administered to adolescents with T1D participating in a multi-site clinical trial of a behavioral intervention. 136 participants (M_{age} 15.4 ± 1.3, 56% female, $M_{T1D\ duration}$ 6.6 ± 3.7 years, 64% White, Non-Hispanic, 18% Black, Non-Hispanic, 7% Hispanic, 6% Asian, 5% Other/Not Specified) completed surveys and descriptive analyses were conducted to identify the most common barriers to CGM usage.

Results: 106 participants currently used CGMs, 18 previously wore CGMs, and 12 had never worn CGMs. 59% of current and past CGM users started their CGMs with an educator in-clinic, 38% started their CGMs at home, and 3% started their CGMs with a company educator. Prior to starting on the CGM, participants would have liked more information about accuracy (48%), how the CGM works (44%), how the CGM is worn (44%), and cost (16%). Reported reasons why participants stopped using their CGMs included that they experienced pain/discomfort (39%), didn't like to wear them during exercise/school (33%), had problems with the adhesive (28%), and didn't like having them on their bodies (28%).

Conclusions: This study describes barriers to CGM use among a diverse sample of adolescents and highlights areas where CGM education may be helpful/lacking. Additional research is needed to explore how to deliver this information to youth and how to troubleshoot once barriers to CGM use are encountered.

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Topic: ***AS05-Glucose Sensors***

COST-EFFECTIVENESS OF FLASH GLUCOSE MONITORING WITH OPTIONAL ALARMS IN SWEDISH ADULTS WITH DIABETES AND IMPAIRED AWARENESS OF HYPOGLYCAEMIA, USING INTENSIVE INSULIN

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Background and Aims: Impaired awareness of hypoglycaemia (IAH) in diabetes leads to an increased risk of severe hypoglycaemic events (SHEs). RCTs of continuous glucose monitoring (CGM) have demonstrated reductions in SHEs compared with blood glucose monitoring (BGM). Flash continuous glucose monitoring (FCGM) is a CGM with an optional alarm that may reduce potential CGM-associated alarm fatigue, typically at a lower acquisition cost than other CGMs. This analysis assesses the cost-effectiveness of FCGM versus routine BGM in a Swedish population with IAH using intensive insulin therapy.

Methods: The IQVIA CORE Diabetes Model (CDM, v9.0) simulated the impact of FCGM versus BGM over 50 years from a Swedish perspective. Published trial evidence informed cohort data, intervention effects, and resource utilisation; the IN CONTROL study provided the reduced rate of SHEs compared with BGM. Published studies and Tandvårds-Läkemedelsverket (TLV) sources informed utilities and costs. Scenario analyses explored the impact of altering base case inputs and assumptions.

Results: Base case analysis showed medical costs for FCGM were SEK1.64 million versus SEK1.48 million for BGM for a typical patient. FCGM provided 0.72 additional quality-adjusted life years (QALYs) compared with BGM (12.37 versus 11.65). The incremental cost effectiveness ratio (ICER) is SEK226,000/QALY. Main drivers were reduced costs and disutility associated with lower SHEs for FCGM and lower utility associated with using BGM. ICERs for all scenarios were under SEK300,000/QALY, which is below the threshold typically considered acceptable in Sweden.

Conclusions: From a Swedish perspective, FCGM for people with IAH using intensive insulin may be considered cost-effective compared with BGM.

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Topic: ***AS05-Glucose Sensors***

TWO YEARS OF FREESTYLE LIBRE (FSL) USE: IMPACT ON GLYCAEMIC CONTROL AND HYPOGLYCAEMIA AWARENESS IN PEOPLE WITH DIABETES: ASSOCIATION OF BRITISH CLINICAL DIABETOLOGISTS NATIONAL AUDIT

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Background and Aims: We have previously shown beneficial effectsof FSL monitoring on glycaemic control and hypoglycaemia awareness in people living with diabetes. In this study we investigate the long term (≥ 2 years) effect of FSL on glycaemic control and hypoglycaemia awareness.

Methods: Clinicians from 106 NHS hospitals in the U.K. submitted FSL user data, collected during routine clinical care, to a secure web-based tool held within the NHS N3 network. The student t-test was used to compare the baseline and follow-up HbA1c, GOLD score (measure of hypoglycaemia awareness) and other baseline demographic characteristics.

Results: A total of240 FSL users with ≥2 years follow-up were identified, mean age of 36.2 ± 19.8 years, 50% females, diabetes duration 20.1 ± 16.4 years, BMI of 24.5 ± 5.7 kg/m^2 and mean follow-up 2.85 ± 0.79 years. These participants showed a -4.6 mmol/mol change in HbA1c, reducing from 62.4 ± 14.8 mmol/mol to 57.8 ± 11.9mmol/mol at follow-up (P = 0.0002). The HbA1c reduction was greater in those with a high baseline HbA1c (≥69.5 mmol/mol) reducing from 81.5 ± 13.0mmol/mol to 66.5 ± 14.4 mmol/mol (P < 0.0001). The baseline GOLD score was 2.8 ± 1.7, which improved to 2.1 ± 1.2 (P < 0.0001) at follow-up.

Conclusions: People living with diabetes who used the FSL for >2years demonstrated benefits in both glycaemic control and hypoglycaemia awareness.

EP118 / #265

Topic: *AS05-Glucose Sensors*

A GUIDE FOR THE USE OF FGM METRICS IN CLINICAL PRACTICE: EXPERT OPINION OF AN ITALIAN STUDY GROUP ON DIABETES AND TECHNOLOGY

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Background and Aims: The wider access to CGM, including FGM, has enabled people with diabetes to achieve glycemic goals and improved their quality of life. We aim to support appropriate use of FGM metrics in clinical practice through dedicated algorithms for (i) non-fragile patients with type 1 or type 2 diabetes; (ii) fragile patients with type 1 or type 2 diabetes; (iii) pregnant women with type 1 or type 2 or gestational diabetes.

Methods: This is an expert paper from three Italian societies for diabetes care.

Results: We developed six-step algorithms. Step 1 entails the evaluation of FGM data sufficiency, with at least 70% of readings in the last 14 days being required for analysis. Step 2 implies the GMI assessment as a measure of overall glucose control in the short term. Step 3 involves identifying the appropriate target glucose range for each patient and evaluating TIR and TBR. Three alternative pathways unfold if (i) TBR and TIR are at the target levels, (ii) high TBR is a concern, or (iii) low TIR is a concern. Step 4 entails the evaluation of AGP in search of either hypoglycemia or hyperglycemia patterns. Glucose patterns are classified according to time of occurrence and severity. Step 5 implies assessing glucose variability through the CV. When CV is >36%, Step 6 requires daily glucose printouts to be reviewed to double-check when patterns of low/high glucose occur.

Conclusions: Structured interpretation of FGM data may ensure effective use of healthcare resources and maximize outcomes for people with diabetes.

EP119 / #287

Topic: *AS05-Glucose Sensors*

FREESTYLE LIBRE 2 VS FREESTYLE LIBRE 1 COMPARISON IN GLYCEMIC CONTROL OUTCOMES IN PEOPLE WITH DM1

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Background and Aims: Freestyle Libre (FSL) 1 was the first interstitial glucose monitoring system funded for patients with DM1. Since May 2020, it has been replaced by an updated product, the FSL2. The objective is to determine the improvement in glycemic control results in people with type 1 diabetes who start monitoring with FSL 2, compared to those who started monitoring with FSL 1.

Methods: We recruited 128 patients over 18 years of age with DM1 who started using the FSL monitoring system consecutively between May 1, 2019 and September 1, 2021. Data were downloaded from the monitoring system 30 days after initiation. FSL2 users were surveyed by telephone on the use of alarms.

Results: 36 patients initiated the FSL 1 device and 92 patients initiated the FSL 2 device, of whom 30 (32.61%) did not activate the alarm system. There were no differences in demographic variables. The results on glycemic control are shown in Table 1.

Conclusions: FSL2 improves on the performance of FSL1 by achieving less hypoglycemia and improved glycemic variability, as long as the alarm system is used.

Table 1	FSL1 (n=36)	FSL2 Alarma ON (n=62)	p FSL2ON vs FSL1	FSL2 alarm OFF (n= 30)	p FSL2OFF vs FSL1
TIR (%)	58.08 (SD 19.96)	61.50 (SD 17.39)	0.196	55.04 (SD 17.32)	0.162
T>180 (%)	34.56 (SD 21.56)	35,16 (SD 19.02)	0.457	39.58 (SD 18.99)	0.083
T<70 (%)	7.19 (SD 7.34)	3.84 (SD 3.93)	**<0.001**	5.38 (SD 5.31)	0.123
CV (%)	38.64 (SD 11.66)	33.02 (SD 8.62)	**0.010**	39.18 (SD 6.84)	0.432

EP120 / #294

Topic: *AS05-Glucose Sensors*

LONGITUDINAL ANALYSIS OF HYPOGLYCEMIA IN RT-CGM USERS FROM GERMANY, SWEDEN, AND THE UNITED KINGDOM (2018-2020)

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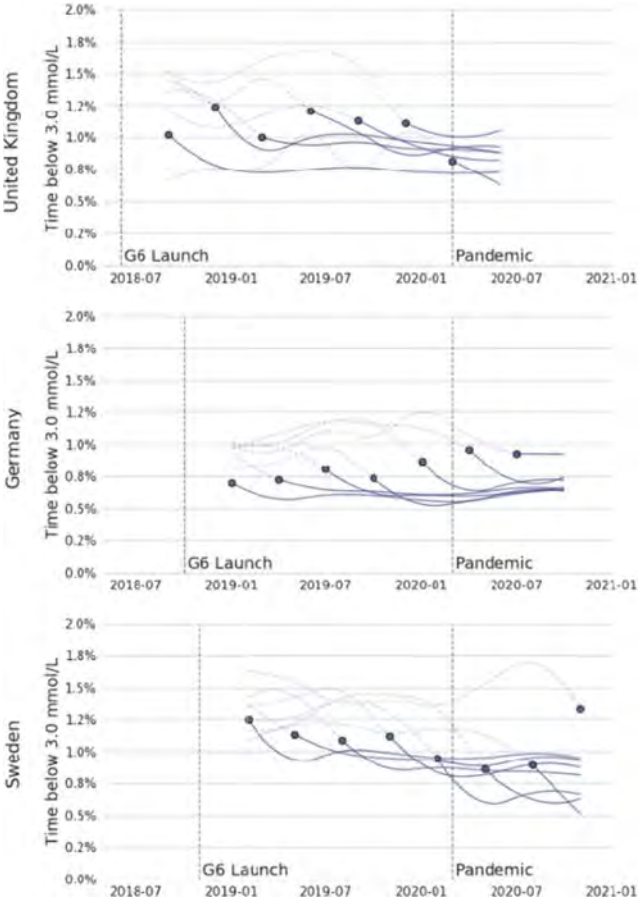
Background and Aims: Population-level data collected from real-time continuous glucose monitoring (RT-CGM) systems may be used to evaluate regional patterns of glycemic outcomes. We analyzed the impact of RT-CGM utilization on hypoglycemia in three European cohorts from 2018-2020.

Methods: In this observational study, deidentified RT-CGM data (uploaded to Dexcom CLARITY) were from real-world users who transitioned from the Dexcom G5 to the G6 in 2018. Percent time in hypoglycemia (<3 mmol/L and <3.9 mmol/L) and urgent low soon (ULS) alert utilization were calculated at 3-month intervals in the 2-year study window post-G6 launch for users from Germany, Sweden, and the UK.

Results: Across all regions, the transition from G5 to G6 was associated with a clear decrease in hypoglycemia (Figure). In months 0-3 after switching to G6, the percent of time <3 mmol/L and time <3.9 mmol/L decreased by 0.27 and 0.51 percentage points, respectively, with another 0.20 and 0.34 percentage point decrease in months 3-6. Six months after switching, users who met consensus targets for <4% of time <3.9mmol/L and <1% of time <3.0 mmol/L increased by an average 10.3 and 14.9 percentage points, respectively. ULS utilization was highest in the first 3 months (96.7% enabled), followed by a 9.5 percentage point decrease in the subsequent 6 months.

Conclusions: There were immediate and sustained improvements in hypoglycemia after switching from G5 to G6 in all countries. The early decrease in ULS utilization may be due to alarm fatigue. RT-CGM technology may help improve glycemic outcomes with long-term use.



EP121 / #314

Topic: ***AS05-Glucose Sensors***

PREGNANT PATIENTS WITH T1D WHO ARE OVERWEIGHT HAVE SIGNIFICANTLY WORSE GLYCEMIC CONTROL THROUGHOUT PREGNANCY THAN THOSE WITH NORMAL BMI – ANALYSIS OF CGM DATA

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Background and Aims: According to current guidelines, continuous glucose monitoring (CGM) devices are recommended for pregnant patients with T1D. In this study, we aimed to compare the long-term glycemic control and neonatal outcomes in overweight and obese pregnant patients with T1D and those with normal pregestational BMI.

Methods: We conducted a single-center retrospective cohort study. Our study cohort included 75 pregnant patients with T1D treated with insulin pumps with CGM systems. We divided our study participants into two subgroups – a group with normal BMI (≤25 kg/m^2) (n - 59), and the second that included patients with BMI over 25 kg/m^2 (n - 26). To assess long-term glycemic control, we determined the HbA1c levels and collected the CGM data in each trimester of pregnancy. We calculated the following glycemic control parameters – mean glucose values, time in/above/below range, coefficient of variations (%CV), mean amplitude of glycemic excursions (MAGE), and mean of daily differences (MODD).

Results: Patients with normal BMI had significantly lower second (5.28 ± 0.51% vs. 5.59 ± 0.63%) and third trimester (5.61 ± 0.51% vs. 5.97 ± 0.69%) HbA1c values. Moreover, they had lower mean glucose values and spent significantly more time in target glucose levels in each trimester of pregnancy. Interestingly, there were no between-group differences in %CV, MAGE, and MODD values reflecting the levels of glucose fluctuations throughout pregnancy and in the proportion of large-for-gestational-age newborns (i.e., 16/59 (27%) in mothers with normal BMI and 9/26 (35%) in the women with excessive body weight).

Conclusions: Increased pregestational BMI is associated with worse glycemic control in pregnant patients with T1D.

EP122 / #330

Topic: ***AS05-Glucose Sensors***

REAL LIFE IMPLEMENTATION OF THE FLASH GLUCOSE MONITORING SYSTEM IN A TERTIARY HOSPITAL: ANALYSIS OF METABOLIC CONTROL AND GLYCOMETRIC PARAMETERS AT TWO YEARS FOLLOW-UP

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Background and Aims: In the Balearic Islands the Fresstyle Libre (FSL) received funding by the public health system for patients with type 1 diabetes (T1DM) since September 2018. The aim of the study is to evaluate the use of FSL with an educational program on metabolic control and glucometric parameters at long-term follow up.

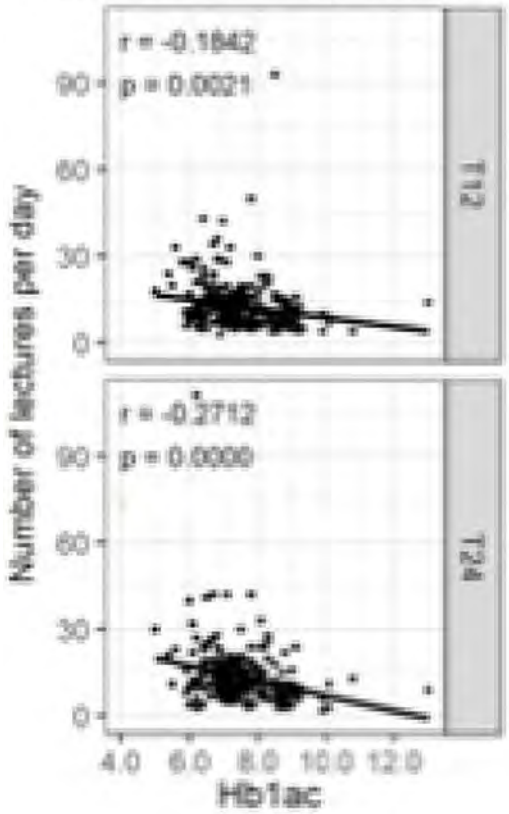
Methods: A total of 249 patients with T1DM were included (pregnancy excluded): mean age (41,7 ± 14,4 years), female sex 55.7%, diabetes duration (21,0 ± 12.9 years) and MDI/ICSI treatment (81.4 vs 18.6 %). Three nurses developed an educational program based on two initial group sessions and an individual visits at 3, 6, 12 and 24 months.

Results:

Table 1. Results at 12 and 24 months of the variables related to metabolic control.

	0M	12M	24M	p 0 vs 12	p vs12 24
Hb1Ac	7,54 (7,4 7,6)	7,10 (7-7,2)	7,1 (7-7,2)	0,000	0,000
GM	161,62 (158-165,2)	155,35 (153-160,7)	155,59 (152-159,2)	0,001	0,001
CV	41,81 (41-42,6)	38,55 (39,5-41,0)	36,68 (35,9-37,4)	0,000	0,000
TIR 70-180	55,91 (54,3-57,5)	58,94 (57,2-60,7)	64,87 (63-66,8)	0,000	0,000
TAR >180	35,02 (33,1-36,9)	31,17 (29,1-33,2)	31,74 (28,6-34,9)	0,001	0,024
TBR <70	9,06 (8,3-9,8)	7,97 (6,9-8,9)	5,12 (4,5-5,7)	0,1793	0,000

Image 1. Correlation between FSL readings and Hb1Ac at 12 and 24 months



Conclusions: The FSL system with an educational program results in a reduction of HbA1c and leads to a progressive increase of TIR and a reduction of TBR at 12 and 24 month.There is a negative correlation between the number of FSL readings and Hb1Ac values.

EP123 / #338

Topic: ***AS05-Glucose Sensors***

TECHNOLOGY USE IN EMERGING ADULTS WITH T1D: DATA FROM THE 'VERONA DIABETES TRANSITION PROJECT'

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Background and Aims: Therapeutic goals are often unmet in emerging adults with T1D and technology is still underused. We aimed to assess technology use in emerging adults with T1D belonging to the ''Verona Diabetes Transition Project'' (VDTP).

Methods: The VDTP is a structured program, shared between pediatric and adult clinic, to evaluate clinical, socio-demographic and psychological factors in young adults with T1D. HbA1c value and new metrics reported by CGM/FGM were assessed at first adult clinic attendance and after 36 months.

Results: In 161 (M/F = 86/75) young adults with T1D (mean±SD: age 24.8 ± 6.1 years, HbA1c 8.2 ± 1.2%, duration of disease: 14.5 ± 6.9 years) the use of technological devices was 19% at first adult clinic attendance and increased to 65% over the time, especially the use of CGM/FGM (from 14% to 62%). A lower frequency of poor diabetes acceptance ($p = 0.02$) was reported in CGM/FGM users. After 36 months, an improvement in HbA1c value (from 8.31 ± 1.19% to 7.42 ± 0.72%, $p < 0.001$) and in new metrics of glucose was reported: TIR increased from 50.1 ± 15.1% to 59.4 ± 17.1% ($p < 0.001$), TAR >250 and in TBR <54 decreased (from 18.5 ± 12.9% to 12.7 ± 9.2%, $p = 0.008$ and from 2.6 ± 2.7% to 1.1 ± 1.5%, $p = 0.003$, respectively) and coefficient of variation decreased from 41.8 ± 7.7% to 38.3 ± 7.2% ($p = 0.005$). In regression analysis, sensor use and fear of hypoglycemia were associated, in opposite way, with HbA1c value at 36 months ($\beta^{st} = -0.24$, $p = 0.02$; $\beta^{st} = 0.23$, $p = 0.03$, respectively).

Conclusions: In emerging adults with T1D, the use of technological devices increased over the time and use of CGM/FGM was associated with improved glucose control.

EP124 / #339

Topic: ***AS05-Glucose Sensors***

IMPACT ON QUALITY OF LIFE AND GLYCAEMIC OUTCOMES IN ADULTS WITH TYPE 1 DIABETES AFTER TWO-YEAR USE OF FLASH GLUCOSE MONITORING.

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Background and Aims: A previous study demonstrated that the implementation of Flash Glucose Monitoring System (FGM) improved Quality of LIfe (QoL) and reduced fear of hypoglycemia after 6 months in our clinical practice. The present follow-up study assesses the effects of FGM 2 years later.

Methods: This prospective, real world study involved adults with type 1 diabetes (T1D) who started with a FGM system for the

first time. Patients reported QoL and fear of hypoglycemia questionnaires (EsDQUOL and Hypoglycemia Fear Survey –HFS-) at the beginning of the study and after 6 and 24 months. Glycaemic outcomes (HbA1c, mean glucose levels, time-in-range, severe hypoglycemias) and other clinical parameters were registered.

Results: 229 patients (treated with multiple daily insulin injections -72,5%- or continous subcutaneous insulin infusion -27,5%-) were included (mean age: 47 ± 13 years,mean HbA1c at baseline: 7,65 ± 1%). After 2-year of follow-up EsDQUOL and HFS scores improved significantly *(p < 0,01)*. Although there was not observed any significant change in HbA1c, time- in-range (70-180 mg/dl) improved throughout the study. There were not significant differences in severe hypoglycemias but time-below-range (<70 mg/dl) was reduced and the number of patients who reported hypoglycemia unawareness was lower at the end of the study (14% vs 7% , *p < 0,05)*. Most of the individuals did not present any significant adverse effect caused by FGM (76%) or reported mild skin reactions (22%).

Conclusions: As seen in clinical trials and other real-world studies, the use of FGM is associated with sustained improvement of quality of life and glycaemic outcomes after 2 years.

EP125 / #35

Topic: ***AS05-Glucose Sensors***

WHICH DETERMINES ISCGM SENSOR ACCURACY, PATIENT OR SENSOR ITSELF?

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Background and Aims: In clinical practice, intermittently scanned CGM (isCGM) sensors may have inter-individual variability in accuracy. However, whether the accuracy of the isCGM sensor is determined by the patient or sensor is unknown. Therefore, we studied regarding inter-individual variability of sensor accuracy.

Methods: This was a prospective observational study. Twenty outpatients with type 2 diabetes wore an isCGM (FreeStyle Libre) over 12 weeks using six sensors. Self-monitoring of blood glucose (SMBG) was performed once a day before breakfast using glucometers compliant with ISO15197:2013. Sensors where the mean absolute relative difference (MARD) could be evaluated more than nine times were included in this study.

Results: The sensors in all patients (n = 120) significantly correlated with the distribution of MARD (n = 120 × max 14) (correlation ratio: $\eta^2 = 0.45$, $p < 0.001$). For 17 out of 20 patients, the sensors [n = 6] significantly correlated with the distribution of MARD (n = 6 × max 14) ($\eta^2 = 0.15$-0.55, $p = 0.047$–<0.001). The patients (n = 20) significantly correlated with the distribution of MARD (n = 20 × max 84) ($\eta^2 = 0.19$, $p < 0.001$) (Table).

Conclusions: Both the patient and sensor may affect the accuracy of the isCGM sensor.

Patients	MARD on Sensor 1	MARD on Sensor 2	MARD on Sensor 3	MARD on Sensor 4	MARD on Sensor 5	MARD on Sensor 6	Mean of MARD	η^2	p
A	5.0 ± 2.9	10.2 ± 7.0	19.8 ± 4.7	13.7 ± 6.2	15.3 ± 6.1	6.6 ± 4.1	11.8 ± 7.3	0.49	<0.001
B	7.3 ± 4.4	8.3 ± 6.4	14.2 ± 5.2	10.8 ± 4.8	6.3 ± 3.8	12.4 ± 4.5	9.8 ± 5.6	0.27	0.002
C	25.7 ± 13.9	14.8 ± 6.7	17.0 ± 6.7	20.6 ± 5.1	25.2 ± 7.1	17.6 ± 4.9	20.3 ± 8.9	0.22	0.005
D	7.8 ± 3.7	11.2 ± 9.9	5.2 ± 3.1	12.5 ± 7.2	5.8 ± 4.1	8.1 ± 6.0	8.3 ± 6.3	0.17	0.06
E	18.2 ± 4.4	15.6 ± 3.9	16.3 ± 4.2	19.3 ± 6.6	15.5 ± 3.5	14.4 ± 4.4	16.6 ± 4.8	0.13	0.06
F	30.9 ± 11.3	18.3 ± 6.4	18.8 ± 6.2	19.8 ± 4.3	23.5 ± 7.5	20.6 ± 9.5	22.0 ± 8.9	0.26	<0.001
G	11.4 ± 10.7	36.0 ± 24.0	12.4 ± 10.0	17.1 ±6.6	5.5 ± 4.4	13.0 ± 5.4	16.1 ± 15.4	0.41	<0.001
H	16.5 ± 5.2	11.9 ± 5.6	9.4 ± 8.3	12.6 ± 5.3	6.4 ± 5.3	6.0 ± 4.3	10.5 ± 6.7	0.33	<0.001
I	20.0 ± 5.6	6.8 ± 5.9	6.9 ± 4.6	18.0 ± 4.8	18.5 ± 7.1	15.4 ± 4.9	14.3 ± 7.7	0.51	<0.001
J	17.7 ± 12.3	13.9 ± 6.8	12.8 ± 6.6	7.7 ± 3.8	15.3 ± 7.4	6.7 ± 4.8	12.4 ± 8.4	0.23	0.003
K	12.4 ± 7.1	17.1 ± 5.9	5.4 ± 5.0	8.6 ± 6.0	5.6 ± 5.1	50.1 ± 60.8	16.1 ± 27.9	0.29	<0.001
L	7.8 ± 5.8	4.3 ± 3.1	8.2 ± 6.6	6.6 ± 4.2	8.5 ± 4.3	5.1 ± 5.3	6.8 ± 5.1	0.1	0.28
M	22.3 ± 4.4	22.5 ± 4.3	25.8 ± 4.3	32.8 ± 4.0	19.3 ± 4.3	21.5 ± 8.8	24.0 ± 6.8	0.43	<0.001
N	4.9 ± 3.4	5.8 ± 4.2	8.8 ± 7.6	5.1 ± 3.9	8.7 ± 4.9	2.9 ± 3.0	6.1 ± 5.1	0.16	0.02
O	15.0 ± 8.6	16.7 ± 10.0	27.8 ± 8.4	23.5 ± 11.0	21.1 ± 6.2	13.9 ± 7.3	19.4 ± 9.7	0.23	0.002
P	17.1 ± 13.6	12.3 ± 8.9	12.0 ± 8.7	31.8 ± 9.0	29.7 ± 9.2	30.9 ± 10.2	22.8 ± 13.0	0.44	<0.001
Q	19.2 ± 15.5	11.4 ± 7.5	10.8 ± 9.0	11.3 ± 7.7	7.8 ± 5.2	10.1 ± 8.8	11.9 ± 10.0	0.15	0.047
R	16.7 ± 8.1	5.5 ± 4.3	8.1 ± 6.1	6.6 ± 5.1	12.1 ± 6.0	7.1 ± 4.8	9.4 ± 6.9	0.32	<0.001
S	14.9 ± 10.5	12.3 ± 10.9	7.2 ± 6.0	5.2 ± 5.7	14.6 ± 6.2	17.2 ± 7.5	11.8 ± 8.8	0.25	0.001
T	16.7 ± 4.4	14.2 ± 5.4	4.7 ± 3.6	7.4 ± 5.2	26.0 ± 12.0	16.8 ± 6.4	14.2 ± 9.8	0.55	<0.001
The η^2 and p values (η^2 0.19, p<0.001) show the correlation between patients and distribution of MARD (P).							0.19	(P) η^2 (All S)	0.45
The η^2 and p values (η=0.45, p<0.001) show the correlation between sensors in all patients and distribution of MARD (All S).							<0.001	(P) p (All S)	<0.001

EP126 / #371

Topic: ***AS05-Glucose Sensors***

FREE-LIVING ISCGM SHOWS EXERCISE INCREASES GLYCAEMIC VARIABILITY AND HYPOGLYCAEMIA IMMEDIATELY AFTER AND THE NEXT DAY AFTER EXERCISE IN PEOPLE WITH T1D

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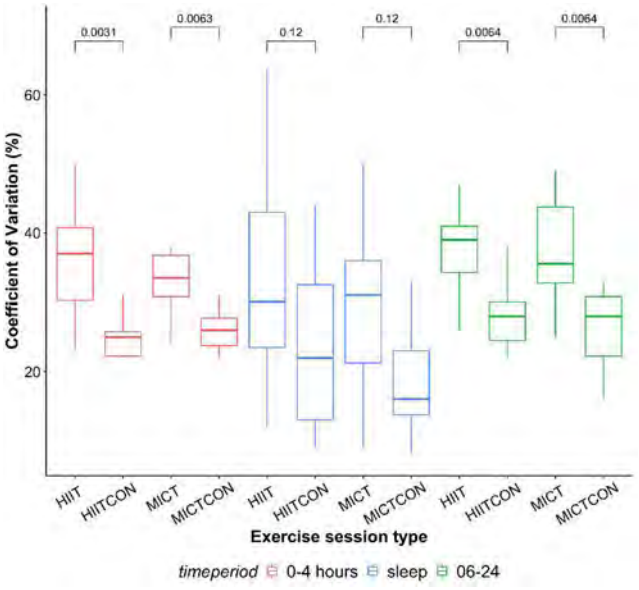
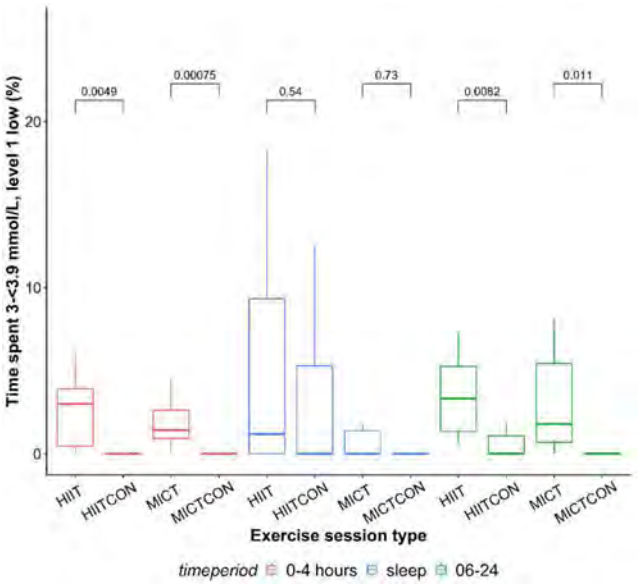
Background and Aims: People with type 1 diabetes (T1D) face barriers to exercise such as fear of hypoglycaemia and increased glycaemic variability. We assessed the impact of two modes of free-living, home-based exercise on glycaemia using intermittently scanned continuous glucose monitoring (isCGM).

Methods: Ten adults living with T1D performed three 14-day intervention periods: home-based high intensity interval training (HIIT), home-based moderate intensity continuous training (MICT), non-exercise period (CON). Exercise periods consisted of 6 unsupervised non-time-controlled sessions, interspaced by 48h. Free-living isCGM data was collected using the Abbott FreeStyle Libre. We compared post-HIIT/MICT glycaemia to the average CON period, matched for time of day and day of the week. We evaluated glycaemic variability and hypoglycaemia for 0-4h, overnight (00:00-06:00) and next day (06:00-24:00) after exercise.

Results: In both HIIT and MICT periods, coefficient of variation (CV) and time in level 1 hypoglycaemia (L1H) was increased, as compared to CON, in 0-4h post exercise (CV: HIIT p = 0.003, MICT p = 0.006 and time L1H: HIIT p = 0.005, MICT p = 0.0008) and the day after exercise (CV: HIIT p = 0.006, MICT p = 0.006 and time L1H: HIIT p = 0.008, MICT p = 0.011). No difference was observed overnight (p > 0.05). Average glucose, TIR (3.9-10mmol/L) and time spent elevated (>10/ >13.9mmol/L) were similar to non-exercise days (p > 0.05).





Conclusions: Both HIIT and MICT increase glycaemic variability and hypoglycaemia in the 4 hours after and the day after exercise, but not overnight, during free-living. It is possible to assess the impact of exercise in free-living environments using isCGM, this may improve the management of post-exercise blood glucose in people with T1D and reduce barriers to exercise.

EP127 / #373

Topic: ***AS05-Glucose Sensors***

HOW DO BEDTIME SNACK AND NO SNACK OPTIONS AFFECT OVERNIGHT GLYCEMIA IN YOUNG CHILDREN WITH DIABETES: PRELIMINARY CGM RESULTS

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Background and Aims: To determine if young children require a bedtime snack to maintain overnight glycemia, and the impact of bedtime snack options.

Methods: In randomized cross-over study, containing 10 g carbohydrate equivalent of milk, yoghurt and kefir compared to no snack in 28 children (aged 5-8 years) using MDI therapy. Continuous glucose monitoring (isCGM) was used to measure 6-hour glucose levels after snacks. If capillary glucose value reaches 300 mg/dL or falls below 70 mg/dL, the trial was ceased. Glycemic metrics were analyzed for the early (0 to 2 hours) and late (2 to 6 hours) postprandial period with generalized linear mixed model based on International CGM consensus.

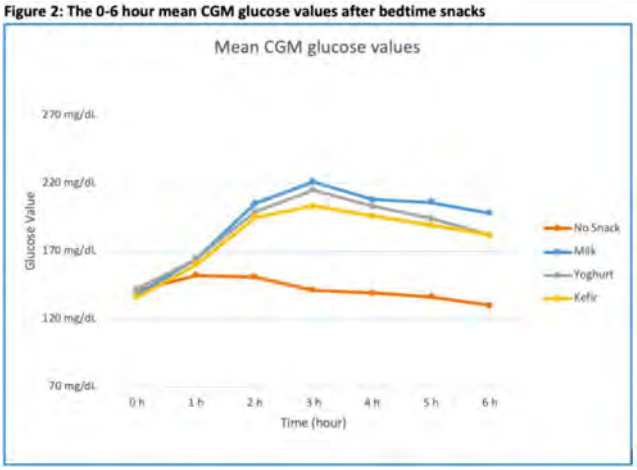
Results: The 0-6 hour mean TIR were 37,0%, 38,3%, 45,8% and 75,0% milk, yoghurt, kefir, and no snack groups respectively.TIR of the no snack option was higher and mean glucose was lower than snack options ($p < 0.001$) (Figure 1 and 2). In the late postprandial period, TAR2 was higher in the milk group than in the no snack and yogurt groups, while TAR1 was similar among the snack options. For the milk, yoghurt and kefir and no snacks options, the percentages of children who were ceased early due to high values were 28,5%, 14,3%, 3,6% and 0%; due to low values were 0%, 4,0%, 0% and 7,1% respectively.

Conclusions: Our results suggest that no bedtime snack seems to be better option compared to snack options. But in regards of prevention of hypoglycemia, sensor glucose cut-off values need to be determined for the bedtime snack recommendation.

Figure 1. Analysis of 0-2 h, 2-6 h, 0-6 h glucose values for 3 bedtime snacks and no snack option

		TIR (70-180)	(<70) (%)	(<54) (%)	(>180) (%)	(>250) (%)	Mean glucose (mg/dL)	SD	CV%
Milk	0-2 hour (n=28)	47,28	0,0	0,0	39,87	12,85	186,54	35,36	0,19
	2-6 hour (n=26)	25,86	0,0	0,0	32,67	41,84	220,50	60,54	0,28
	0-6 hour (n=26)	36,95	0,0	0,0	38,87	24,34	201,54	43,14	0,21
Yoghurt	0-2 hour (n=28)	49,11	0,0	0,0	43,90	7,21	182,28	36,26	0,20
	2-6 hour (n=27)	29,29	0,50	0,0	50,00	20,37	204,52	55,66	0,27
	0-6 hour (n=27)	38,34	0,46	0,0	49,39	12,15	192,18	40,84	0,21
Kefir	0-2 hour (n=28)	58,75	0,45	0,0	32,74	8,99	176,72	30,34	0,17
	2-6 hour (n=28)	40,09	1,00	0,0	34,09	25,01	195,49	54,05	0,28
	0-6 hour (n=28)	45,83	0,86	0,0	34,22	19,64	188,88	41,44	0,22
No snack	0-2 hour (n=28)	74,78	2,30	0,0	22,92	0,00	151,61	34,85	0,23
	2-6 hour (n=28)	72,27	4,88	0,16	13,69	3,30	134,21	46,13	0,34
	0-6 hour (n=28)	74,93	6,02	0,11	17,04	2,21	141,29	37,44	0,26

Figure 2: The 0-6 hour mean CGM glucose values after bedtime snacks



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Topic: ***AS05-Glucose Sensors***

CONTINUOUS GLUCOSE MONITORING IN CYSTIC FIBROSIS RELATED DIABETES; A CASE SERIES

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Background and Aims: Cystic Fibrosis Related Diabetes (CFRD) affects up to 50% of adults with Cystic Fibrosis (CF). Despite paucity of data from clinical trials, use of Continuous Glucose Monitoring (CGM) may be helpful in pathophysiology understanding, diagnosis and management of CFRD. We present data from CGM use in three adults with CF.

Figure 1

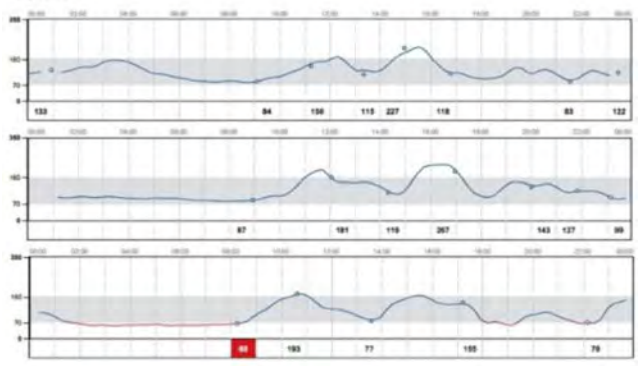


Figure 2

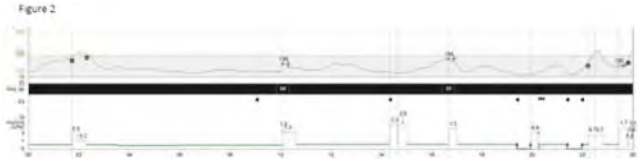
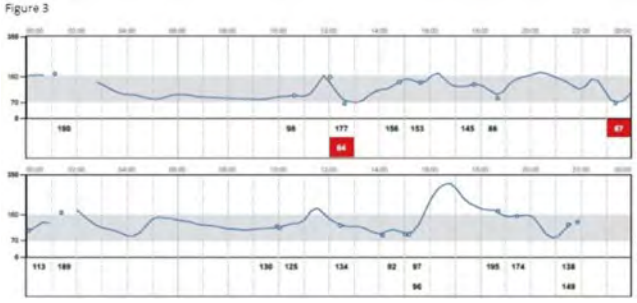


Figure 3



Methods: Case 1: A 41 years old male with Impaired Fasting Glucose, Impaired Glucose Tolerance and HbA1c: 6.1% was evaluated using intermittently scanning CGM (Abbott, FreeStyle Libre). Case 2: A 20 years old female with one year history of CFRD was evaluated after 12 weeks use of insulin pump with Predictive Low Glucose Suspend (Medtronic 640G, SmartGuard). Case 3: A 41 years old male with 22 years history of CFRD on multiple daily injections of insulin analogues was evaluated using FreeStyle Libre.

Results:

In case 1, use of CGM revealed post prandial glucose excursions above 200mg/dl, as well as episodes of asymptomatic hypoglycemia. Fasting hyperglycemia was not detected (Figure 1). Treatment with prandial insulin was initiated. A bolus/basal ratio >60/40 and minimal between meals glucose variations in cases 2 and 3 (Figures 2, 3, respectively) are indicative of potential core role of defective first phase insulin secretion both in early and long standing CFRD.

Conclusions: CGM may be a useful tool for the early detection of CFRD and CF related hypoglycemia. Management of post prandial hyperglycemia is essential for optimal glycemic control in CFRD.

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Topic: ***AS05-Glucose Sensors***

REAL-LIFE EVALUATION OF THE NEW SENSOR GLUCOMEN DAY CGM.

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Background and Aims: Continuous glucose monitoring (CGM) is increasingly used in patients with type 1 diabetes (T1D) and new sensors are being launched with different characteristics. The aim was to evaluate real-world outcomes with the new GlucoMen Day CGM sensor.

Methods: A prospective study including T1D pediatric and adult patients who started the GlucoMen Day CGM sensor was designed. The participants had had issues with other CGM systems or were naïve to CGM. HbA1c, hypoglycaemia awareness questionnaires, fear of hypoglycaemia survey (HFS), quality of life (DQoL), experience with the glucose monitoring (C-EMG), skin reactions and user satisfaction questionnaires were evaluated at baseline and after 3 months of use.

Table 1. Clinical outcomes.

	Baseline	3 months	p
HbA1c (%)	7.5 ± 1.3	7.2 ± 0.8	0.185
GS or CS ≥ 4 (%)	35	31	0.057
HFS	43.9 ± 22.2	39.5 ± 20.2	0.329
DQoL	89.2 ± 24.1	87.8 ± 22.8	0.205
C-EMG	3.9 ± 0.4	3.8 ± 0.5	0.215

- *N = 16*
- *GS and CS (Gold and Clarke scores) to analyse hypoglycaemia awareness, ≥ 4: impaired awareness of hypoglycaemia; HFS (Hypoglycaemia Fear Survey): lower scores indicating less fear of hypoglycemia; DQoL (Diabetes Quality of Life): lower scores indicating a better quality of life; C-EMG (experience with the glucose monitoring) higher scores indicating higher satisfaction with the monitoring system.*

Results: 20 patients were included, age: 30 ± 13 years, 55% females, duration of diabetes 17 ± 11 years, previous treatment: 40% FreeStyle Libre, 25% Guardian sensor 3, as part as a closed-loop system, 20% SMBG, 15% Dexcom. 8 patients used both sensors during the study. 3 patients stopped using the new sensor.

At 3 months, the parameters of glucose control were as follows: sensor glucose: 168.4 ± 34.1 mg/dl, time 70-180 mg/dl: 59.6 ± 20.8%, time <70 mg/dl: 3.3 ± 2.2%, time <54 mg/dl: 1 ± 1.4%, time >180 mg/dl: 37.3 ± 21.5%, time >250 mg/dl: 12.6 ± 12.7% and sensor use: 71.4 ± 24.4% No differences in skin reactions were found. 69% of the subjects would accept to keep using the system. Mean overall satisfaction score was 3.1 out 5.

Conclusions: The usability of the new GlucoMen Day CGM, in real life practice, was satisfactory.

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Topic: ***AS05-Glucose Sensors***

THE INFLUENCE OF THE PARTIAL PRESSURE OF OXYGEN VALUES ON FOUR SELF-MONITORING BLOOD GLUCOSE DEVICES

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Background and Aims: Self-monitoring blood glucose (SMBG) devices are an essential tool for self-care management of diabetes. SMBG devices are based in enzymatic assays (glucose oxidase (GOX) or glucose dehydrogenase (GDH)). Devices accuracy can be influenced by abnormal values of partial pressure of oxygen (pO_2) when devices use GOX assay. Our objective is to evaluate pO_2 interference in four different devices.

Methods: One hundred venous blood samples were collected in heparinised blood gas syringe. Glucose concentrations were measured in: OnCall® (ACON LABS INC), OneTouch® Select Plus (Johnson & Johnson), GlucoMen® areo (Menarini) and CONTOUR®Next One (Ascencia Diabetes Care). pO_2 levels were measured on a POCT (RapidPoint® 1250) and the reference glucose concentration was measured on an Atellica® Solution (hexokinase method) both analysers from Siemens Healthineers. According to on ISO 15197:2015, acceptable glucose changes were considered ±15 mg/dL or ±15 % differences for samples at glucose concentration <100 or >100 mg/dL, respectively. More stringent criteria were applied. Minimal deviation from the respective reference measurement results within which 95% of results of the SMBG devices were found was calculated

Results: pO_2 and glucose ranges were 14-105 mmHg (NV:20-60) and 62-259 mg/dL (NV:65-110), respectively. Figure 1 shows percentages of samples with acceptable changes and minimal deviation including 95% of the results. CONTOUR®Next One presented the best results, and fulfilled ISO 15197:2015 specifications.

Conclusions: Health care professionals and patients should be aware of the SMBG limitations and select the device that would fit best the individual situation of each patient, especially in settings where low pO_2 values may be observed.

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Topic: ***AS05-Glucose Sensors***

THE IMPACT OF GLYCEMIC VARIABILITY ON THE RELATIONSHIP BETWEEN HYPOGLYCEMIA AND HBA1C

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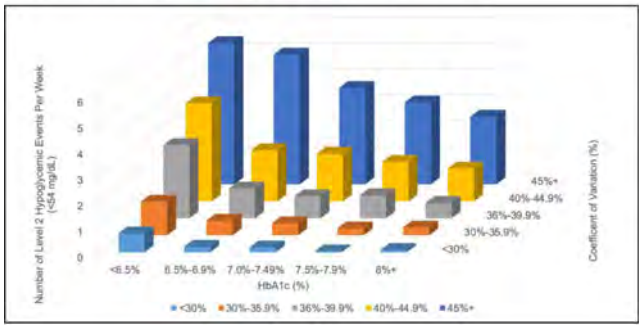
Background and Aims: Continuous glucose monitoring (CGM) guidelines suggest a target glycemic variability, as measured by coefficient of variation (CV) ≤36%, to mitigate hypoglycemia in people with type 1 diabetes (T1D). However, they provide no context to hemoglobin A1c (HbA1c) values. The aim of this study was to evaluate the relationship between CV, hypoglycemia, and HbA1c among adults with T1D.

Methods: A retrospective sample of adults (≥18 years) with T1D from the Barbara Davis Center for Diabetes who had available ambulatory glucose profiles and laboratory-measured HbA1c were analyzed at the patient-visit level between 2014 and 2020. Negative binomial regression of aggregated data over 7 days was used to estimate the number of level-2 (<54 mg/dL) hypoglycemic events at cross-sections of HbA1c and CV for a maximum of 2 weeks, after adjusting for time of CGM use.

Results: Among 466 adults with T1D (mean age = 37 years) at 1,648 visits, percentage of CGM use was 91%. We observed wide variation in level 2 hypoglycemic events across CV and HbA1c categories (Figure 1). The highest mean estimated number of events was 3.5 (95% CI: 2.4, 4.6) per week, found in patients with CV >36%, HbA1c<6.5%.

Figure 1. Relationship between glycemic variability, HbA1c, and hypoglycemia in patients with T1D



Conclusions: Glycemic variability (CV) provides meaningful insights about level 2 hypoglycemia that should be used in combination with HbA1c and other factors to inform clinical decision making to help mitigate risk for possible hypoglycemia.

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Topic: *AS05-Glucose Sensors*

EVALUATION OF PERSONALIZED GLYCEMIC RESPONSE BASED DIABEFLY-PRO DIGITAL THERAPEUTICS PROGRAM FOR IMPROVEMENT IN TIME IN RANGE IN PEOPLE WITH TYPE 2 DIABETES

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Background and Aims: Continuous glucose monitoring can provide insights into the glycemic response of individuals to diet and physical activity. Digital therapeutics programs based on these insights about personalized glycemic response (PGR) of individuals can help in more effective glycemic control. The study aims at the analysis of the variation in time-in-range (TIR) after participation in PGR-based Diabefly-Pro™ program in people with type 2 diabetes (T2D).

Methods: De-identified data of 167 participants (Mean age: 50.60 ± 12.53 years, Females 39.52 %) was analyzed for 7 days, pre and post the introduction of a modified lifestyle plan created based on insights from PGR of individuals. Diabefly-Pro™ is a 90-days digital therapeutics program which provides a structured plan for behavioral and lifestyle modification. The outcomes of the study involved analysis of average blood glucose, TIR (70-180 mg/dl), time-above-range (TAR, >180 mg/dl), time-below-range (TBR, <70 mg/dl) and glucose management indicator (GMI). Paired t-test was used for statistical analysis with $P < 0.05$ considered as significant.

Results: After 7 days of modified lifestyle plan, mean glucose significantly reduced from 154.56 ± 53.13 mg/dl to 141.60 ± 49.92 mg/dl ($P < 0.0001$). The TIR significantly improved from 56.56 ± 25.95 % to 61.88 ± 26.82 % ($P < 0.0001$). The TAR significantly reduced from 37.68 ± 29.28 % to 30.76 ± 29.47 % ($P < 0.0001$) while no significant increase was observed in time-below-range ($P = 0.14$). GMI significantly improved from 7.01 ± 1.27 % to 6.70 ± 1.19 % ($P < 0.0001$).

Conclusions: A significant improvement in glycemic control and subsequent reduction in glycemic excursions was observed after 7 days of modified lifestyle plan.

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Topic: *AS05-Glucose Sensors*

DIABETIC NEUROPATHY AND GLYCAEMIC CONTROL

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Background and Aims: Diabetic neuropathy is a chronic microangiopathic complication that can occur in patients with DM1. The aim of this study is to determine if there are differences in glycaemic control between diabetics with and without neuropathy.

Methods: Descriptive cross-sectional study. Data recruited from 116 patients aged 18 years and older with DM1 who started using the freestyle monitoring system between May 1, 2019, and May 1, 2021. Signs and symptoms of autonomic neuropathy were evaluated with a validated questionnaire[1] with twelve questions. Two affirmative responses being considered suggestive of neuropathy. 1-M. Fernández-Balsells et al. Endocrinología (1998).

Results: Patients were divided according to the presence or absence of neuropathy signs. Demofraphic variables and glycemic control data were analyzed in Table.

Conclusions: Patients with diabetc neuropathy have more episodes of severe hypoglycemia.

Neuropathy	Yes
Number	35
Sex %	
Male	60
Female	40
Age	40.63 (SD 3.1)
TIR%	55.45 (SD 2.93)
Time above range%	39.34 (SD 3.33)
Time below range%	5.02 (SD 1)
Events hypoglycaemia	8.6 (SD 1.33)
Duration of hypoglycaemias (<54 mg/dL) (min)	85.77 (SD 9.89)
Time in severe hypoglycaemia (min)	0.727 (SD 0.27)
CV%	37.16 (SD 1.15)
Number or readings	13.6 (2.77)
Hb1AC	8.26 (SD 0.25)

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Topic: *AS05-Glucose Sensors*

EVALUATING THE EFFICACY OF FREESTYLE LIBRE FLASH GLUCOSE MONITORING IN THE OLDER POPULATION

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Background and Aims:

Background: Frailty associated with older age increases the risk of complications for diabetes and its treatment, in particular hypoglycaemia. FreeStyle Libre is a form of flash glucose

monitoring that has been commissioned for use in people living with type 1 diabetes who meet NHS criteria and can reduce hypoglycaemia.

Aims: Evaluate whether patients ≥65-years-old across Birmingham Heartlands Hospital (BHH) and Solihull Hospital (SOL) are meeting AATD time in range CGM targets.

Methods: BHH and SOL patients ≥65-years-old using FreeStyle Libre until June 2021 were included in the study population. Patient data such as average scans per day, TIR, TAR, TBR and time <3.0mmol/L were transferred from Libreview. Demographic and HbA1c data were retrieved from electronic patient records.

Results: 65 patients were identified, 44 were eligible for inclusion. 68.2% (30/44) met the TIR target of >50%, 45.5% (20/44) met the TAR target of <10% and 18.2% (8/44) met the TBR target of <1%. Further analysis of TBR, comparing patients to the AATD recommendation for younger people, found that 75% (33/44) spent <4% of time below range. 18.2% (8/44) spent <1% in hypoglycaemia (<3mmol/L) and 81.8% (36/44) spent ≥1% in hypoglycaemia.

Conclusions: Despite using FreeStyle Libre, older patients remain at significant risk of hypoglycaemia. This risk should be managed in outpatient clinics using hypo-awareness and frailty scores. FreeStyle Libre data can be used as per the ABCD risk stratification criteria for triaging these patients with high risk hypoglycaemia during the COVID-19 recovery phase.

EP135 / #410

Topic: ***AS05-Glucose Sensors***

GLUCOSE VARIABILITY AND CARDIOMETABOLIC STATUS IN TYPE 2 DIABETES

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Background and Aims: Glucose variability became an important parameter of glucose control,is correlated with oxidative stress in type 2 diabetes and influences development of chronic complications**.**This study investigated the relation between cardiometabolic risk factors(CMRF)and glucose parameters evaluated by continuous glucose monitoring(CGM)in persons with type 2 diabetes.

Methods: 30 persons with T2D(8 women/22 men,insulin-treated-14/oral-treatment-16, mean diabetes duration-11.43years, mean age-56.59years)were assessed by CGM.CMRF:body weight, BMI, waist circumference, physical activity, smoking, alcohol consumption, lipid profile (total cholesterol(T-col), HDLc, tryglycerides(TG),LDLc), blood pressure(systolic–SBP, diastolic-DBP), personal and family history of CVD,family history of diabetes. Glucose parameters:glycated haemoglobin A1c(A1C), glucose variability(GV), mean amplitude of glucose excursions (MAGE), number of glucose values(time), area under the curve (AUC, glucose exposure), mean glucose values (glucose amplitude) on domains–hypoglycemic(<70mg/dl), intermediate (70-180mg/dl), hyperglycemic(>180 mg/dl), optimal(90-130mg/dl).

Results: GV and MAGE were higher in women, as well as number and percent of glucose values >180 mg/dl, total AUC, diurnal AUC, and percent AUC >180 mmg/dl. These differences were not significant at next CGM visit, after 3 months.-Body weight was inversely correlated with GV and MAGE.Persons with SPB >130 mmHg had lower percent of hypoglycemic values and hypoglycemic AUC,higher total AUC,higher diurnal and nocturnal AUC and higher glucose amplitude(mean).TG values were directly correlated with diurnal AUC and inversely related to nocturnal AUC.HDLc was directly correlated with AUC 70-180 mg/dl.Persons with family history of diabetes had higher time spent(number) and AUC in hypoglycemia.Direct relation between worse metabolic control and hyperglycemic exposure(AUC) was close to significance,although non-significant.

Conclusions: Women had initial worse glucose status that improved after 3 months.Body weight was inversely correlated with GV/MAGE.SBP was lower in persons with higher hypoglycemic exposure and directly correlated with total glucose status.TG and HDLc were also directly correlated with total glucose status.

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Topic: ***AS05-Glucose Sensors***

STRATEGY AND RESULTS OF THE MASSIVE IMPLEMENTATION OF REIMBURSED CONTINUOUS GLUCOSE MONITORING IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Widespread use of continuous glucose monitoring (CGM) in Type 1 Diabetes (T1D) under nationwide reimbursement, has shown an improvement in glucometrics, acute complications and patient satisfaction. Following the last phase of the reimbursement program for CGM in Catalonia (Spain), the feasibility and effectiveness of a decision tree algorithm addressed to its massive implementation was evaluated during COVID-19 pandemic.

Methods: A straightforward decision tree algorithm was developed to systematically detect and categorize T1D patients from our Diabetes Unit. An administrative assistant, supported by healthcare-staff, contacted candidates and enrolled them into the program if willing to and according to: previous self-financing and digital skills. New users received information about the device, a contact number and 5 training webinars links. Patients unfamiliar with technology received a face-to-face education program.

Results: Over a 3-month period, 1519 candidates were contacted by phone (52% women, mean age 43.82 ± 15.29 years, mean HbA1c 7.71% ± 1.19, 19% of them were pump users). 320 (21%) self-financed CGM previously, 1045 patients (69%) initiated reimbursed CGM use, 331 (22%) declined the use of the device and we could not get in touch with 143 (9%) of patients. 292 patients (29%) joined the Diabetes educator-led webinars, while only 39 (3%) required face-to-face training. No major acute complication or relevant clinical issues were reported.

Conclusions: Massive implementation of reimbursed CGM in T1D population in a short period of time is feasible, effective and safe using coordinated strategies between healthcare and non-healthcare professionals including on-site, virtual visits and a web-site education package.

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Topic: ***AS05-Glucose Sensors***

PROSPECTIVE RANDOMIZED CLINICAL STUDY ASSESSING THE IMPACT OF CONTINUOUS VS FLASH GLUCOSE MONITORING DURING A 8 WEEKS PERIOD IN CHILDREN WITH TYPE 1 DIABETES

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Background and Aims: To assess the impact of Continuous Glucose System (CGM) instead of first generation Flash Glucose Monitoring (FGM) on hypoglycemia in children and adolescents with type 1 diabetes.

Methods: In this randomized controlled trial, youth with type 1 diabetes used CGM or FGM during 8 weeks. We evaluated change in time below range, severe hypoglycemia (SH), HbA1c, glycemic variability, impaired hypoglycemia awareness (IHA) with CGM in comparison with FGM.

Results: 37 participants were randomly assigned to the CGM group (n = 19) or FGM group (n = 18). At 8-week, there were no change in time below range but there was a reduction in the time below 70 mg/dl during night time. Reduction of time below range was positively correlated with percentage of time below 70 mg/dl at baseline in the CGM group. When we studied participants with a time below range >5% at baseline, we showed in the intervention group an improvement of the time below range, the time spent in hypoglycemia during the night and the LBGI. There was a reduction in the number of SH and of participants with IHA in the intervention group compared to the control group but no change in HbA1c.

Conclusions: The use of CGM versus FGM decreases the risk of severe hypoglycemia and improves impaired hypoglycemia awareness in young people with type 1 diabetes. The patient's history should be taken into account when advising on the method of blood glucose monitoring and CGM should be reserved for young patients at high risk for SH.

EP138 / #433

Topic: ***AS05-Glucose Sensors***

MONITORING THE INCIDENCES OF ALLERGIC CONTACT DERMATITIS AND OTHER SKIN REACTIONS ASSOCIATED WITH CONTINUOUS GLUCOSE MONITORING SYSTEMS

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Background and Aims: The CDC reports 1 in 10 Americans have Diabetes and that number only continues to rise each year. Diabetes is a lifestyle altering condition that requires those diagnosed to monitor their blood sugar daily. Traditionally finger prick blood draws were the only method to do this and it put many at increased risk for infection and reduced digit sensation, until Continuous Glucose Monitoring (CGM) was later developed. CGM's are unique because they can attach to any part of the body and upload data to smart devices. Unfortunately, CGM's brought about new issues for diabetics. As CGM use increased, as did incidences of allergic and irritant contact dermatitis (ACD & ICD), preventing many from continuing its use. The purpose of this Literature Review is to assess current articles focused on ACD, ICD, and other skin conditions related to CGM use and consider how diabetics can prevent and treat these side effects to safely resume CGM use.

Methods: Articles were searched for on PubMed, Cochrane, and EMBASE database. Some search terms included "Diabetes","Glucose Monitoring", and "Dermatitis". Studies were excluded that did not have a control group.

Results:

Table 1: Literature Review Study Findings

Author, Year	Study Type Topic	Setting/ Method	Study Findings	Limitations
Beman, de Montjoye, Damm Geneser & Baeck (2018)	Study Type: Literature Review Topic: Review of previous contact dermatitis cases and causes	Varied number of people and ages in studies. All studies done in Europe	- Sometimes the exact materials are not written by the manufacturer - Patch testing is essential "Applying a thin hydrocolloid dressing ... allowed the sensors to be better tolerated"	- 2007 study showed 18% of 22 patients with CGM were hypersensitive (small study sample, no patch testing to confirm).
Herman, Berrigaide, de Montjoye & Baeck (2019)	Study Type: Cohort study Topic: Tried finding the agent causing dermatitis reactions	12 children under 18 with T1 DM from Belgium with a reaction to medical devices	- 10 reacted to the material. Found that allergic contact dermatitis was common in the pediatric diabetic population	- Small sample size - Not all participants received the same patch test (2 were a different material)
Ivery, Lioppa & Vieluner (2019)	Study Type: Retrospective Case Control study Topic: Contact dermatitis reactions with suspected link to glucose sensors	70 patients with suspected contact dermatitis in South Finland	- 51 of the 63 LifeStyle Libre users tested positive for contact dermatitis - 5 of the 7 Medtronic Enlite users tested positive for contact dermatitis - 6 months was the median amount of use before dermatitis was shown -Contacted manufacturers and authorities with findings - one company revised adhesive formula	- Mentioned that many manufacturers do not put all their ingredients in the information
Messer, Berger, Benton, Polsky & Forlenza (2018)	Study Type: Literature Review Topic: Reactions of different issue in systems, looked for solutions contact dermatitis	Varied number of people, ages and locations of studies.	- Realized that device placement plays a large part in development of contact dermatitis - Suggested that grants should be given to those who will study ways to preserve skin integrity in devices	- Not many reports would compare skin complications from multiple devices - Need more studies on solutions to the skin integrity concerns
Herman, De Montjoye, & Baeck (2020)	Study Type: Case Control Topic: To see if the cases of skin reactions were actually ACD occurrences	52 patients with skin reactions were patch tested	17 patients had no skin reactions to the adhesive	- Did not find what other culprit caused the skin reactions
Kamana, Heinemann & Oppel (2019)	Study Type: Randomized Control Trial Topic: Does hydrocolloid barrier reduce the incidence of dermatitis	8 patients who were both diabetics and known occurrence of ACD	All patients were able to continue with the use of isCGM systems when using plasters as a barrier between system and skin	- Only tested w/ isCGM - Small sample size - Reports of reduced redness/itching, risk for poor reading due to misalignment of sensor and the barrier film hole
Oppel, Kamana, Raiefd & Hegg (2019)	Study Type: Randomized Control Trial Topic: Finding alternative monitoring device for diabetics who report ACD incidences when using Freestyle Libre	8 patients were tested for allergens, Dexcom and Freestyle were tested for IBOA, and then each participant wore Dexcom	- Each participant had IBOA allergy and so one had a skin reaction for the two days while on Dexcom - Patients with Freestyle Libre who have IBOA allergies can use Dexcom.	- Small sample size - Evidence is lacking on frequency to patients using devices - ACD can still occur to acrylates other than IBOA being on Dexcom and other devices - Follow up needed on most recent version of Freestyle Libre

Conclusions: Current literature reveals that CGM device side effects make them unusable for many due to adverse skin reactions. Diversifying patch testing and consciously using non-irritant biomaterials needs to be the future of practice for companies. It is the providers job to weigh in on potential outcomes for patients to set realistic expectations before CGM use and to continuously update patients.

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Topic: ***AS05-Glucose Sensors***

HYPERGLYCEMIA ALERT DISABLEMENT AND TRANSIENT GLYCEMIC PERTURBATIONS IN A CONTINUOUS GLUCOSE MONITORING SYSTEM

J. Van Der Linden, J. Welsh, G. Zammit, T. Walker

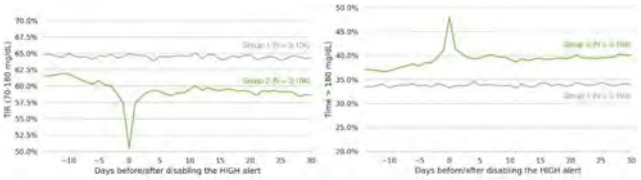
Dexcom, Clinical Affairs, San Diego, United States of America

Background and Aims: The Dexcom G6 CGM System's hyperglycemia alert is enabled by default and is triggered by glucose concentrations ranging from 120 to 400 mg/dL. We compared population-level attributes of users who enabled the alert consistently to users who disabled it during their tenure.

Methods: Data were from anonymized convenience samples of US-based G6 users whose initial data were uploaded in the 12 months ended 6/30/2021. Group 1 had the alert consistently enabled; Group 2 had the alert enabled initially before permanently disabling it. The groups were case-matched with respect to data uploading dates. Both groups uploaded valid readings every day in the 2 weeks prior and 4 weeks subsequent to the index (alert disablement) date.

Results: Group 1 represented 87.1% and Group 2 represented 12.9% of the population. In Group 2, the mean duration of uploading prior to alert disablement was 74 days (median, 27 days). As shown in the Figure, median time in range (TIR) trajectories for the groups were different, with Group 2 having a gradual deterioration in glycemic control in the days prior to alert disablement and an abrupt fall in TIR on the index date, attributable to more time in hyperglycemia. TIR subsequently improved and stabilized in Group 2, with no apparent trends in Group 1. TIR for Group 1 was consistently higher than TIR for Group 2.

Conclusions: Most G6 users maintain the hyperglycemia alert function in its default (enabled) state. Users who disable the function experience transient decreases in glycemic control that are not completely reversible.



EP140 / #456

Topic: *AS05-Glucose Sensors*

HYPOGLYCEMIA ALERT DISABLEMENT AND TRANSIENT GLYCEMIC PERTURBATIONS IN A CONTINUOUS GLUCOSE MONITORING SYSTEM

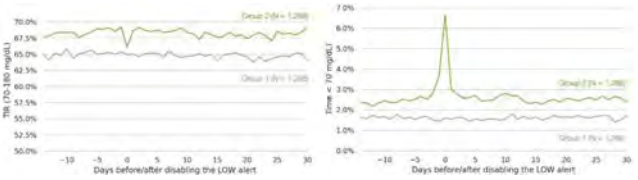
J. Van Der Linden, J. Welsh, G. Zammit, T. Walker

Dexcom, Clinical Affairs, San Diego, United States of America

Background and Aims: The Dexcom G6 CGM System's hypoglycemia alert is optional and enabled by default. We compared population-level attributes of users who enabled the alert consistently to users who disabled it during their tenure.

Methods: Data were from anonymized convenience samples of US-based G6 users whose initial data were uploaded in the 12 months ended 6/30/2021. Group 1 had the alert consistently enabled; Group 2 had the alert enabled initially before permanently disabling it. The groups were case-matched with respect to data uploading dates. Both groups uploaded valid readings every day in the 2 weeks prior and 4 weeks subsequent to the index (alert disablement) date.

Results: Group 1 represented 95.1% and Group 2 represented 4.9% of the population. In Group 2, the mean duration of uploading prior to alert disablement was 91 days (median, 46 days). As shown in the Figure, median time below range (TBR) and time in range (TIR) trajectories for the groups were different.



Group 2 had an abrupt rise in readings <70 mg/dL and a decrease in readings 70-180 mg/dL on the index date, with subsequent improvement and stabilization. There were no apparent trends in Group 1 with respect to TIR or TBR.

Conclusions: Most G6 users maintain the hypoglycemia alert function in its enabled state. Disabling the low alert was associated with abrupt but largely reversible deteriorations in glycemic control.

EP141 / #487

Topic: *AS05-Glucose Sensors*

HIGH ACCURATE GREEN DESIGN BLOOD GLUCOSE MONITORING BASED ON INNOVATIVE OPTICAL TRANSMISSION ABSORBANCE SYSTEM

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Terumo corporation, General Hospital Company, Yamanashi, Japan

Background and Aims: Blood glucose monitoring system (BGMs) is essential for glycemic control in diabetes care and management. Moreover, accurate sensors are required for both daily personal and clinical use. Since disposable test strips used in daily blood glucose control are composed of precious metal electrode materials and rare metals as reactants, BGMs are not regarded as sustainable green design device. In this study, we report the evaluation results of newly developed high accurate green design BGMs.

Methods: To realize the highly accurate and green design BGMs, we have developed a highly sensitive reagent, with a brand-new enzyme and an original absorption dye for test strip, and accurate glucose and hematocrit measurement algorithm, with a small multi-LED module for compact meter. To realize the green design test strip, we have developed an optical test strip without using precious metal electrode layer. The accuracy of the BGMs was evaluated reference to ISO 15197:2013 with venous blood.

Results: The new BGMs achieved accuracy more than 95% of data within ±6% and met the ISO 15197:2013 requirement.

Conclusions: We have developed a novel green design BGMs with innovative optical transmission absorbance system. The BGMs achieved accuracy more than 95% of data within ±6% and met the ISO 15197:2013 requirement. In the next step, we will achieve accuracy within ±5% through development including algorithm improvement.

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Topic: *AS05-Glucose Sensors*

USE OF CONTINUOUS GLUCOSE MONITORING DEVICES IN TYPE 2 DIABETES TO TRACK DISEASE PROGRESSION AND THERAPY EFFECTIVENESS

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Background and Aims: The increasing use of continuous glucose monitoring (CGM) devices in individuals with type 2 diabetes (T2D) opens the door to the use of patient generated data to track disease progression and/or therapy effectiveness. The key parameter quantifying the quality of glucose control is the disposition index (DI), the product between insulin sensitivity (S_I) and residual beta-cell function (Φ). Different methodologies were proposed in the literature for DI calculation, like the Oral Minimal Model (OMM), but all require collecting plasma measurements during hospitalized setting. Here we propose a method to quantify DI in everyday life conditions, using CGM data, and validated it against OMM.

Methods: The method was tested *in silico* using the 100 virtual subjects of the Padova T2D Simulator (Visentin et al., 2020). Two single-meal scenarios (75g carbohydrates) were performed, with subjects receiving either placebo or a hypothetic treatment, designed to improve both S_I and Φ by 50%.

Plasma glucose, insulin and C-peptide concentrations were measured for 6 hours after each meal and used for the estimation of the reference DI with the OMM (DI^{MM}), while CGM sensor data were employed for the calculation of DI with the sensor-based method (DI^{SB}).

Results: DI^{SB} well correlated with DI^{MM} and both were able to significantly detect ($p<<0.001$) DI improvement in treatment vs placebo (Fig. 1).

Conclusions: The DI^{SB} can be used to assess DI in subjects with T2D wearing CGM. Future work will include testing the method on real data of T2D with different stage of disease progression.

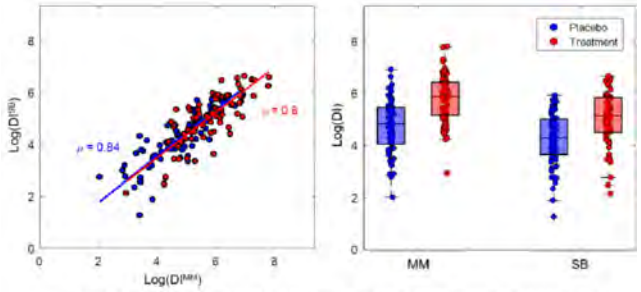

Fig 1. Regression (left) and boxplot (right panel) of log-transformed DI measures obtained with the Oral Minimal Model (MM) vs Sensor-Based method (SB) in the placebo (blue) and treatment arms (red circles). Differences between treatment and placebo are statistically significant ($p<<0.001$) with both methods.

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Topic: ***AS05-Glucose Sensors***

MODERATOR ANALYSES OF THE COMPARISON BETWEEN REAL-TIME AND INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN ADULTS WITH TYPE 1 DIABETES: A SUB-ANALYSIS OF THE ALERTT1 TRIAL

M. Visser[1], S. Charleer[1], S. Fieuws[2], C. De Block[3], R. Hilbrands[4], L. Van Huffel[5], T. Maes[6], G. Vanhaverbeke[7], E. Dirinck[3], N. Myngheer[7], C. Vercammen[6], F. Nobels[5], B. Keymeulen[4], C. Mathieu[1], P. Gillard[1]

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Background and Aims: ALERTT1 showed that switching from isCGM to rtCGM with alert functionality improved time in range (TIR; 70-180 mg/dL), HbA1c, time <54 mg/dL, and Hypoglycemia Fear Survey worry score (HFS-worry) in adults with type 1 diabetes (T1D). It is not known whether certain subgroups benefit more from switching to rtCGM than others.

Methods: This post-hoc analysis of ALERTT1 verified whether the 6-month difference in means of rtCGM versus isCGM (delta) for TIR, HbA1c, time <54 mg/dL, and HFS-worry depended on different patient characteristics, by including the interaction of 14 variables with the delta in a moderator analysis. Analyses were performed for each of these variables separately (univariable analysis); variables with $p<0.10$ in the univariable analysis were combined into a single model (multivariable analysis).

Results: Univariable analyses showed no statistically significant dependency of delta TIR on another variable; only dependency of delta HFS-worry on HbA1c was observed ($p=0.0059$), indicating less worry with the use of rtCGM in people with low (≤6.5%) or high (≥8%) baseline HbA1c. Given $p<0.10$ for the dependency of delta TIR on insulin therapy ($p=0.0851$; favoring multiple daily injections), baseline HbA1c ($p=0.0537$), and baseline TIR ($p=0.0615$), these variables were combined into a multivariable analysis. None of the interactions were statistically significant.

Conclusions: Except for HFS-worry, no interactions between 14 variables and the 6-month intervention effect of rtCGM on TIR, HbA1c, or time <54 mg/dL were observed, supporting the conclusion of ALERTT1 that the benefit of switching from isCGM to rtCGM with alert functionality applies to a wide range of people with T1D.

EP144 / #513

Topic: ***AS05-Glucose Sensors***

THE LINK BETWEEN MICROVASCULAR COMPLICATIONS AND A 10% CHANGE IN TIR IN PEOPLE WITH TYPE 1 DIABETES.

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[1]University of Antwerp, Faculty Of Medicine And Health Sciences, Wilrijk, Belgium, [2]University Hospital Antwerp, Endocrinology-diabetology-metabolism, Edegem, Belgium, [3]University of Antwerp, Laboratory Of Experimental Medicine And Pediatrics And Member Of The Infla-med Centre Of Excellence, Wilrijk, Belgium

Background and Aims: HbA1c is strongly associated with complications of type 1 diabetes (T1D) but does not inform about hypoglycaemia risk or glucose variability and is not well suited to guide therapeutic adjustments. Time in range (TIR, 70-180 mg/dL) measured by real-time continuous glucose monitoring (CGM) might be a better marker but its association with microvascular complications still needs elucidation. Therefore, we investigated the significance of a 10% change in TIR over two years.

Methods: Glucometrics and chronic complications of 308 consecutive patients with T1D using CGM (age: 46 ± 16 years,

duration of diabetes: 27 ± 14 years, HbA1c: 7.67 ± 1.15%, M/F: 57/43%, CSII/MDI: 22/78%) were evaluated over 24 months. Comparisons were made between group A with a 10% decrease in TIR (n = 62), group B with a 10% increase in TIR (n = 189) and group C (-10%<ΔTIR <10%, n = 57) at 24 months.

Results: A 10% decrease in TIR over 24 months was associated with risk for retinopathy (group A = 61.3% / B = 50.9% / C = 42.3%; p = 0.03), but not with neuropathy nor microalbuminuria. Logistic regression analysis showed that mean glucose (measured by CGM) was a better predictor than TIR for retinopathy (p < 0.001) and micro-albuminuria (p = 0.003). Other significant variables were: the use of antihypertensive drugs (p = 0.032), HbA1c (p = 0.019) and duration of diabetes (p < 0.001) for both complications. Gender was associated with microalbuminuria (p = 0.040) and BMI with retinopathy (p = 0.004).

Conclusions: A 10% decrease in TIR over 24 months was associated with a higher risk for retinopathy. However, mean glucose (by CGM) appeared to be a better predictor for retinopathy and microalbuminuria than TIR.

EP145 / #543

Topic: *AS05-Glucose Sensors*

CHARACTERIZATION AND PREDICTION OF POST-BARIATRIC HYPOGLYCEMIA FROM CONTINUOUS GLUCOSE MONITORING DATA

F. Prendin[1], D. Herzig[2], A. Tripyla[2], G. Cappon[1], L. Bally[2], A. Facchinetti[1]

[1]University of Padova, Information Engineering (dei), Padova, Italy, [2]University of Bern, Department Of Diabetes, Endocrinology, Nutritional Medicine And Metabolism Inselspital, Bern, Switzerland

Background and Aims: Post-bariatric hypoglycemia (PBH) is a complication of gastric bypass surgery, characterised by rapid post-meal glucose spikes with consecutive hypoglycemia. Due to the potentially deleterious consequences and the high rate of hypoglycaemia unawareness, continuous glucose monitoring (CGM) may open new avenues to forecast PBH for timely preventive actions. In this work, we aimed to characterize PBH episodes and evaluate the feasibility of CGM-fed real-time prediction of these episodes.

Methods: CGM data (recorded using Dexcom G6) from 39 previously confirmed PBH cases followed for a mean duration of 40 days (min: 3, max: 418 days) were processed to reduce CGM noise and artefacts, followed by descriptive statistics. An Auto-Regressive (AR), an Auto-Regressive Integrated Moving-Average (ARIMA) and a simple neural-network (NN) model were used to predict PBH (CGM <54mg/dL for ≥15min) with a prediction horizon of 15 min and the performance were evaluated using precision, recall, false-positive-per-day (FP/day) and time gain (TG).

Results: We observed 644 PBH episodes (median [25th-75th percentile] duration: 25 [20-35] min) at a frequency of 2 episodes every 5 days, most often at 8-10 pm. PBH occurs 55 [35-80] min after the post-meal peak glucose (165 [125-209] mg/dL) with ROC of -2.5 [-1.4 - -4] mg/dL/min. The performance of the prediction algorithms (ARIMA-AR-NN), evaluated on an independent test set, are: precision 72.15%-36.11%-68.29%, recall 98.28%-98.11%-96.55%, FP/day 0.27-1.15-0.32, and a TG of 15min-10min-15min.

Conclusions: Preliminary results indicate that an ARIMA model, fed by CGM data only, predicts effectively and in real-time PBH episodes with a median TG of 15 min.

EP146 / #549

Topic: *AS05-Glucose Sensors*

IS THERE A CORRELATION BETWEEN OBESITY AND GLUCOMETRICS IN PEOPLE WITH TYPE 1 DIABETES?

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Background and Aims: Obesity is increasingly prevalent in type 1 diabetes (T1D), leading to comorbidities. We investigated whether obesity shows a correlation with continuous glucose monitor (CGM) parameters such as time-in-range (TIR), time-above-range (TAR), time-below-range (TBR), and glycemic variability (GV). It is unclear whether obesity and glucometrics are correlated, which could aid clinical decisions.

Methods: We evaluated glucometrics in obese subjects with T1D (BMI ≥30 kg/m^2) compared to non-obese subjects with T1D matched for gender, diabetes duration, and age (1:2 ratio). CGM usage <70% was excluded. Data were derived from a clinical database (NCT04664036). TIR (70-180 mg/dl), TAR (>180 mg/dl), TBR (<70 mg/dl), GV and mean glucose were retrieved from CGM devices.

Results: Mean age of the cohort (N = 125) was 49 ± 16 years and mean diabetes duration was 28 ± 15 years. TIR was 55 ± 14%. Fourteen subjects (11%) reached TIR ≥70%. HbA1C did not differ between obese (N = 42) and non-obese subjects (7.6 ± 0.8 vs. 7.4 ± 1.1%). We found no significant differences in TIR (52 ± 11 vs. 56 ± 15%, p = 0.073), TAR (41 ± 13 vs. 37 ± 17%, p = 0.083), TBR (7.1 ± 6.5 vs. 7.8 ± 7.1%), mean glucose level (172 ± 26 vs. 164 ± 33mg/dl), GMI (7.5 ± 0.1 vs. 7.3 ± 0.1%), and GV (42 ± 8 vs. 41 ± 9%) between obese subjects and controls. Only two subjects in the obese group had a TIR ≥70% (4.8%), compared to 12/83 controls (14.5%) (p = 0.088). Regression analyses did not show a correlation between BMI and any of the glucometrics.

Conclusions: In people with T1D and fair metabolic control, TIR and TAR tended to be worse in obese subjects, but just failed to reach statistical significance.

EP147 / #578

Topic: *AS05-Glucose Sensors*

DEVELOPMENT OF A MULTI-DISCIPLINARY CONSENSUS AND GUIDANCE FOR THE THE MANAGEMENT OF ADHESIVE SKIN REACTIONS SECONDARY TO THE USE OF DIABETES DEVICES IN ADULTS.

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[1]Guys and St Thomas NHS Foundation Trust, Diabetes And Endocrinology, London, United Kingdom, [2]Guys and St Thomas

NHS Foundation Trust, St Johns Institute Of Dermatology, London, United Kingdom, [3]King's College London, Department Of Diabetes, London, United Kingdom, [4]King's Health Partners, Institute Of Diabetes, Endocrinology And Obesity, London, United Kingdom, [5]Guy's and St Thomas' Hospital NHS Trust, Department Of Diabetes & Endocrinology, London, United Kingdom

Background and Aims: With increasing use of diabetes devices, there has been a dramatic rise in skin reactions from adhesives, with CGM studies suggesting 5.5-8% of users [1,2]. With the further anticipated use of devices in wider groups, including type 2 diabetes, professional guidance involving dermatologists and diabetes carers is needed.

Methods: A steering committee and writing group consisting of dermatologists with international expertise in cutaneous skin reactions and diabetes care professionals (diabetologists, diabetes nurses and educators) with significant experience in diabetes devices was formed. Guidance was formulated by reviewing the literature, discussing cases and management approaches. Appraisal was provided by a larger group of clinicians from both departments and people with diabetes.

Results: Following over four meetings, a pathway, education resources, as well as a pragmatic step-by-step management approach were drafted. A management strategy consisting of the following were devised: Key questions in history and features of reactions (Fig. 1) ii) Recording and reporting for both local audit and device regulators iii) Management based on severity of reaction (Fig 2.) iv) Referral to dermatology and for diagnostic patch testing v) Good practice tips were devised. Current steps include audit of this pathway and working with national diabetes and dermatological organisations to support this.

Fig 1.

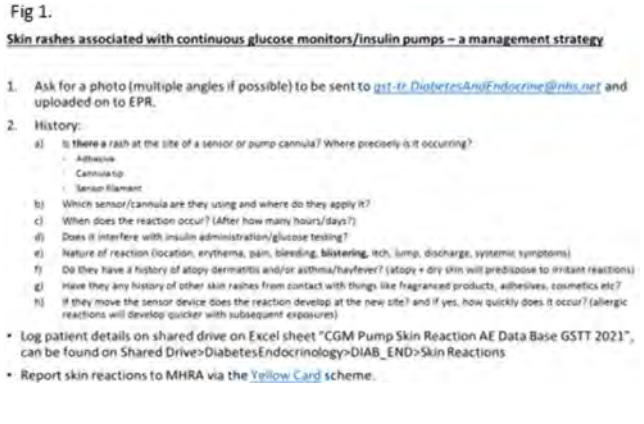
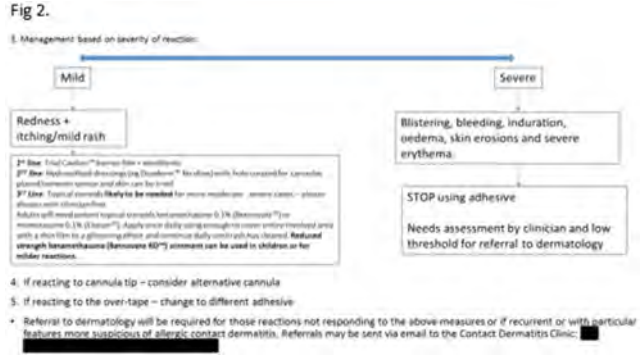


Fig 2.



Conclusions: We provide one of the first shared approaches between diabetes and dermatology for this common situation. Whilst we hope sharing this guidance will promote good medical practice and reduce burden for those with diabetes, a change in diabetes device regulation is urgently needed to ensure adhesives are detailed by industry.

1. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. Lancet. 2016 Nov 5; 388(10057):2254-2263.

2. Jeroen Pyl, Ella Dendooven, Ine Van Eekelen, Marieke den Brinker, Hilde Dotremont, Annick France, Kenn Foubert, Luc Pieters, Julien Lambert, Christophe De Block, Olivier Aerts. Prevalence and Prevention of Contact Dermatitis Caused by FreeStyle Libre: A Monocentric Experience. Diabetes Care Apr 2020, 43 (4) 918-920.

EP148 / #601

Topic: ***AS05-Glucose Sensors***

MULTIPLE AND PROGRESSIVELY WORSENING ADVERSE SKIN REACTIONS TO DIABETES DEVICES IN A 39-YEAR-OLD FEMALE.

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[1]Guy's and St Thomas' Hospital NHS Trust, Department Of Diabetes & Endocrinology, London, United Kingdom, [2]Guys and St Thomas NHS Foundation Trust, 2. st Johns Institute Of Dermatology, London, United Kingdom, [3]King's College London, Department Of Diabetes, London, United Kingdom, [4]King's Health Partners, Institute Of Diabetes, Endocrinology And Obesity, London, United Kingdom

Background and Aims: We present the case of a 39-year-old female, with long-standing type 1 diabetes and seropositive rheumatoid arthritis treated with adalimumab, who presented with multiple and progressively worsening adverse skin reactions to various diabetes devices.

Methods: She was assessed by dermatology and patch tested with an extended European baseline series of contact allergens, acrylates, other allergens associated with glucose sensors, insulin pumps and medicaments allergens. IQ™ chambers (Chemotechnique Diagnostics, Vellinge. Sweden) were used for the initial assessment and aluminium Finn chambers™ for the second reading.

Fig 1.

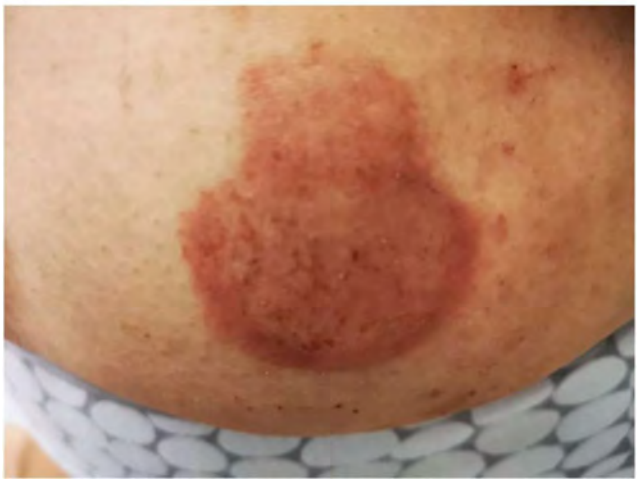
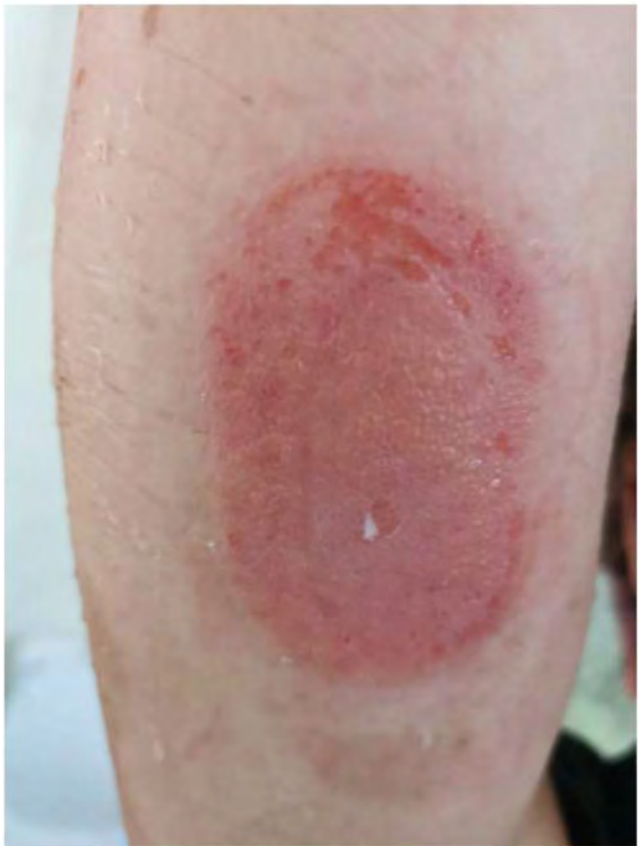


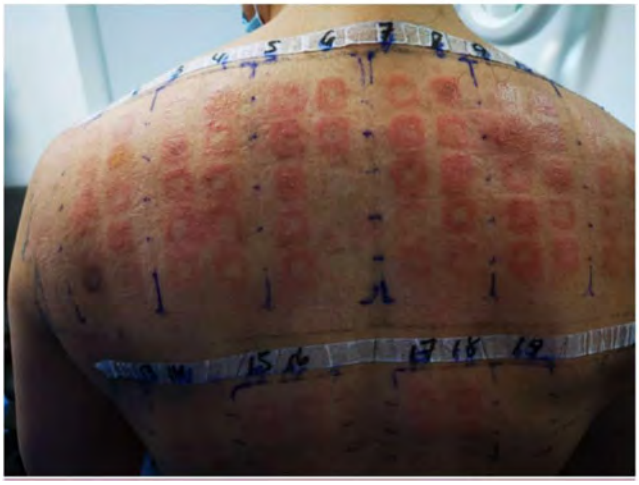
Fig 2.



Results: Over several years, she successively developed low-grade skin reactions to Medtronic 640G cannula adhesive, and more severe reactions to enlite sensors (Figure 1), Freestyle Libre 1 and 2, Guardian 3 sensors, Dexcom G6 sensors (Figure 2) and Duoderm®, despite using barrier films, dressings and low dose steroid creams. It was unclear whether this occurred due to cross sensitisation or because of an excessively vigour ''excited back'' phenomenon due to the strength of the primary sensitisations. Repeat patch testing using Finn chambers™ was organised for 6 weeks later and multiple positive reactions were noted (Figure 3).It proved impossible to obtain details of the chemical composition from manufacturers.

Conclusions: This case reflects likely cross-sensitisation to multiple antigens via adhesive components. Therefore adverse skin reaction from commonly used diabetes adhesive devices can pose significant challenges for people with diabetes. Future legislations must mandate full ingredient and chemical composition labelling (as is the case with cosmetics and medicines) by industry, with a legal responsibility to use chemicals with lower sensitization capacities.

Fig 3.



EP149 / #625

Topic: ***AS05-Glucose Sensors***

COMPARISON BETWEEN ISCGM FREESTYLE LIBRE 1, FREESTYLE LIBRE 2 AND CAPILLARY SMBG IN YOUNG PEOPLE WITHOUT DIABETES MELLITUS.

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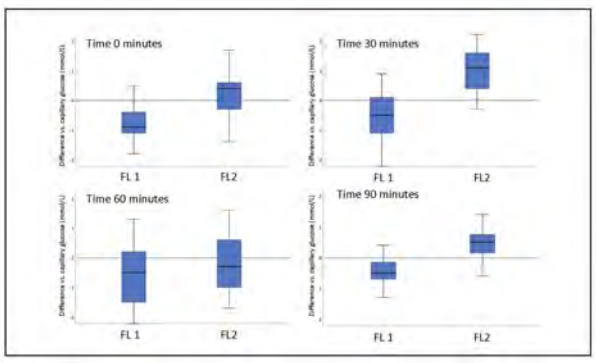
Background and Aims: IsCGM has become a valuable tool to improve glucose variability, long-term metabolic control, and quality of life in people with diabetes. It has, in several clinical contexts, replaced SMBG as the standard method of self-care monitoring. However, issues about reliability in the lower-glucose intervals and the responsiveness in situations with high glucose fluctuations have been raised. This study aimed to evaluate time in hypoglycemia and responsiveness between SMBG, Freestyle Libre 1 and Freestyle Libre 2 in young people without diabetes.

FIGURE 1.



Methods: Ten people between 16 and 21 years of age (8 females, BMI 21) were randomized to wear Freestyle Libre 1 on their right or left upper arm for two weeks and Freestyle Libre 2 (Abbott inc) on the other. SMBG was measured using Contour Next One (Ascensia). During the period, each participant performed four meal stress-tests (2xhigh-calorie and 2xfast-carbohydrate).

Results: The participants did not experience any discomfort using or applying the isCGM-devices. isCGM-data were available for 86% of the measuring time. Time spent in, below, and above range according to the different measuring methods are given in Figure 1. The boxplots (median, 25-75 percentiles, and min/max) in Figure 2 represent differences from SMBG before and during the meal stress tests.

Conclusions: The responsiveness of isCGM to stress-meals in young people without diabetes was satisfactory from a clinical point of view. Freestyle Libre 2 did not, in contrast to Freestyle Libre 1, seem to over-diagnose hypoglycemia in people with well-controlled glucose-metabolism.

EP150 / #635

Topic: ***AS05-Glucose Sensors***

UPDATED GLUCOSE MONITORING COMMUNICATION (GMC) SURVEY

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Background and Aims: The rapid evolution of diabetes technology highlights the need for psychosocial surveys that include technology use. Thus, we updated the Blood Glucose Monitoring Communication survey and assessed its psychometric properties in youth with T1D and their parents.

Methods: Participants (N = 119) and their parents completed the updated GMC survey with six additional items inquiring about negative affect related to monitoring glucose via CGM (e.g., ''*I feel scared when the CGM alarms for low numbers*''). Youth and parents also completed measures of depressive symptoms and diabetes distress.

Results: Youth (49% female) were aged *(M±SD)* 13.2 ± 2.7 years, with diabetes duration 6.6 ± 3.5 years and HbA1c 7.9 ± 0.9%. Updated youth and parent GMC demonstrated good internal consistency (youth, $\alpha = 0.88$; parent, $\alpha = 0.86$). There was low correlation between youth and parent scores ($r = 0.21$, $p = 0.03$). Higher GMC scores (greater negative affect) were associated with more depressive symptoms and diabetes distress for both youth ($r = 0.60$, $r = 0.71$, both $p < .0001$) and parents ($r = 0.28$, $p = 0.003$; $r = 0.62$, $p < .0001$). Higher parent GMC scores were associated with less youth CGM wear ($r = -0.20$, $p = 0.04$); neither youth nor parent scores were significantly associated with youth HbA1c.

Conclusions: The updated GMC survey has strong psychometric properties. Associations of more negative affect around glucose with less favorable youth and parent characteristics (i.e., more depressive symptoms and diabetes distress) underscores the intersection of assessment of glucose results, a fundamental component of diabetes self-management, with important patient-reported outcomes that impact self-care. Further research can assess the predictive validity of the GMC on durability of CGM use.

EP151 / #651

Topic: ***AS05-Glucose Sensors***

IMPACT OF AMBULATORY GLUCOSE PROFILE ON HBA1C, EXERCISE REGULARITY, AND DRUG COMPLIANCE AMONGST DIABETIC PATIENTS IN CENTRAL INDIA.

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Background and Aims: Regular exercise is necessary for good Glycaemic control. Exercise is an important strategy in the management of diabetes and obesity. The Exercise is tailored to the individual's preferences and metabolic goals. Newer monitoring techniques, such as continuous glucose monitoring systems (CGM), are now finding their way into diabetes care and exercise treatment. AGP can assist diabetes patients to maintain a regular exercise program, increase drug compliance, and reduce blood sugar levels.

Methods: 60 patients.Age 15–65 years.with T1DM and T2DM. Randomly allocated to two groups of 30 persons each. In the first group blood, sugar measurement was carried out via AGP for 14 days and another group was on routine blood sugar monitoring technique (SMBG). The participants were monitored for HBA1C, Surveyed for exercise patterns adjudged by a questionnaire at 3 months.

Results: HBA1C reduction in the AGP group was 2.2% as compared to 1% in the SMBG group.The number of patients achieving the target goal of 7% HBA1C was better in the AGP group (82%) as compared to the Non-AGP group (54%).74% of patients in the AGP group did regular exercise as compared to 38% in the Non-AGP group.78% have accepted to have better drug compliance as compared to 62% in the Non-AGP group.

Conclusions: AGP has a significant impact on the patients' lifestyle changes. If activity is based on AGP readings, it can lead to more consistent exercise routines and improved blood sugar control. Health care practitioners should advocate the usage of AGP. Proper use of AGP can improve drug compliance in patients.

EP152 / #741

Topic: ***AS05-Glucose Sensors***

AMBULATORY GLUCOSE PROFILE: WHAT ABOUT MONITORING INTERVAL?

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Background and Aims: 14-day ambulatory glucose profile (AGP) is reflective of the following 30-day glucose control in type 1 diabetes (T1D). Analyzing more data could improve this prediction. We sought to investigate differences between 14-day and 28-day AGP parameters and its association with hemoglobinA1c (HbA1c).

Methods: Adults with T1D treated with continuous subcutaneous insulin infusion (CSII) and using flash glucose monitoring (Abbott FreeStyle Libre®) were included. A 14-day and 28-day AGP report was created for each individual and HbA1c was determined on the same date. Study endpoints included

differences between time in ranges, average glucose, glucose variability and average duration of low glucose events. HbA1c was compared with glucose management indicator (GMI).

Results: Sixty subjects were enrolled (72% female; age 36.9 ± 9.2y; HbA1c 7.1 ± 0.8%). Comparing 14-day and 28-day AGP reports, no differences were found regarding average glucose (157.2 ± 32.0mg/dlvs.158.5 ± 33.3mg/dl) and glucose variability (39.5 ± 6.0%vs.39.2 ± 5.9%). 14-day AGP report showed more time in the 'low' range vs. 28-day AGP report (5.0%vs.4.6%, $p = 0.012$). No differences were found in ''very high'' (10.7%vs.10.8%), ''high'' (20.8%vs.20.9%), ''target range'' (61.5%vs.61.7%) and ''very low'' (2.0%vs.1.9%) times. Average duration of low glucose events (100.7min vs.96.0min) and average daily scans (11.7/d vs.11.5/d) did not differ between 14-day and 28-day reports. Mean HbA1c (7.12%) correlated well with mean 14-day and 28-day GMI (7.10% and 7.13%, respectively).

Conclusions: In adults with T1D on CSII the 14-day AGP report showed a longer time in the 'low range' when compared to the 28-day report. Increased treatment adherence immediately before the medical appointment could explain this finding. Standardizing the 28-day AGP report might have benefits.

EP153 / #750

Topic: ***AS05-Glucose Sensors***

IMPACT OF CONTINOUS GLUCOSE MONITORING (CGM)USE AFTER 2 YEARS IN T1D SUBJECTS WITH FREQUENT HYPOGLYCEMIC EVENTS.

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Background and Aims: The use of CGM has proved benefits in type 1 diabetes (T1D), especially in reducing hypoglycemic events and quality of life. In Spain, public health administrations started to reimburse the use of CGM systems in T1D in 2019, prioritizing those affected by more hypoglycemic events. The aims of this study is to analyze the impact in the real world of CGM use in T1D subjects with frequent hypoglycemic events.

Methods: We included 30 T1D adult subjects with >4 hypoglycemia per week, nocturnal hypoglycemia or >2 severe hypoglycemia in the year before starting ''flash'' CGM system (Freestyle Libre®). Patients completed Clarke questionnaire and the Hypoglycemia Fear Survey (HFS) at baseline and after 2 years. Glucometric variables (2 weeks period) from the start of CGM and 2 years later have been collected from Libreview® platform.

Results: Patients reduced significantly the time below 54 mg/dl (from 3.6% to 1.1%; $p < 0.001$). In addition, there was a reduction in the percentage of patients with impaired hypoglycemia awareness measured by Clarke questionnaire (from 26.7% at baseline to 16.7%), although without statistical significance. Furthermore, a significant reduction in the total HFS score (74.9 ± 16.3 vs. 67.2 ± 19.2; $p < 0.01$) was observed, at the expense of the worry score. No differences were observed in the other parameters analyzed (time in range, mean glucose, time in hyperglycemia, coefficient of variation).

Conclusions: After 2 years of CGM use, level 2 hypoglycemia was significantly reduced and patients presented less worry for hypoglycemia measured by HFS. No differences were observed in other glycemic control related parameters.

EP154 / #754

Topic: ***AS05-Glucose Sensors***

INSIGHTS INTO THE CONCEPT OF SAFE RAMADAN FASTING USING CGM-DERIVED METRICS

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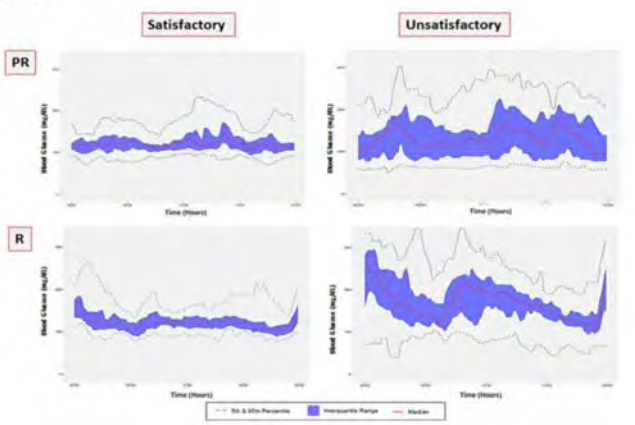
Background and Aims: Ramadan fasting (RF) in patients with diabetes increases risk of dysglycaemia, and glycaemic variability (GV). Patient's perception of safe RF focuses mainly on hypoglycaemia risk. We have used paired CGM data during pre-Ramadan (PR) and (R) periods to investigate magnitude and direction of changes in glycaemic parameters in patients with satisfactory and unsatisfactory control PR and relate this to specific treatment modalities.

Methods: 10 patient pairs (PP) with complete CGM data were selected based on treatment modalities and were divided into satisfactory (glucose in range 70-180 mg/dL >70% of time) and unsatisfactory glucose control groups. Raw CGM blood glucose (BG) data were then analysed and median (IQR) BG was plotted using cgmanalysis package (R-studio) and EasyGV.

Results: In OHA-treated patients, those prescribed sulphonylureas displayed the widest range of GV (80-350 mg/dL). Compared to T2DM patients on insulin (150-300 mg/dL), T1DM patients showed better control during Ramadan (100-180 mg/dL); PANEL A. In patients with unsatisfactory control pre-Ramadan, there was a significant and marked deterioration in markers of overall control, risk and glucose variability with RF. The difference between satisfactory and unsatisfactory control groups (in CONGA, LI, J-Index, MODD, MAGE, ADRR, CV, excursion >180 mg/dL and HBGI) was exaggerated during RF ($p \leq 0.05$; PANEL B); Table 1.

Conclusions: Patients with unsatisfactory control before Ramadan show a marked deterioration with RF. Patients on insulin and/or sulfonylureas show the greatest detrimental change.

Figure 1. The effect of Ramadan fasting (RF) on blood glucose in patients with diabetes under satisfactory and unsatisfactory glycaemic control (GC)



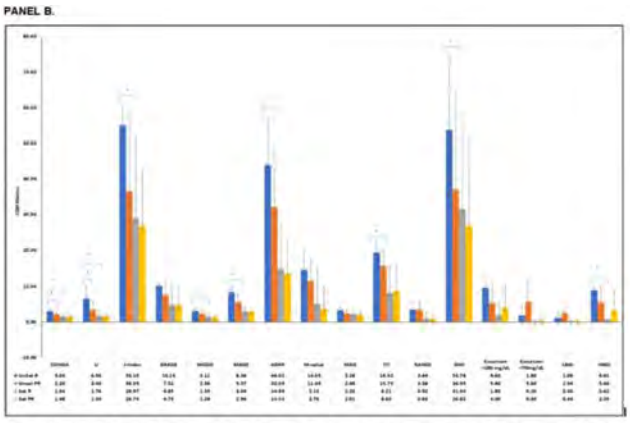


Figure 1. The effect of Ramadan fasting (RF) on blood glucose in patients with diabetes under satisfactory and unsatisfactory glycaemic control (GC). For the patient with diabetes selected (n=10); patients showing unsatisfactory glycaemic control were (n=5; Pts 1, 3, 5, 7 and 9) and patients showing satisfactory glycaemic control were (n=5; Pts 2, 4, 6, 8 and 10). Median blood glucose values with 25th (Q1) and 75th (Q3) percentiles indicating the interquartile range (IQR); and 5th and 95th percentiles, were plotted using the cgmanalysis package in R-studio software. PANEL A. Various CGM metric were calculated and statistical analysis was conducted with significance at the 0.05 level; PANEL B.

Table 1.

	Pre-Ramadan (PR)		Ramadan (R)	
	Satisfactory Glycaemic Control (Sat-GC) (n=5)	Unsatisfactory Glycaemic Control (UnSat-GC) (n=5)	Satisfactory Glycaemic Control (Sat-GC) (n=5)	Unsatisfactory Glycaemic Control (UnSat-GC) (n=5)
Median (IQR)	118.00 (111.50-124.50)	126.00 (94.00-176.00)	115.00 (112.50-136.00)	161.05 (121.00-210.00)
CV	0.20 (0.15-0.29)	0.28 (0.24-0.38)	0.17 (0.15-0.23)	0.38 (0.3-0.44)
eA1c	5.70 (5.60-6.30)	6.50 (4.9-8.15)	5.70 (5.60-6.60)	7.70 (7.3-7.60)
Percent of TIR (70-180 mg/dL)	97.88 (82.95.8-99.29)	(85.31)47.58-78.81)	99.20 (83.37-100.00)	56.63 (51.92-69.42)
Percent of TBR level 1 (54-70 mg/dL)	0.35 (0.00-1.50)	7.91 (0.00-22.64)	0.00 (0.00-0.32)	0.24 (0.00-3.32)
Percent of TBR level 2 (<54 mg/dL)	0.00 (0.00-0.06)	0.00 (0.00-8.48)	0.00 (0.00-0.00)	0.90 (0.00-8.26)
Percent of TAR level 1 (180-250 mg/dL)	1.42 (0.00-17.40)	19.82 (0.49-41.70)	0.80 (0.00-14.53)	28.28 (24.71-34.51)
Percent of TAR level 2 (>250 mg/dL)	0.00 (0.00-0.00)	0.33 (0.00-12.41)	0.00 (0.00-2.48)	12.20 (7.43-17.62)
LBGI	1.53 (0.57-2.21)	3.13 (0.41-10.06)	1.16 (0.57-1.47)	4.04 (0.73-8.53)
HBGI	1.33 (0.96-5.10)	6.73 (1.58-10.64)	1.17 (0.91-4.12)	11.48 (8.66-12.18)

Table 1. Key CGM metrics. Various metrics were chosen for patients with diabetes on various treatment modalities classified per glycaemic control (satisfactory and unsatisfactory) during Pre-Ramadan (PR) and Ramadan (R) time periods. For the patient with diabetes selected (n=10), patients displayed both unsatisfactory (n=5) and satisfactory (n=5) glycaemic control. Key metrics for CGM data analysis and reporting are shown for both groups in both PR and R periods.

CGM-derived indicators of good control need to be incorporated into the concept of ''safe Ramadan fasting''.

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EP155 / #776

Topic: ***AS05-Glucose Sensors***

PERFORMANCE EVALUATION OF SUBCUTANEOUS GLUCOSE MONITORING IN CLINICAL DEVELOPMENT—OPTICAL MEASUREMENT PROFUSA LUMEE GLUCOSE PLATFORM

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Background and Aims: Lumee Glucose is a small soft glucose-sensitive hydrogel (5.0x0.75x0.65mm hydrated) in clinical development intended for permanent subcutaneous placement by injection to continuously monitor glucose. The sensor is comprised of a hydrogel scaffold containing fluorescent molecules producing near infrared light proportional to glucose concentration when interrogated by an optical skin reader placed over the hydrogel. The reader utilizes a set of LEDs to excite the fluorophores within the hydrogel and communicates wirelessly with a tablet (Figure 1).

Methods: Sensor performance was assessed in clinical studies during ~five 8-hour in-clinic visits in 16 subjects (7 female, 43 yrs [20-72], BMI 26[kg/m^2] [19.7-40.3]) with insulin-dependent diabetes over a 3-month period. A carbohydrate-rich meal was served during that time and frequent venous blood glucose measurements were obtained as reference (Super GL analyzer). Sensor signals were subjected to a retrospective data processing algorithm and a 3-point glucose reference calibration developing machine learning approach. Sensor performance has been assessed based on iCGM criteria including 2156 paired glucose measurements.

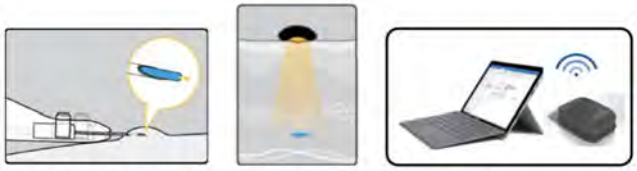

Figure 1: Schematic of subcutaneous hydrogel injection (left) and reader placement on the skin surface (right).

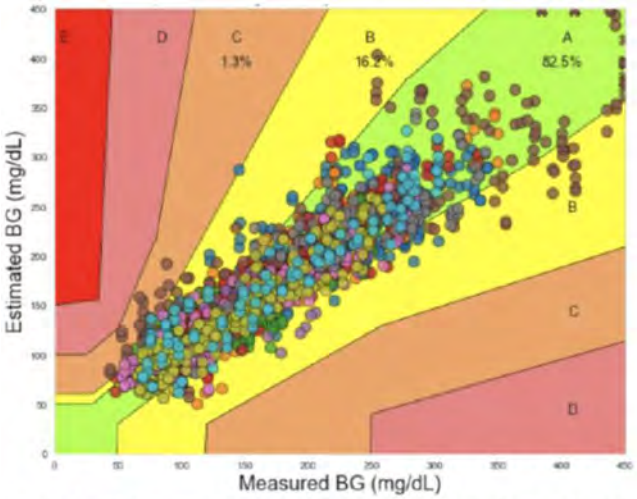

Figure 2: Error Grid representation of paired glucose values color coded by subject (n=16).

Blood Glucose range (mg/dL)	Number of Paired	% BG within 15/15% of BG	% BG within 20/20% of BG	% BG within 30/30% of BG	% BG within 40/40% of BG	% BG greater than 40/40% of BG
Overall	2156	68.0%	80.5%	92.0%	96.2%	4.4%
0-54	8	0.0%	12.5%	37.5%	62.5%	37.5%
54-70	49	30.6%	46.9%	67.3%	73.5%	26.5%
70-180	1252	68.2%	79.6%	90.2%	95.3%	4.7%
180-250	496	77.0%	88.7%	96.8%	99.4%	0.6%
> 250	351	61.3%	78.1%	96.6%	98.9%	1.1%

Table 1: Distribution of differences between paired Lumee – reference glucose values.

Results: he average MARD for all paired values during the monitoring period of 6-91 days was 13.4%. The distribution differences by iCGM glucose range are listed in table 1.

Conclusions: Following injection the hydrogel is suitable for long-term non-invasive glucose monitoring for a minimum period of three months. Projected performance parameters are within the range of currently available glucose monitoring devices. Signal processing algorithms are further being optimized considering compensation for signal perturbations including motion, temperature, and ambient light.

EP156 / #791

Topic: *AS05-Glucose Sensors*

DYNAMICS OF CHOLESTEROL AND BLOOD PRESSURE IN 4,484 ADULTS WITH TYPE 1 OR TYPE 2 DIABETES AFTER INITIATION OF CGM

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Background and Aims: Does initiation of continuous glucose monitoring (CGM) have beneficial effects on total cholesterol levels and blood pressure in adults with type 1 diabetes (T1D) or type 2 diabetes (T2D)?

Methods: We used data of the diabetes prospective follow-up registry (DPV) to identify individuals with T1D or T2D ≥18 years of age starting CGM use in 2015 or later and follow-up information available. Total cholesterol, systolic (SBP) and diastolic blood pressure (DBP) in the year prior to CGM start were compared to a follow-up period with CGM use for >6 months. Repeated measurements linear regression models were used adjusting for sex, age at diabetes onset and respective baseline parameters. Analyses were stratified by diabetes type.

Results: 4,484 adults (2,999 with T1D (mean follow-up 1.8 years) and 1,485 with T2D (mean follow-up 1.9 years)) were studied. Total cholesterol decreased significantly after CGM initiation in T1D (baseline: 187.7 mg/dl (95%-CI: 186.4-189.0), follow-up: 183.7 mg/dl (182.0-185.4) and T2D (baseline: 182.6 mg/dl (181.3-183.8), follow-up: 177.4 mg/dl (175.8-178.9)). SBP and DBP increased slightly in individuals with T1D (SBP: 127.2 mmHg (126.8-127.5) to 127.6 mmHg (127.3-128.0), DBP: 75.7 (75.5-75.9) to 76.3 mmHg (76.0-76.5)), while SBP declined in T2D with CGM use (136.0 mmHg (135.5-136.6) to 135.7 mmHg (135.1-136.3)). DBP did not change after CGM initiation in T2D.

Conclusions: CGM initiation might be associated with improvement in healthy lifestyle (changes in diet, increased physical activity) which might result in beneficial effects on cholesterol and blood pressure in adult individuals with T1D and T2D.

EP157 / #813

Topic: *AS05-Glucose Sensors*

CHARACTERISTICS OF PEOPLE WITH DIABETES THAT SPEND 15% OR MORE TIME BELOW RANGE

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Background and Aims: The goal for most people with diabetes using continuous glucose monitoring (CGM) is to spend less than 4% of time below 70mg/dL also defined as time below range. Hypoglycemia can lead to serious complications.

Methods: This was a retrospective chart review and used cross-sectional data via the LibreView data platform, which records data from intermittently scanned CGM (isCGM). The inclusion criteria were greater than 15% of time below 70mg/dL and at least 50% data sufficiency over 14 days. The electronic medical record was used to determine type of diabetes, diabetes medications, and most recent A1C corresponding to the CGM report date. Other CGM key metrics were recorded including time in range 70-180mg/dL, time above range 180mg/dL and coefficient of variation (CV). Data was analyzed using descriptive statistics.

Results: Twenty-seven people were identified with 15% or more time below 70mg/dL (range 15%-52%, mean 24.7%). Other CGM key metrics included a mean 8.8% time below 54mg/dL (range 1%-37%), and a mean 11.9% above 180mg/dL (range 0%-48%). The mean CV was 40% indicating high glycemic variability (range 21%-57.6%). In total, 4 people (15%) had a hypoglycemia disorder without diabetes, 15 (55%) had type 2 diabetes, and 8 (30%) had type 1 diabetes (30%). Only 8 (30%) had a prescription for glucagon within the past 2 years.

Conclusions: This study showed that type 2 diabetes was the most common diagnosis in people that spend 15% or more time below range. Despite this high risk population, less than one-third had a prescription for glucagon.

EP158 / #83

Topic: *AS05-Glucose Sensors*

PATIENT PERSPECTIVES ON FACTORS AFFECTING CGM ACCURACY, UTILITY AND DECISION MAKING IN PEOPLE WITH DIABETES WITHIN THE T1D EXCHANGE COMMUNITY

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America, [4]LifeScan Global Corporation, Marketing, Malvern, United States of America, [5]LifeScan, Medical Affairs, Madrid, Spain, [6]LifeScan Global Corporation, Medical Affairs, Malvern, United States of America

Background and Aims: Continuous glucose monitoring (CGM) offers a deeper understanding of multiple factors affecting glucose management. We sought to quantify factors patients thought impacted sensor performance or decision making.

Methods: An online survey was reviewed by an Institutional Review Board and offered to people ages 18+ with type 1 (T1D) or type 2 diabetes (T2D) who were former or current CGM users within the T1D Exchange community. Analyses were conducted by T1D Exchange.

Results: 563 current and 42 former CGM users (504 T1D, 101 T2D) responded. 67% current users used Dexcom, 19% Medtronic and 13% Abbott Libre systems. 49% (n = 295/605) had previously temporarily stopped using CGM, of whom 59% (173/295) stopped for ≥1 month. Despite 90% stating majority of sensors were accurate, 42% (251/605) thought accuracy varied from sensor to sensor. 15% stated ≤6/10 sensors could be described as accurate (88/605). 26% (158/605) agreed poor sensors often affected their confidence dosing insulin or ability to make diabetes management decisions (25%, 149/605). 35% (211/605) were concerned about the effect of over-the-counter or prescription medications on sensor accuracy, with 43% (259/605) or 32% (195/605) suspecting either pain relief or cold/flu remedies affected sensor accuracy, respectively.

Conclusions: CGM users expressed concerns about individual and sensor to sensor accuracy, the impact of potential interferents and how these issues affected insulin dosing and diabetes management decisions.

EP159 / #115

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ENGAGEMENT AND WEIGHT LOSS FROM A COACHED DIGITAL SUPPORT PROGRAM IN PEOPLE WITH TYPE 2 DIABETES

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Background and Aims: The prevalence of obesity and comorbidities including type 2 diabetes (T2D) continue to increase worldwide. According to state-by-state obesity data, the prevalence of obesity is above 20% in all US states[1], highlighting a need for interventions supporting weight loss.

Methods: An open invitation was sent to OneTouch Reveal® diabetes app users in the US to experience NOOM® weight loss program (app) for 16 weeks free of charge. Participants self-reported a diagnosis of T2D and A1c ≥ 7.5%. Data analysed from NOOM app.

Results: 52156 in-app actions were recorded from 400 participants over 16 weeks. 65% (136/208) of those with available weights, lost weight. Engaged participants (those performing ≥1 app action in 8 of 16 weeks) lost 9.9lbs (49/208) compared to -1.9lbs (159/208) for those non-engaged. 53.5% (214/400) messaged their NOOM coach. Participants who messaged in 8 of 16 weeks lost 9.5lbs (55/208) compared to -1.7lbs (153/208) not messaging at this frequency. App engagement manifested by 19209 lifestyle articles read, 15484 meals recorded, 6223 weight measures, 3518 coaching messages and 1481 group postings.

	≥ 1 NOOM app action per week for all 16 weeks		≥ 1 NOOM app action in at least 8 of 16 weeks		NOOM coach messaged in at least 8 of 16 weeks	
	Yes (N=49)	No (N=159)	Yes (N=102)	No (N=106)	Yes (N=55)	No (N=153)
Weight change from baseline (lbs)	-9.9	-1.9	-6.4	-1.3	-9.5	-1.7
% change in weight from baseline (engaged vs non-engaged)	-3.6 95% CI: (-5.0, -2.2) P < 0.05		-2.4 95% CI: (-3.2, -1.5) p < 0.05		-3.6 95% CI: (-4.9, -2.3) P < 0.05	

Conclusions: These results indicate that a coached, digital support program for people with diabetes promotes weight loss via a holistic lifestyle intervention which emphasizes psychoeducation and self-monitoring in a real-world setting.

EP160 / #157

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

THE CLINICAL EFFECT OF STEN-O STARTER - A DIGITAL UNIVERSE FOR CHILDREN AND ADOLESCENTS WITH DIABETES IN REGION NORTH DENMARK - PRELIMINARY RESULTS

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Background and Aims: Being diagnosed with diabetes change your life instantaneously, especially if you are a child. Sten-O Starter is a digital universe organized around an mHealth app with eye-level communication, interactive exercises, illustrations, and videos, for children with diabetes and their relatives to cope with their new reality. The aim of this study was to evaluate the clinical effect of Sten-O Starter.

Methods: HbA_{1c} values within the first 8 months of diagnosis were extracted for all children and adolescents (aged ≤18) diagnosed in the period SEP-2020 to AUG-2021 (Sten-O Starter) and in the period SEP-2017 to AUG-2019 (Standard of Care). The monthly change in HbA_{1c} based on the last available value and the value at diagnosis for all included people were analyzed with two general linear models as a function of Steno-O Starter vs Standard for Care. The first model was crude, whereas the second was adjusted for age, sex, body mass index, and HbA_{1c} at diagnosis.

Table 1: Baseline characteristics and outcomes

	Sten-O Starter	Standard of Care
Number of people	40	80
Age (yrs), mean (SD)	9.7 (4.2)	9.9 (4.1)
Sex, n (%)		
Female	20 (50.0)	45 (56.3)
Male	20 (50.0)	35 (43.7)
Body mass index (kg/m^2), mean (SD)	18.6 (6.5)	17.4 (2.7)
HbA_{1c} at diagnosis (mmol/mol), mean (SD)	99.3 (30.8)	95.6 (28.1)
Outcomes		
Person months of exposure, mean (SD)	5.0 (2.3)	6.6 (1.1)
Monthly change in HbA_{1c} (mmol/mol), mean (SD)	-11.8 (10.9)	-7.4 (4.7)
Difference in monthly change in HbA_{1c} (mmol/mol)	Estimate (95% CI; p)	
Sten-O Starter – Standard of Care	-4.4 mmol/mol (-7.2 to -1.6 mmol/mol; p=0.0026)[1]	
	-3.9 mmol/mol (-6.1 to -1.8 mmol/mol; p=0.0004)[1,2]	

[1] Estimates are from a general linear model
[2] Adjusted for age, sex, body mass index, and HbA_{1c} at diagnosis.

Results: Baseline characteristics for the people included in the study ($n = 120$) can be seen in table 1 together with the outcomes for HbA_{1c}. Use of Sten-O Starter was associated with an adjusted estimated difference in monthly change from baseline in HbA_{1c} of -3.9 mmol/mol (95% CI: -6.1 to -1.8 mmol/mol; $p = 0.0004$) compared to Standard of Care.

Conclusions: Preliminary results indicate a clinical effect on HbA_{1c} for children and adolescents diagnosed with diabetes enrolled in the Sten-O Starter digital universe compared with Standard of Care. The final results are planned to be published ultimo 2022.

EP161 / #179

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

MULTIDIRECTIONAL CHANGES IN THE LEVELS OF IRISIN AND APELIN PREDICTED HEART FAILURE WITH PRESERVED EJECTION FRACTION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: Irisin is skeletal muscle-derived peptide that produced by a proteolytic cleavage of fibronectin type III domain-containing-5 transmembrane protein. Apelin is a powerful regulatory peptide acting as an autocrine regulator of cardiac and vascular reparation. The aim of the study was to investigate whether serum levels of both irisin and apelin predict HF with preserved ejection fraction (HFpEF) in patients with Type 2 diabetes mellitus (T2DM)

Methods: One hundred and eight HF patients with T2DM having HFpEF (EF >50%; n = 58), HF with mildly reduced ejection fraction (HFmrEF, EF <40%; n = 22), HF with reduced ejection fraction (HFrEF, EF <40%; n = 28) aged from 41 to 62 years and 20 non-HF patients with T2DM. Healthy control group was consisted of 25 individuals matched with age and sex.

Results: We found that the levels of irisin were significantly higher in HFpEF patients than in HFrEF individuals, whereas healthy volunteers and T2DM non-HF patients demonstrated lower concentrations of these peptides. Apelin levels were significantly increased in HF patients mainly with HFrEF. There were not significant differences between the levels of these biomarkers in HFrEF and HFmrEF ($P = 0.42$ for all cases). Using ROC curve we revealed that cut-off points for irisin and apelin that distinguished HFpEF from HFrEF/HFmrEF were (6.50 ng/mL; AUC = 0.78; 95% confidence interval [CI] = 6.85 - 10.66 ng/mL and 4.12 ng/mL, AUC = 0.72; 95% CI = 3.90-5.75 ng/mL, respectively).

Conclusions: We found that multidirectional changes in the levels of irisin and apelin in T2DM patients had better predictive value for HFpEF that simultaneous increase and decrease in the circulating levels of these peptides.

EP162 / #184

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

TELEMEDICIN A TOOL FOR THE TREATMENT OF NEW ONSET TYPE 1 DIABETES IN PEDIATRICS: TWO YEAR FOLLOW-UP IN ARGENTINE PATAGONIA

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Background and Aims: Background: The care of pediatric patients with new-onset type 1 diabetes in remote areas of Patagonia presents multiple challenges. The current pandemic has presented additional difficulties. We describe the follow-up through telemedicine by an interdisciplinary team of pediatric patients living in rural areas after two years from the start of the SARS COV2 pandemic. Aims: Report on the follow-up of 20 new-onset type 1 diabetes cases in children. The cases were diagnosed in different areas of Patagonia Argentina located more than 200 km from the referral center and were treated through a mixed method : face-to-face and virtual.

Methods: Telemedicine was used from the first day to contact the specialist. The management included diabetes education for the patient and family. The patients used multiple daily insulin injections and used software to generate ambulatory glucose profiles. Subsequently, the follow-up was carried out in a mixed modality.

Results: The patients achieved adequate glycemic control and reached the diabetes education goals; the management of the cases did not require transfers to the referral center during the first year.

Conclusions: These cases show the usefulness of telemedicine to guarantee accessibility to the health systems when the patient's attendance at the referral centers it's not possible.Telemedicine can be used to achieve glycemic control of the patient, for diabetes education in a safe, efficient way and with the satisfaction of the users.The mixed method allows to strengthen the relationship between the team and the patient and the meeting of families in educational workshops.

EP163 / #205

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IMPROVING DEEP SEGMENTATION OF DIABETIC RETINOPATHY LESIONS BY VOTING

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Background and Aims: Diabetic Retinopathy (DR) is a fast-progressing disease, often resulting in blindness, early diagnosis being crucial to prevent further damage. Automated detection of individual lesions in Eye Fundus Images (EFI) helps visualizing the lesions, characterizing their location, size and severity, and also detecting the degree of DR [1] automatically. Deep learning is state-of-the-art in segmentation, but quality segmenting eye fundus lesions is sub-optimal. Add voting multiple automated segmentations to improve quality.

Methods: IDRID Diabetic Retinopathy dataset with 55 train and 28 test Eye Fundus Images (EFI), together with corresponding groundtruth label masks; Lesions include microaneurisms MA, soft and hard exudates SE and HE, hemorrhages HM. Evaluation of quality of segmentation based on jaccard index (JI), a.k.a. degree of region match (IoU) of each lesion instance to groundtruth. The voting parts include two best performing deep learning networks (DeepLabV3 and Fully Convolutional Network FCN), plus a handcrafted segmentation algorithm.

Results: IoU performance improvement from best deep learning network (eye fundus EF 82%; MA 0.7%; HM 9.4% HE 21%; SE 10%; optical disk OD 72%; avg over all 32%) to best voting-based result of (eye fundus EF 96%; MA 5.3%; HM 23% HE 30%; SE 28%; optical disk OD 81%; avg over all 44%), a significant improvement.

Conclusions: Results show that voting over multiple approaches, both deep learning and handcrafted, can improve lesions segmentation quality significantly.

EP164 / #206

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

GLUCOSYNTH - GENERATING SYNTHETIC GLUCOSE TRACES USING DIFFERENTIALLY-PRIVATE GENERATIVE ADVERSARIAL NETWORKS

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Background and Aims: The sharing of diabetes data, e.g., continuous glucose readings, enables improved therapy development, technological advances and support of future research studies. However, there are well documented privacy concerns with the sharing of such granular, time-series data. The goal of this project is to develop a technology to facilitate sharing of diabetes data while preserving patient privacy. To this end, we introduce GlucoSynth, a data generation scheme in which a set of synthetic glucose traces that conserve desired properties of the real traces are generated in a privacy-preserving way, such that the amount of information disclosed about any individual is bounded. From there, these *synthetic* traces can be shared and used for various analyses.

Methods: Generative Adversarial Networks (GANs) are a promising method for generating synthetic data, but they themselves do not uphold any privacy guarantees. Differential Privacy is a formal notion of privacy that bounds the risk to any individual who provides data to an algorithm. GlucoSynth generates synthetic glucose traces using differentially private GANs, in which noise is added to the weights of the neural networks used in the GAN to preserve patient privacy.

Results: We test the suitability of previous approaches and find them lacking either in their ability to conserve time series characteristics of the traces, or to uphold reasonable privacy guarantees. We then evaluate the feasibility of our approach on a large real world data set of glucose traces.

Conclusions: GlucoSynth offers an opportunity to generate high-quality synthetic glucose traces which can be shared with reduced privacy concerns.

EP165 / #22

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IRISIN PREDICTED HEART FAILURE WITH PRESERVED EJECTION FRACTION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: Recent studies have shown that circulating levels of irisin were considered to be prognostic factor in heart failure (HF), but no data are available on the role of irisin in patients with diabetes mellitus (DM) having different phenotypes of HF. The purpose of the study was to investigate whether serum levels of irisin predict HF with preserved ejection fraction (HFpEF) in patients with T2DM.

Methods: The study was retrospectively involved 59 patients with type 2 DM with HFpEF (n = 28) and HF with reduced ejection fraction (HFrEF; n = 21) and 20 non-HF patients with T2DM. Healthy control group was consisted of 25 individuals matched with age and sex. Data collection included demographic and anthropometric information, hemodynamic performances and biomarkers of the disease including N-terminal pro-brain natriuretic peptide (NT-proBNP), fasting glucose, insulin and the homeostatic model assessment (HOMA) index. Serum levels of insulin and NT-proBNP were determined by ELISA.

Results: The levels of irisin were significantly higher in HFpEF patients than in HFrEF individuals, whereas non-HF T2DM patients demonstrated lower levels of irisin when compared to healthy volunteers. In multivariate logistic regression analysis we found that the irisin level >6.5 ng/mL predicted HFpEF in diabetics (odds ratio = 1.52; 95% CI: 1.16 – 2.86; P = 0.001) regardless of NT-proBNP.

Conclusions: Irisin level >6.5 ng/mL predicted HFpEF independently from NT-proBNP in T2DM patients, but discriminative potency of irisin was not sufficient for prognostication of HFrEF in patients with T2DM. This finding could open new approach for HFpEF risk stratification in T2DM patients

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Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

THE MULTIDISCIPLINARY TEAM IN DIAGNOSING AND TREATMENT OF PATIENTS WITH DIABETES AND COMORBIDITIES: PROTOCOL FOR A SCOPING REVIEW

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Background and Aims: Patients with diabetes and comorbidities experience a range of complexities regarding their diagnosing and treatment. Complexities include lack of coordination and incoherent patient pathways, poor treatment outcomes, dissatisfaction, and impaired quality of life. Multidisciplinary team (MDT) meetings have been suggested as an intervention to improve these challenges. However, evidence concerning MDTs within the diabetes field remains sparse. This review aims to identify key characteristics of MDTs for patients with diabetes and comorbidities including the use of digital health solutions for MDTs.

Methods: A scoping review will be performed according to the PRISMA-ScR guidelines. The review will consider studies that include adult subjects with a diagnosis of diabetes and comorbidity, studies that assess any type of MDT, and studies with various health-related outcomes. Full-text studies in English, Danish, Norwegian, and Swedish will be considered. A systematic search will be performed in PubMed, EMBASE, CINAHL, and Cochrane Library. Data extraction will include details about populations, study designs, interventions, use of digital health solutions, and outcomes of significance.

Results: The results of the review are expected to provide a scope of the evidence within the fields of MDT including digital health, diabetes, and comorbidity. Further, it is expected to highlight possible knowledge gaps and thereby dictate future studies to improve diagnosing and treatment for patients with diabetes and comorbidities.

Conclusions: This scoping review is important as the number of MDTs is increasing worldwide but continues to be very heterogeneously defined, including how digital health solutions are applied to support MDTs.

EP167 / #268

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

"IT CHANGED EVERYTHING WE DO": PARENT AND YOUTH EXPERIENCES WITH EARLY INITIATION OF PHYSICAL ACTIVITY TRACKERS AND EXERCISE EDUCATION IN NEWLY DIAGNOSED TYPE 1 DIABETES.

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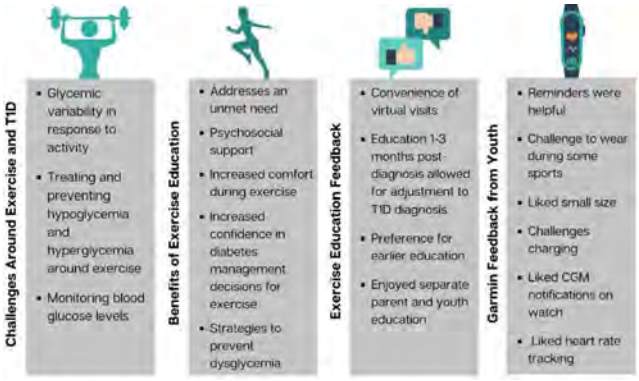
Background and Aims: The 4T exercise pilot study started youth with new-onset type 1 diabetes (T1D) on continuous glucose monitoring (CGM), physical activity trackers, and exercise education ~1-month post-diagnosis. The overall study goal is to increase knowledge and education around safe exercise strategies for youth with new-onset T1D. We present data from focus groups aiming to understand the parental and youth experiences on exercise education after T1D diagnosis and wearing activity trackers.

Methods: Semi-structured interviews were conducted to obtain feedback and experiences, benefits, and challenges with starting activity trackers and exercise education shortly after T1D diagnosis. Groups and interviews were audio recorded, transcribed, and analyzed using content analysis.

Results: A total of 6 parents (age 40 [32, 48] years; 83% female; 33% non-Hispanic White) of 7 youth (age 12 [12, 14] years; 43% female; 43% non-Hispanic White) engaged in exercise education and all youth were initiated on activity trackers 11 [6, 28] days post-diagnosis. Findings are presented in Figure 1. Parents reported the exercise education addressed an unmet need and shared the convenience of virtual visits. Youth enjoyed the small size of the activity trackers and found the exercise education provided new strategies to maintain glycemic control around exercise.

Conclusions: This is the first study to assess a parent and youth structured exercise education program shortly following T1D diagnosis. Overall, both parents and youth found that exercise education ~1-month post-diagnosis increased their confidence in diabetes management decisions around exercise and the program was even referred to by two parents as a ''game-changer''.



EP168 / #279

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

GLYCEMIC CONTROL OF PATIENTS WITH DIABETES IN RUSSIA WHO WERE USING THE CONTOUR®PLUS ONE BGMS WITH CONTOUR®DIABETES APP.

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Background and Aims: To date, little is known about glycemic control of diabetes patients who are using mobile diabetes apps in Russia. The CONTOUR ®PLUS ONE (CPO) BGMS

Table 1: Estimated mean Odds Ratio

N of Users: 2422				95% Conf. Intervals		
Event	BGR levels	N of ORs	Mean OR^	LCL	UCL	P-value*
A	≤54mg/dL	47	1.03	0.84	1.24	0.3923
B	≤70mg/dL	169	1.29	1.10	1.52	0.0000
C	≥180mg/dL	953	2.79	1.94	4.12	0.0000
D	≥250mg/dL	337	3.63	2.62	4.92	0.0000

Blood Glucose Reading (BGR); Odds Ratio (OR) is Odds of Event in first 30 days/ Odds of Event in last 30 days; Lower Confidence Level (LCL); Upper Confidence Level (UCL).
^Mean Odds ratio > 1 implies the likelihood of event is greater in the first 30 days compared to last 30 days of CDA system use.
*P-value < 0.05 implies Odds Ratio significant different from 1

with CONTOUR DIABETES App (CDA) (further ''CDA system'') has been used in Russia since 2018. We evaluated HbA1c and estimated frequency of blood glucose readings (BGRs) outside of target range (OTR) in patients, who were using CDA system for 210 days in Russia.

Methods: Anonymized data of CDA system users for 210 days were extracted from CDA database. Analysis of Variance (ANOVA) was performed to compare HbA1c from patients, who had such records for first and last 30 days. Odds Ratios (OR) were used to estimate expected changes in the frequency of OTR BGRs from 2422 patients, who reported ≥5 BGRs during first and last 30 days. OTR BGRs were divided in four Events : A-**very low** (≤54 mg/dL), B- **low** (≤70 mg/dL), C- **high** (≥180 mg/dL) and D - **very high** (≥250 mg/dL).

Results: The mean HbA1c decreased from 7.59% (59.5 mmol/mol) to 6.33% (45.7mmol/mol) ($P < 0.0001$). The more remarkable decline of expected OTR BGRs, expressed as an increased mean OR, was observed for Events D,C and B (Table 1).

Conclusions: This is first real-world study assessing glycemic control of diabetes patients in Russia using CDA system and it has shown the significant improvement of self-reported HbA1c and decreased likelihood of OTR BGRs. These findings are supportive that use of CDA system for at least 6 months can be beneficial to optimize glycemic control in diabetes patients in Russia.

EP169 / #299

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

TELEMEDICINE-BASED TYPE 1 DIABETES (640 G INSULIN PUMP) INTEGRAL ACCOMPANIMENT ("CADENA DE FAVORES") PILOT PROGRAM

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Background and Aims: Aimed at developing an interdisciplinary DM1 program through quarterly individual specialist consultations and psychoeducational group telemedicine-based interventions to enhance empowerment, improving Medtronic 640 insulin pumps users' living standard. Funded by different sponsors through the Mexican Diabetes Association of Mexico City, A.C, (AMD).

Methods: 5 DM1 patients participated in this 1-year program, beginning in April 2021.

Health team: 2 endocrinologists, 2 nutritionists, 1 educator, 2 psychologists, 1 ophthalmologist and a clinical technology specialist. First evaluation (endocrinology and nutrition) was face-to-face. Metabolic and anthropometric variables were obtained; follow-up was telemedicine-based. Before starting, a psychological and general knowledge assessment was done (to be replicated at the end, April 2022).

Results: Program: Psychoeducational group, 12 sessions; medical care, 4; education, 4; nutrition, 3. Technical training in Medtronic 640 pump: 12-hour. The following variables were obtained after the first clinical evaluation: average age 23.4 years (+/-7.8), Hb1ac of 8.3% (+/-1.3%), weight 56.2 kg (+/-10.09 kg), BMI 21.8 Kg / m2 (+/-1.8 Kg / m2) body fat 31.4% (+/-5-4%) and retinopathy screening.

Conclusions: Interdisciplinary T1D program development is possible via telemedicine. Integration of a psychoeducational group facilitates emotional accompaniment, fostering motivation and attachment, reducing distress and increasing self-efficacy while enhancing empowerment. The use of telemedicine as a fundamental tool improves people's living standard.

EP170 / #306

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EVALUATING THE IMPACT OF A COMBINED REAL-TIME CGM/DIGITAL HEALTH SOLUTION ON GLUCOSE CONTROL FOR PEOPLE WITH TYPE 2 DIABETES

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Background and Aims: Optimizing glucose management for people with type 2 diabetes requires them to know their glucose data and understand what to do with it. We hypothesized that combining rtCGM with AI-driven digital health coaching can thus have significant impact on glucose control.

Methods: We reviewed real-world data from individuals with type 2 diabetes who were enrolled in a program that provided both a rtCGM system as well as a digital health coaching platform. Enrollment targeted individuals with type 2 diabetes who were not prescribed insulin. The data were de-identified according to our internal data use policy. We examined time in range (TIR), time below range (TBR), and the glucose management indicator (GMI) at baseline and after 24 weeks of enrollment in the program. We also identified three cohorts by duration of rtCGM use: continuous use for 24 weeks (highest users), use between 13 and 24 weeks (intermediate users), and use less than 13 weeks (lowest users).

Results: Of the 75 participants in the program, 55% were male, and the mean age was 51 years (SD+/- 11). Participants used their rtCGM device for a mean of 17 weeks out the 24 weeks (72%).

Table 1: Overall results

participant group	n	TIR			TBR			GMI		
		baseline	end of study	p value	baseline	end of study	p value	baseline	end of study	p value
all participants	75	49	57	0.02	0.8	0.3	0.197	8.0	7.8	0.174
baseline mean glucose>180mg/dL	39	20	46	0.000003	0.2	0.5	0.175	9.2	8.2	0.0003

Table 2: Analysis by CGM usage time for participants with baseline mean glucose > 180 mg/dL

cohort	n	TIR			TBR			GMI		
		baseline	end of study	p value	baseline	end of study	p value	baseline	end of study	p value
highest CGM use	11	21	58	0.0037	0	0.1	0.09	9.1	7.6	0.0025
intermediate CGM use	16	18	47	0.0009	0	0.1	0.13	9.2	8.2	0.02
lowest CGM use	12	21	34	0.04	0.7	1.5	0.22	9.1	8.7	0.16

Conclusions: The combination of rtCGM and a digital health solution significantly improved glycemic measures. The degree of improvement appeared to be correlated with duration of rtCGM use. The mechanisms for this improvement and the specific patterns of engagement with the digital health solution require further study.

EP171 / #32

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PERSONALIZED GLUCOSE-HBA1C RELATIONSHIP FOR CLINICAL MANAGEMENT OF INDIVIDUALS WITH DIABETES

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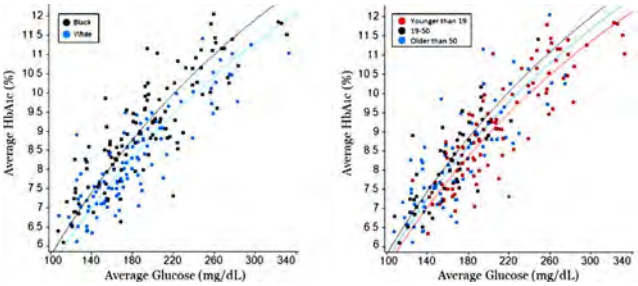
Background and Aims: HbA_{1c} shows disparity between racial groups for reasons that are only partially understood. We characterized the effect of race, as well as age and gender, on the relationship between average glucose and HbA1c.

Methods: Three months of continuous glucose monitoring (CGM) and HbA1c data were obtained from 216 individuals with type 1 diabetes (T1D). Apparent glycation ratio (AGR) was calculated using the recently described kinetic model and employing the formula: $AGR = (AG^{-1}+K_M^{-1})/(HA_{1c}^{-1}-1)$, where AG is CGM-obtained average glucose and K_M is glucose affinity for GLUT1. AGR was subsequently compared across different groups.

Results: Number of black and white individuals was largely similar at 106 and 110, respectively (120 women and 96 men). Mean age (range) was 30 (8-72) with n = 94 younger than 19 years of age, n = 78 between 19-50 years and n = 44 older than 50 years. Overall calculated K_M value was 464 mg/dL with AGR (mean±SD) showing differences in the white and black populations at 69.9 ± 5.8 and 74.2 ± 7.1 ml/g, respectively ($p < 0.001$). AGR was highest in those aged >50 years at 75.4 ± 6.9 ml/g, decreasing to 73.2 ± 7.8 ml/g in 19-50 years, with a further drop to 71.0 ± 5.8 ml/g in the youngest group ($p < 0.05$). In contrast, AGR values were similar in men and women at 71.5 ± 7.5 and 72.5 ± 6.6 ml/g ($p = 0.27$).



Conclusions: Both race and age, but not gender, affect the relationship between average glucose and HbA_{1c}, with large within-group individual variation. Calculation of personal AGR will help to develop individualized HbA_{1c} targets and optimize glycemic management.

EP172 / #329

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A MOBILE-APP ASSISTED CARBOHYDRATE COUNTING STRATEGY IMPROVES GLUCOSE CONTROL IN TYPE 1 DIABETES

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Background and Aims: Background: carbohydrate counting is often performed inaccurately by patients with type 1 diabetes (T1D). We hypothesized that mobile App ''Dietrometro'', that estimates CHO content of food figures, would ameliorate glucose control. **Aim**: to study the effect of ''Dietometro'' on glucose control.

Methods: Methods: 54 T1D subjects (aged 18-60 years, 26 males), on multiple daily injections (n = 23) or continuous subcutaneous insulin infusion (n = 31), were randomly assigned to three groups: no counting (group 1; n = 19), ''self-managed'' counting (group 2; n = 19) and App-assisted counting (group 3; n = 16). Outcomes were one- and three months follow-up TIR (time in range), TAR (time above the range) and TBR (time below the range), estimated by flash or continuous glucose monitoring, and HbA1c

Results: Results: at the baseline TIR were similar between groups, while HbA1c was lower in group 3 compared to group 1 (6.9 ± 1.06 vs. 7.8 ± 0.85%; $p < 0.05$). At one-month follow-up, TIR was higher in group 2 and 3 compared to group 1 (63.58 ± 11.55 vs. 52.32 ± 13.22%; $p = 0.014$, and 71.25 ± 9.75 vs. 52.32 ± 13. 22%, respectively; $p < 0.001$). TAR at one-month follow-up was significantly lower in group 3 (31.25 ± 19.18 vs. 22.31 ± 10.89%; $p < 0.001$), while no differences were observed in TBR . At three-months follow-up, groups 2 and 3 had a lower HbA1c than group 1 (7.16 ± 0.647 vs. 6.56 ± 1.91 vs. 7.96 ± 1.0%; $p < 0.05$).

Conclusions: Conclusions: app-assisted CHO counting might improve glucose control. Larger sample size and longer follow-up are needed to define the long-term effect of this system.

EP173 / #346

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IN-BROWSER SIMULATION OF CLOSED-LOOP CONTROL FOR TYPE 1 DIABETES

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Background and Aims: Among patients and medical staff, there is still a widespread discomfort with closed-loop systems, often caused by lack of understanding of how they work. Tools that allow to try out such devices in numerical simulations might help alleviate fears, and have long been standard in development, but their use is largely reserved for experts. This contribution presents an open source tool to perform closed-loop simulations in any modern web browser.

Methods: The new simulator is programmed in JavaScript and has a modular structure consisting of numerical solver, physiological model, AID algorithm, and frontend; meals and their announcement can be configured as desired. The individual components can be easily exchanged via defined interfaces, which makes the simulator versatile. The current version includes the OpenAPS algorithm oref0 and the UVA/Padova model.

Results: The simulator has been tested on numerous end devices. Simulating a period of ten hours takes about 0.5 to 3 seconds, depending on the device. In addition to the numerical results, the simulator also outputs the log entries of the AID algorithm, thus providing insight into its operation. A free online version is available at https://lt1.org.

Conclusions: With the ability to change settings easily, the simulator invites users to playfully explore closed-loop systems and become familiar with their operation and configuration. Experts have the opportunity to view different virtual patients and analyze the effects on the controller's behavior. The simulator can also be an asset for training courses. Developers can use it to safely test and verify new versions of their algorithms.

EP174 / #347

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IDENTIFYING INSULIN PRESCRIBING AND NEEDLE STICK ERRORS TO IMPROVE IN-HOSPITAL MANAGEMENT OF DIABETES

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Background and Aims: A recent Australian audit has shown that 39% of hospital inpatients receiving insulin have errors relating to insulin use, which commonly occur at point of prescribing and administration, and lead to harm. Common causes of error include poorly legible prescriptions, and confusion between insulin brand names and doses. In addition, insulin needles are leading cause of needle stick injuries in hospitals. The aim of this study was to survey healthcare professionals about their perceptions of the most harmful insulin errors and needle stick injuries to inform work on improving insulin safety and reducing needle stick injuries in the hospital setting.

Methods: A 12-question rating scale survey was distributed to Australian Diabetes Society (ADS) and National Association of Diabetes Centres (NADC) membership, at the beginning of September 2021 for 8 weeks.

Results: Of 96 respondents, 24% were endocrinologists and 62% diabetes educators who predominantly worked in tertiary services (52%) or private practice (31%). The following were considered to potentially cause the most harm (weighted average): unclear instructions about when supplemental scales should be administered; basal insulin inappropriately omitted/withheld; insulin injection into area of lipodystrophy; the band name Humalog being confused with Humalog Mix; regular subcutaneous insulin omitted or not correctly charted; inadequate fluids given with diabetic ketoacidosis or hyperglycaemic hyperosmolar state protocols; and recapping of insulin delivery needle. More education surrounding administration of insulin was considered to be most helpful intervention.

Conclusions: The results of this survey will be used to improve the safety and clinical outcomes of inpatients with diabetes requiring insulin treatment.

EP175 / #41

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

TELEMEDICINE FOLLOW-UP OF ADOLESCENTS WITH TYPE 1 DIABETES MELLITUS WITH ONE TOUCH REVEAL® MOBILE APP

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Background and Aims: Adolescence is the most challenging age for achieving optimal metabolic control of T1DM. The use of telemedicine may be associated with better glycemic control, but there are limited data in adolescents. The aims of the study were to assess the effectiveness and safety of a virtual visits combined with mobile app for adolescents with T1DM.

Methods: Study included adolescents aged ≥14 and 18 years with a T1DM duration >3 months. The duration of the study was 26 weeks. There were 3 face-to-face and at least 4 two-way telemedicine visits with glucose data shared by patients via the OneTouch Reveal® mobile app. All patients underwent standard examination, measure of HbA1c, assessments of progress and modification of treatment. At the end of the study participants and physicians completed self-report questionnaires regarding the convenience of telemedicine consultation supported by mob.app.

Results: 56 patients were included and 49 completed all study procedures. HbA1c significantly decreased by the 3rd and 6th months of the study:–0.3%; $p = 0.005$ and –0.5%; $p < 0.001$, respectively. There was a significant improvement in both the total assessment of the QoL by patients (+2.9 points; $p = 0.008$) and individual components of QoL. The majority (>90%) of physicians and patients assessed their participation in the study positively, highlighting convenience of the telemedicine and mob app.

Conclusions: Telemedicine follow-up using the OneTouch Reveal® mobile app is a safe and effective approach for adolescents with T1DM in terms of glycemic control and quality of life and facilitates simple and convenient telemedicine consultations.

EP176 / #417

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

MOBILE PHONE APPLICATION FOR FACILITATING GLYCEMIC CONTROL AND SELF-MANAGEMENT OF TYPE 2 DIABETES MELLITUS IN A LOW-INCOME COMMUNITY IN RIO DE JANEIRO: THE SIM PROJECT

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Background and Aims: Chronic non-communicable diseases (NCDs) are the main cause of hospitalizations, disability, and death in Brazil. The increased prevalence of type 2 diabetes mellitus (T2DM) combined with the complexity of their treatment, reinforces the need for effective and feasible educational programs for public health services. We evaluate the clinical impact of an educational program via mobile phone on metabolic control of individuals with T2DM.

Methods: This study was an open-label, parallel-group trial, involving patients diagnosed with T2DM regularly seen at the Family Health Clinic, in Rio de Janeiro/Brazil. Ethical approval for this study was granted by the Secretaria Municipal de Saúde do Rio de Janeiro Ethics Committee. Patients with diabetes were randomly allocated into 2 groups: intervention group (received a backpack containing health care devices and a mobile phone for remote monitoring provided with educational material for diabetes) or control group (standard of care). All outcome measures were collected at baseline and after a 3-month period. Changes in HbA1c were compared between groups using the modified Wald test.

Results: a total of 360 patients completed the study (174intervention, 183 control group). The study included 65% of women, who were a mean (SD) age of 64,28 (11,38). There was a significant decrease in weight ($p < 0.05$), waist circumference ($p < 0.01$), Body Mass Index ($p < 0.01$), and glycated hemoglobin ($p < 0.01$) when comparing before and after the intervention.

Conclusions: Mobile phone apps are an effective component to help glycemic control and could be considered an affordable and widely available adjuvant intervention to the standard self-management for patients with T2DM.

EP177 / #425

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

WHICH DIABETES APP FEATURES IMPROVE GLYCEMIC CONTROL IN TYPE 2 DIABETES? A SCOPING REVIEW

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Background and Aims: Diabetes applications (DM apps) have the potential to support glycemic control in type 2 diabetes (T2D). However, there is a lack of evidence regarding the effect of the individual features of the apps in regards to glycemic control. Thus, the aim of the present review was to explore the effect of specific features in apps for people with T2D on glycemic control.

Methods: A systematic search of literature was performed in PubMed, EMBASE, and CINAHL. After removal of duplicates, titles and abstracts were screened with respect to the inclusion and exclusion criteria (Table 1). The remaining articles underwent full text assessment. The article selection process was reported in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Figure 1). The included articles were critically assessed by ''The Critical Appraisals Skills Program'' (CASP) checklists.

Results: Seven articles were included in the review (Table 2). The synthesis identified five features that were assessed in regards to glycemic control. Three features showed significant effect on glycemic control: 1) ''monitoring and feedback-system'', 2) ''gamification'', and 3) ''diabetes education''.

Conclusions: DM apps may support glycemic control in T2D. It seems that DM apps should contain an educational feature, gamification, and a feature for sharing data with healthcare professionals to improve glycemic control. However, more evidence is needed to determine the effect of individual features in DM apps.

Inclusion criteria	Exclusion criteria
• Language: English, Danish, Swedish, Norwegian • Primary literature **About:** • T2D • Features in DM-apps • Outcome: blood sugar	• If the results were not divided into T1D, T2D and GDM • If the features in DM-apps were not divided into the results

Table 1: Criteria for selection of articles

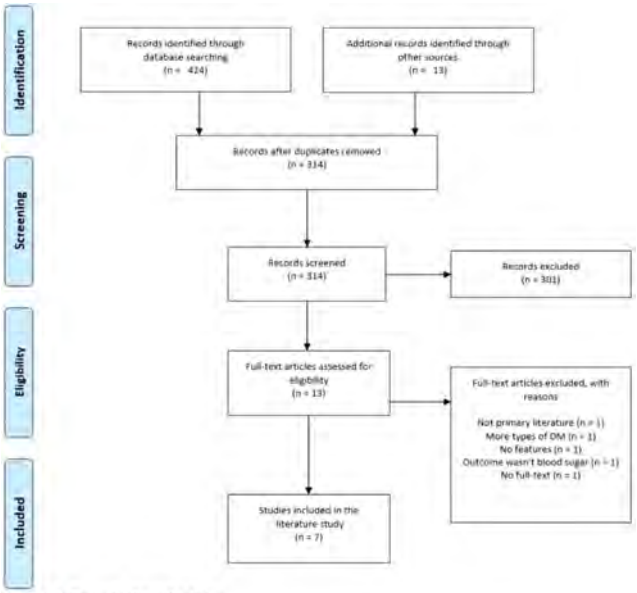

Figure 1: The selection of articles.

Author (year)	Participants (I=Intervention/C=Control)	Follow-up	Study design	Effect on HbA1c	Feature
Bee et al. (2016)	I: 33; 29 C: 33; 30	6 months	Pilot-RCT	None	Insulin titration algorithm with immediate feedback mechanism
Bramwell et al. (2019)	I: 42 C: 50	3 months	Pilot	None	Feedback from Health professionals
Höchsmann et al. (2019)	I: 18; 18 C: 18; 17	24 weeks	RCT	None	Gamification
Kerfoot et al. (2017)	I: 227; 227 C: 229; 225	6 months 12 months	RCT	Positive	Gamification
Munster-Segev et al. (2017)	I: 9; 7	8 and 16 weeks	One-group pre- and posttest	None	Biofeedback-assisted relaxation
Yang et al. (2020)	I: 150; 145 C: 97; 94	3 months	RCT	Positive	Glucose-monitoring and feedback system
Zhang et al. (2020)	I: 3.011	12 weeks	Cohort	Positive	Diabetes education

Table 2: Key features from the seven included articles.

EP178 / #442

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

INITIATING CGM OVER TELEHEALTH IS WELL ACCEPTED BY PARENTS OF NEWLY DIAGNOSED YOUTH WITH T1D

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Background and Aims: Initiating continuous glucose monitoring (CGM) shortly after T1D diagnosis has potential glycemic and quality of life benefits for youth with T1D and their families. The COVID-19 pandemic necessitated a rapid shift to virtual delivery of CGM initiation visits. We aimed to understand parents' experiences with receiving virtual care to guide starting CGM within 30 days of diagnosis.

Methods: We held focus groups and interviews with parents of T1D youth who initiated CGM over telehealth within a month of diagnosis during the COVID-19 pandemic. We used a semi-structured interview guide to understand experiences of starting CGM virtually. Groups and interviews were audio-recorded, transcribed, and analyzed using thematic analysis.

Results: Participants were 16 parents (age 43 ± 6 years; 63% female) of youth (age 9 ± 4 years; 47% female; 47% non-Hispanic White, 20% Hispanic, 13% Asian, 7% Black, 13% other; diabetes duration 9 ± 3 months) who started CGM through a virtual visit within 30 days of diagnosis. Parents described multiple benefits of the virtual visit: convenience and ease of scheduling; user friendliness; and being in the comfort of home, especially for young children. Most preferred the virtual format to in-person; three parents would have preferred in-person to develop their confidence in starting CGM. Participants felt that clinics should offer families a choice of virtual and in-person for CGM initiation in the future.

Conclusions: Despite initial reservations, most parents appreciated receiving telehealth CGM initiation education and felt it should be an option offered to all families. Further efforts can continue to enhance CGM initiation teaching virtually to address identified barriers.

EP179 / #454

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

RELATIVE VALIDATION OF AN ARTIFICIAL INTELLIGENCE-ENHANCED, IMAGE-ASSISTED MOBILE APPLICATION FOR DIETARY ASSESSMENT IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: People living with type 1 diabetes (T1D) require continuous nutrition counselling. As such, thorough dietary assessment is essential to obtain accurate food and nutrient intakes but is challenging due to limitations of current methods. This study evaluated the relative validity of AI-enhanced image-assisted Keenoa™ food tracker against the validated Automated Self-Administered 24-hour recall (ASA24) platform in healthy individuals and those with T1D.

Methods: Using a randomized cross-over design, participants completed 4 days of Keenoa food tracking and 4 days of ASA24 food recalls in random order. The System Usability Scale (SUS) assessed perceived ease of use. Reported intake differences were analyzed by paired t-tests and correlations by Pearson's coefficient.

Results: Twenty-seven participants with T1D were matched with 27 healthy participants based on gender, age and education level (age 45.9 ± 12.5 years). BMI was not different between groups. Mean energy and macronutrient intakes did not differ between ASA24 and Keenoa in participants with T1D whereas lower carbohydrate intake was reported with ASA24 by healthy participants. Pearson's correlations were significant ($p < 0.05$) for all macronutrients in the healthy group ($r = 0.57$ to 0.77) and for energy and carbohydrates in the T1D group ($r = 0.39$ to 0.69). Mean SUS scores were significantly higher for Keenoa in both groups. Sixty-five percent of healthy, and 74% of participants with T1D preferred Keenoa over ASA24.

Conclusions: The Keenoa application showed strong relative validity for energy and most macronutrients in patients with T1D and is preferred by users. This image-assisted mobile application is an alternative to simplify dietary tracking.

EP180 / #465

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EFFECTIVENESS OF THE USE OF APPLICATIONS ON MOBILE DEVICES (MHEALTH) IN THE MANAGEMENT OF T2D IN PATIENTS DISCHARGED FROM HOSPITALIZATION. RANDOMIZED CONTROLLED CLINICAL STUDY

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Background and Aims: Currently there are no studies that evaluate the effectiveness of the use of applications on mobile devices (mHealth) in T2D when patients move from the hospital environment to the outpatient setting.

Methods: Open-label, randomized controlled clinical experiment. Patients with T2D older than 18 years were included. The effectiveness and safety of mHealth (ClouDi®) were compared

at the 3-month follow-up. The primary outcome was the change in HbA1c by calculating the mean difference. The secondary outcome was hypoglycemic rates using the incidence rate ratio. In addition, satisfaction with the use of insulin and quality of life were evaluated using the ITSQ scale.

Results: 86 patients were included (55% men in mHealth and 54% in usual management). There was a significant reduction in HbA1c in the two groups (mean difference in the usual management of 3.38 CI 2.45, 4.32 $p < 0.001$, vs mHealth of 5.42 CI 4.40, 6.43 $p < 0.001$). The mean HbA1c difference was significant in favor of mHealth (-2.03 CI -3.39, -0.68 $p = 0.004$). A lower incidence rate ratio of hypoglycemia <54 mg / dL (TI 0.45, IRR 0.53; $P < 0.001$), between 54-70 mg (TI 1. IRR 0.72; $P < 0.001$) and hypoglycemia requiring help from a third party (TI 0.06, IRR 0.39; $P = 0.02$). The level of ITSQ satisfaction was better in the mHealth group (Difference of means -30.5% CI -36.7, -24.5; $p < 0.001$).

Conclusions: The use of mHealth in patients with T2D who move from the hospital to the outpatient setting improves metabolic control and could reduce the rates of hypoglycemia.

EP181 / #509

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EXPANDING THE REPLAYBG SIMULATION METHODOLOGY DOMAIN OF VALIDITY TO SINGLE-DAY MULTIPLE-MEAL SCENARIOS

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Background and Aims: We recently developed ReplayBG: a new simulation methodology for the assessment of type 1 diabetes (T1D) treatment strategies. ReplayBG leverages already collected data to identify a personalized model of T1D physiology and simulate the glucose-time course that ''would have been obtained'' by adopting the insulin/carbohydrate therapy under assessment. Previously, we demonstrated that ReplayBG can effectively reproduce the effect of several T1D treatments on glucose concentration in single meal scenarios (Cappon et al., IEEE TBME, 2021, submitted). In this work, we adapted the physiological model of ReplayBG to expand its domain of validity to single-day, multiple-meal simulations.

Methods: The original physiological model of ReplayBG has been expanded to accommodate the intraday glucose dynamics observable within data. Specifically, we incorporated a model of intraday insulin sensitivity, and we differentiate each meal description to account for the different absorption dynamics. The expanded ReplayBG tool was tested on single-day portions of data collected from 12 T1D patients, to test a recently proposed hypotreatment suggestion algorithm for the prevention of hypoglycemia (Camerlingo et al., DTT, 2018) and compare it against the standard 15-15 rule.

Results: show that ReplayBG can reliably reproduce the glucose dynamics seen within data. The considered use-case suggests that the algorithm of Camerlingo et al. outperforms the 15-15 rule.

Conclusions: This study showed that ReplayBG can be used to evaluate new insulin/carbohydrate therapy regimes also in single-day, multiple-meal scenarios. Future work will evaluate and further extend the domain of validity of ReplayBG on a set of benchmark scenarios.

EP182 / #524

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

IMPROVEMENT IN DIETARY BEHAVIOUR AND GLYCEMIC CONTROL FOR PEOPLE WITH TYPE 2 DIABETES ON DIABEFLY® DIGITAL THERAPEUTICS PLATFORM

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Background and Aims: The need for culturally-appropriate and individualized meal-planning becomes a challenge for effective nutritional management in people with diabetes. Digital therapeutics platforms aimed at delivering personalized care can help in achieving better glycemic control.

Methods: De-identified data of 69 participants (mean age: 44.89 ± 11.70 years, 44.29 % females) with type-2 diabetes was analyzed. Diabefly® platform (Fitterfly Healthtech Pvt Ltd, India) enabled mobile-application based digital logging of meals and physical activity while providing access to remote health coaching along with expert driven care (nutritionists, physiotherapists and psychologists). The participants were provided mobile-application based access to a food database containing information about calories, micro and macronutrients for each meal item logged. The program was supported by a coach dashboard which helped in the analysis of post-meal glycemic response thus helping with creation of personalized lifestyle plans for each participant based on the assessment in the first week of the program. The variation in dietary behavior and glycemic control was analyzed at the beginning (first week) and completion (90 days) of the program.

Results: After 90 days on the program, the mean daily calorie intake significantly reduced by 16.28 % ($P < 0.0001$). The daily carbohydrate and fat intake were reduced by 18.49 % ($P < 0.0001$) and 16.05 % ($P < 0.0001$) respectively. Significant mean reduction in HbA1c, weight and BMI was observed by 1.86 % ($P < 0.0001$), 3.17 kg ($P < 0.0001$), and 1.11 kg/m^2 ($P < 0.0001$).

Conclusions: After 90 days on the program, significant changes in dietary behavior were observed. The changes in dietary behavior were associated with improved glycemic control in people with diabetes.

EP183 / #53

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

REAL WORLD EVIDENCE OF IMPROVED GLYCEMIC CONTROL IN PEOPLE USING THE ONETOUCH VERIO REFLECT® GLUCOSE METER WITH THE ONETOUCH REVEAL® MOBILE APPLICATION

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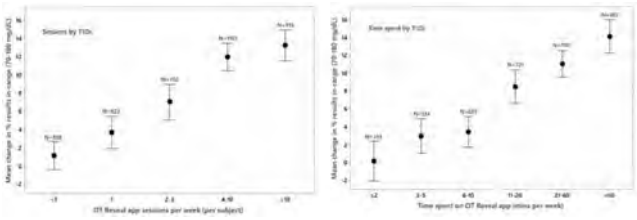
Background and Aims: The OneTouch Verio Reflect® (OTVR) meter provides advanced Color Range and Blood Sugar Mentor™ features that are complemented by the OneTouch Reveal® (OTR) app. We sought to provide evidence that these products support improved glycemic control.

Methods: Anonymous glucose and app analytics were extracted from the LifeScan server for 4154 people with type 1 diabetes (T1D) and 13623 people with type 2 diabetes (T2D). Data from their first 14 days was compared to 14 days prior to a 90 day timepoint using paired within-subject differences.

Results: Percentage glucose results in-range (70-180mg/dl) improved by 8.1% (from 58 to 66.1%) in T1Ds and by 11.2% (from 72.4 to 83.6%) in T2Ds. Hyperglycemic results (>180mg/dl) reduced by -8.5% (from 37.1 to 28.6%) in T1Ds and by -11.3% (from 26.4 to 15.1%) in T2Ds. Mean glucose reduced on average by -14.5mg/dl (from 174.8 to 160.2mg/dl) in T1Ds and by -18.2mg/dl (from 157.8 to 139.6) in T2Ds. 2 to 3 sessions per week or 11 to 20 minutes per week on the OTR app improved results in-range in T1Ds by 7% or 8%, respectively (see graphs below). Similar trends were observed in people with T2D.

Conclusions: Real world data from over 17000 people with diabetes demonstrates significantly improved data in-range and lower mean glucose in those using the OneTouch Verio Reflect® meter and OneTouch Reveal® app.



EP184 / #548

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

MULTI-MODAL MOBILE PLATFORM FOR THE INVESIGATION OF CLINICAL DISORDERS WITH GLYCAEMIC DISARRAYS

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Background and Aims: Recently, we developed IMPACT, a multi-modal platform linking real-time data from continuous glucose monitors (CGM), diary records and wearables to explore and manage diabetes (Cappon et al., JDST, 2021). In this work, we leverage a modified IMPACT to investigate the clinical manifestations and glucose dynamics of an increasingly recognized condition known as post-bariatric surgery hypoglycaemia.

Methods: We followed a state-of-the-art nested design model consisting of four cascading steps (Weijers et al., JMIR, 2021) to ensure effective performance and usability. Each step included both an upstream and downstream validation process by successfully engaging both clinicians and engineers through the process. In particular, the IMPACT mobile app has been expanded for symptom and drug logging as well as an in-app notification system to ensure CGM sensor calibration has been implemented. The adapted web interface received an ad-hoc dashboard and patient monitoring features.

Results: Before the final deployment, a single user testing session has been performed for three weeks showing that the IMPACT adaptations meet all requirements both in data gathering and analysis. The user reported good usability and the clinicians were able to monitor his data in real time, while being able to tune the session settings on the go.

Conclusions: IMPACT has been successfully adapted to explore the increasingly recognized and potentially deleterious condition of post-bariatric surgery hypoglycaemia. The platform leverages the best knowledge from clinical, pathophysiological and technical fields and is ready to be deployed and used in clinical trials and practice.

EP185 / #575

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

UTILIZING PRIMARY CARE PROVIDERS TO ADVANCE DIABETES TECHNOLOGY EQUITY: FINDINGS FROM PROJECT ECHO T1D

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Background and Aims: In the US, many individuals with type 1 diabetes (T1D) do not have consistent access to endocrinologists and therefore rely on primary care providers (PCPs) for their diabetes management. Project ECHO T1D was developed to empower PCPs to independently manage T1D, including diabetes technology initiation and use, to bridge disparities in T1D access.

Methods: PCPs (n = 70) who participated in the pilot ECHO T1D project and completed pre- and post-intervention surveys were included in this analysis. The survey was administered in California and Florida to participating PCPs via REDCap and paper surveys. This survey aimed to evaluate practice demographics, protocols with adult and pediatric T1D management, challenges, resources, and provider knowledge and confidence in diabetes management. Differences and statistical significance in pre- and post-intervention responses were evaluated by Wilcoxon Signed Rank Test.

Table: Primary care provider confidence in diabetes technology management

	Not at all Confident n (%)	Somewhat Confident n (%)	Moderately Confident n (%)	Extremely Confident n (%)	Average Change	p value
Determine which patients with Type 1 Diabetes would benefit from a continuous glucose monitor device (CGM)						
Pre-Intervention	27 (40.3)	16 (23.9)	15 (22.4)	9 (13.4)	+0.7	<0.0001
Post-Intervention	4 (6.0)	23 (34.3)	24 (35.8)	16 (23.9)		
Help make continuous glucose monitor (CGM) device made affordable for my patients with Type 1 Diabetes or to be covered by my patient's health insurance coverage						
Pre-Intervention	41 (60.3)	15 (22.1)	4 (5.9)	8 (11.8)	+0.4	0.0032
Post-Intervention	14 (20.6)	38 (55.9)	12 (17.7)	4 (5.9)		
Prescribe continuous glucose monitor (CGM)						
Pre-Intervention	38 (59.4)	11 (17.2)	4 (6.3)	11 (17.2)	+0.5	<0.0001
Post-Intervention	14 (21.9)	24 (37.5)	17 (26.6)	9 (14.1)		
Utilize and interpret continuous glucose monitoring (CGM) data in patients with Type 1 Diabetes						
Pre-Intervention	36 (53.7)	16 (23.9)	7 (10.5)	8 (11.9)	+0.6	<0.0001
Post-Intervention	13 (19.4)	25 (37.3)	20 (29.9)	9 (13.4)		
Determine which patients with Type 1 Diabetes would benefit from insulin pump therapy						
Pre-Intervention	24 (37.5)	21 (32.8)	13 (20.3)	6 (9.4)	+0.6	<0.0001
Post-Intervention	6 (9.4)	26 (40.6)	19 (29.7)	13 (20.3)		
Manage patients with Type 1 Diabetes on insulin pump therapy						
Pre-Intervention	39 (60.0)	10 (15.4)	9 (13.9)	7 (10.8)	+0.4	0.0007
Post-Intervention	18 (27.7)	28 (43.1)	11 (16.9)	8 (12.3)		
Manage patients with Type 1 Diabetes on insulin pump hybrid-closed loop therapy (i.e. Medtronic 670G System)						
Pre-Intervention	44 (71.0)	10 (16.1)	6 (9.7)	2 (3.2)	+0.4	0.0007
Post-Intervention	28 (45.2)	22 (35.5)	7 (11.3)	5 (8.1)		
Review digital diabetes data of patients						
Pre-Intervention	24 (35.3)	24 (35.3)	11 (16.2)	9 (13.2)	+0.3	0.0254
Post-Intervention	10 (14.7)	35 (51.5)	13 (19.1)	10 (14.7)		
Help make diabetes supplies more affordable and accessible to my patients with Type 1 Diabetes						
Pre-Intervention	33 (49.3)	22 (32.8)	7 (10.5)	5 (7.5)	+0.7	<0.0001
Post-Intervention	8 (11.9)	30 (44.8)	21 (31.3)	8 (11.9)		

Results: PCPs reported improvement in all domains of T1D education and management. From baseline, PCPs reported improvement in their confidence to serve as the T1D provider for their community (+0.4, $p < 0.0001$), manage insulin therapy (+0.5, $p < 0.0001$), troubleshoot psychosocial barriers (+0.5, $p = 0.0001$), and identify symptoms of diabetes distress (+0.7, $p < 0.0001$) post-intervention. In particular, providers reported significant improvement in their confidence in all aspects of diabetes technology utilization (Table).

Conclusions: PCPs who participated in ECHO T1D reported increased confidence in diabetes management, with notable improvement in their ability to prescribe, manage, and troubleshoot diabetes technology. These data support continued and advanced education with PCPs to increase confidence in diabetes technology management as a feasible strategy to advance equity in diabetes technology access.

EP186 / #587

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

GLUCOSE CONTROL AFTER THE LAST MEDICAL APPOINTMENT IN WOMEN WITH GESTATIONAL DIABETES TREATED WITH TELEMEDICINE

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Background and Aims: Stringent glucose control throughout the pregnancy is of utmost importance. However, little is known about glucose self-management after the last contact with the diabetes care team. Therefore, we aimed to evaluate whether telemedicine helps to increase the compliance with self-monitoring of blood glucose after the last medical check-up in women with gestational diabetes (GDM).

Methods: Glucose measurements performed after the last medical appointment until the delivery were retrospectively collected from the glucose meters and compared to the one month period before the last medical appointment. To analyse differences in the telemedicine group and standard care group Wilcoxon matched-pair signed test and Mann-Whitney U test were used for repeated and independent measures, respectively.

Results: The number of glucose measurements in the telemedicine group ($n = 20$) fell from 85.7 % [78.1–97.6] to 66.6 % [41.5–94.8] ($p = 0.006$) and in the standard care group ($n = 25$) from 91.1% [75.5–97.4] to 78.5% [63.5–92.4] ($p = 0.017$). The proportion of glucose concentration above the target in the telemedicine group rose from 7.9% [5.6–18.1] to 9.8% [5.6–23.3] ($p > 0.05$), however, it fell from 9.5% [6.6–20.5] to 6.7% [4.2–15.4] ($p = 0.021$) in the standard care group. No statistically significant difference was found between the telemedicine and the standard care group.

Conclusions: Glucose self-control worsens after the last medical examination regardless of the mode of follow-up. We found even a greater deterioration in women treated with telemedicine. Research on a larger sample is needed.

EP187 / #59

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

OPTIMISING ASYNCHRONOUS TELE-COACHING TO REDUCE GESTATIONAL DIABETES ONSET

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Background and Aims: Gestational diabetes (GDM), defined as high blood sugar levels during pregnancy, is an increasing health problem affecting up to 18% of pregnancies worldwide that multiplies by 7 the risk of developing type 2 diabetes (T2DM) after birth. Strong evidence exists that lifestyle change (diet and physical activity) can reduce the development of T2DM in those at risk. A new mother faces many challenges and weight loss after pregnancy is typically not the highest priority, leading to high numbers of obesity, heart disease and diabetes. Moreover, early fetal programming increases the risk of developing T2DM for the offspring. Current health systems worldwide lack resources to manage the numbers of women at risk and support them in improving lifestyle behaviours. Tele-coaching can help relieve this burden. Language shaping, especially in asynchronous communication, plays an important role in patient outcomes. There is a big potential for using text messages in these interventions, but research on the topic has been scarce

Methods: Text messages analysis and a subsequent language interaction analysis within a randomized trial on tele-coaching for prevention of GDM and postnatal weight loss in 400 women at risk in Australia, Ireland, the UK and Spain (Bump2Baby&Me)

Results: This PhD project will contribute to asynchronous communication research on interventions aiming to prevent lifestyle-related diseases such as T2DM and GDM. It will also

allow to create an asynchronous coaching manual that will be made available in English, Danish and Spanish

Conclusions: A better understanding of text-messages based lifestyle intervention will contribute to better patient outcomes.as well as reduced costs and increased reachability

EP188 / #603

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

EVALUATING THE FEASIBILITY AND BENEFIT OF TRUSTSPHERE: A NOVEL DIGITAL HEALTH SOLUTION FOR CHILDREN LIVING WITH TYPE 1 DIABETES

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Background and Aims: We developed TrustSphere, a digital solution that enables patient-centered, data-driven, collaborative pediatric diabetes care in children living with Type 1 Diabetes (T1D). We describe an iterative approach to test the TrustSphere minimal viable product's (MVP) feasibility of implementation in clinical practice and its benefit to users.

Methods: We engaged parents of children aged <18y, youth aged 16-17y, parents/caregivers of children living with T1D, and pediatric diabetes clinicians. Using participatory design methodology, a stakeholder inclusive approach that supports co-creation of digital solutions, we have conducted surveys, bulletin boards, focus groups, and usability testing sessions to produce the TrustSphere MVP. The MVP will be tested in a clinical pilot at a tertiary pediatric diabetes clinic at BC Children's Hospital in January 2022.

Results: 50 participants living with T1D and their clinicians will be recruited over the 9-month study period. Three cycles of data collection separated by iterative development blocks that integrate users' feedback will occur (cycle 1: MVP (N = 10); cycle 2: MVP*v2.0* (N = 15); cycle 3: MVP*v3.0* (N = 25)). The following data will be collected: perceptions of trust and security, user experience and usefulness, feasibility of clinical implementation, impact on patient reported outcomes (quality of life, satisfaction with care, diabetes self-management practices), and willingness to share their data to research.

Conclusions: The uptake of digital solutions in healthcare has lagged partly because patients and clinicians are not meaningfully engaged in design, development, and implementation. Our study uses principles of co-creation, participatory design and stakeholder engagement to optimize TrustSphere's adoption in clinical care.

EP189 / #620

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

TELEMEDICINE IN WOMEN WITH GESTATIONAL DIABETES DURING THE COVID-19 EPIDEMIC

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Background and Aims: Telemedicine allowed continued care during the COVID-19 epidemic. However, less is known about the role of telemedicine in women with gestational diabetes (GDM). Therefore, we aimed to evaluate whether telemedicine, compared to standard care, provides equivalent clinical outcomes.

Methods: Telemedicine group was treated from home by using videoconference and glucose measurements sent daily to the telemedicine centre. The first and the last medical appointments were performed at the outpatient clinic, with medical consultation and laboratory examination. Primary outcomes were HbA1c at the first and the last medical check-up and gestational weight gain, while secondary outcome was infant's birth weight, adjusted for sex and gestational age when compared to the standard care group.

Results: The telemedicine (n = 39) and the standard care group (n = 39) were equalized by age (31.6 ± 4.1 vs. 33.0 ± 5.3) and prepregnancy body mass index (26.4 ± 5.3 vs. 26.0 ± 4.7). No significant difference was found between groups in gestational weight gain (10.2 ± 4.2 vs. 11.4 ± 5.4). Both groups did not differ significantly in HbA1c at baseline (4.9 ± 0.3 vs. 4.9 ± 0.2), neither was the difference significant at the last visit (5.2 ± 0.3 vs. 5.1 ± 0.3). Furthermore, no difference was found between groups in the birth weight expressed in percentiles (48.0 ± 25.7 vs. 52.6 ± 26.7).

Conclusions: Telemedicine has been shown to be a safe alternative to standard care in women with GDM, giving comparable glycemic outcomes. However, comprehensive studies on a larger sample, with a broader set of perinatal outcomes are needed.

EP190 / #634

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

TELEMEDICIN DURING COVID-19 PANDEMIC, EXPERIENCE FROM A PORTUGUESE CENTER

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Background and Aims: During the COVID 19 pandemic and due to lockdown periods there was a need to adapt diabetes consultations and organize health professionals in order to provide the best response to people with diabetes.

Methods: In order to assess the patient's satisfaction with teleconsultations an on-line user satisfaction questionnaire was sent to all patients of the pediatric and Insulin pump Departments of APDP, who had consultation from March 16th to June 1st 2020.

Results: The questionnaire was sent to 971 persons. The average age was 36.4 ± 19.1 years, mostly female (53.1%), with higher education degree (46.9%). The results for medical consultations showed that 69.1% of the participants totally agree that the doctor was able to correctly interpret the current needs in diabetes management, and 49.5% totally agree and 35.6% agrees

that the therapeutic adjustment was as efficient as if it had been performed in a face-to-face consultation. Regarding nursing consultations 56,7% completely agree or agree that it was possible to maintain adequate monitoring of diabetes. In relationship with nutrition 58,5% completely agree or agree that it was possible to clarify aspects related to food, carbohydrate counting or exercise efficiently.

Conclusions: The results reveal that the majority of the patients felt supported in managing their diabetes and agree that teleconsultation with the multidisciplinary team was an adequate substitute for face-to-face consultation, it was possible to raise and clarify doubts about the management of diabetes and COVID-19 and that this model could complement face-to-face consultations

EP191 / #648

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A 12-MONTH RANDOMIZED CONTROLLED STUDY EVALUATING TELEMEDICINE AS A PARTIAL REPLACEMENT FOR STANDARDIZED CARE

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Background and Aims: With increased use of technology in healthcare and at home, the opportunities to implement digital health as a complement to other care increase. The aim was to evaluate outcomes when standardized return visits were partly replaced by video visits with simultaneous joint analysis of downloaded data.

Methods: In a 12-month randomized controlled study standardized care with visits, every 3rd month was compared with a model where every second of these visits was replaced by three short video visits including analysis of downloaded data. Glucose control, Health, Quality of life, Diabetes treatment satisfaction, Self-efficacy, and Health economic outcomes were analyzed with comparisons at 0, 6, and 12 months. 75 T1D individuals aged 2-17 years volunteered to the study.

Results: The two groups: telemedicine (38) and control (37) were similar in terms of age, duration, gender, glucose monitoring device, insulin treatment model, and HbA1c at the start. The primary outcome, health economy, showed QALY-Telemedicine 1.54 and QALY-Control 1.35 with a 5-year prediction. Telemedicine was cost-effective with ICER 15600 SEK per gained QALY (low cost: <100.000 SEK). Telemedicine was non-inferior in terms of HbA1c and continuously registered sensor values as TIR, TAR, and TBR. Furthermore, Telemedicine was related to significantly higher independence (Disabkids, QoL), higher diabetes treatment satisfaction (DTSQ), and self-efficacy (SED).

Conclusions: Telemedicine is cost-effective as a complement to standardized visits among pediatric patients with T1D. Moreover, glucose control is at least as good after 12 months besides other important patient-related beneficial effects. Today, the model is implemented as an option for all individuals at the clinics.

EP192 / #652

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

DIABETES DEVICE DATA IN VIRTUAL CLINIC VISITS: A NEW HEALTH DISPARTY?

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Background and Aims: The burden of uploading diabetes device shifted from clinic staff to those living with T1D as a result of virtual encounters for COVID-19. Unfortunately, many patients were not familiar with the upload process, causing incomplete data availability. This study compared patients with device data available at the start of their routine virtual clinical visits vs. those that did not.

Methods: Data was collected from individuals <23 years old, with T1D, who received virtual care at a network of tertiary pediatric diabetes clinics in the Midwest USA from 3/2020 to 11/2021. Successfully uploading any device data or having cloud-connected streaming data was defined as having engaged in data sharing.

Results: Observations from 946 telehealth encounters were analyzed. Only 52.9% (n = 383) had device data uploaded before their visit. Mean HbA1c (9.5% vs 8.5%, p-value <0.001), and mean time in range (44.7% vs 35.7%, p-value <0.001) were lower in those that had uploaded/streamed their data before their clinic encounter. Those with a longer duration of diabetes, self-identifying as Black or African American, and those with public insurance were less likely to have data available at the start of their visit.

Conclusions: Data from diabetes devices are integral to routine, effective, and safe management of insulin therapy. Statistically significant differences in access to device data were noted in those with public insurance and those who self-identify as African American. HbA1c and TIR were also lower. This study highlights the importance of equitable access to diabetes devices and continued advancement in auto-data streaming technologies.

EP193 / #654

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

DEVELOPMENT AND VALIDATION OF AN INPATIENT DIABETES DATA DASHBOARD

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Background and Aims: Innovative and reliable programs able to capture hospital glycemic data are needed to monitor the impact of quality improvement interventions. This report presents the validation of a data collection tool. We previously piloted a clinical decision support tool in the electronic medical record (EMR) employing an interrupted time series. It recognized recurrent hyperglycemia in patients with diabetes, stress

hyperglycemia, impending or established hypoglycemia, and inappropriate insulin use, coined as gaps in care. When active, our GlucAlert-CDS notified clinicians in real-time and offered management recommendations. This reduced hyperglycemia in patients with diabetes and stress hyperglycemia, recurrent hypoglycemia, and shortened hospital stay.

Methods: Quantification of gaps in care was designed employing a reporting system from the EMR using language patterned after Structured Query Language. In parallel, we designed a data collection instrument in an EMR agnostic application. This design included specifications of EMR data elements representing variables for clinical, economic and practice performance outcome analyses. We validated the EMR agnostic data collection tool by direct comparison of events with EMR reports.

Results: Over a 10-months period among hospitalized patients, there were 31,270 and 31,278 gaps in care events in EMR reports and EMR agnostic data collection tool respectively. The accuracy of events recognition from EMR agnostic data collection tool was 99.98%. This intelligence program enabled a comprehensive dashboard for reporting of events and variables.

Conclusions: Our EMR agnostic data collection instrument and dashboard enables reporting gaps in care events with high accuracy. They integrate all variables necessary for outcome analysis displaying visualization for end users.

EP194 / #690

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

TRAINING, INITIATION AND ONE-YEAR FOLLOW-UP OF INSULIN PUMP THERAPY BY TELEMEDICINE

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Background and Aims: During the recent COVID-19 pandemic, telemedicine has been used in type 1 diabetic patients to monitor and check metabolic balance, through specific platforms for downloading data. Aim of our study is to describe the experience of remote training, initiation and one-year follow-up of insulin pump therapy and continuous glycemic monitoring in four poorly controlled type 1 diabetic patients, presenting several hypoglycemic episodes.

Methods: In April 2020 four patients were determined to be CSII therapy candidates, primarily to reduce hypoglycemic episodes. The remote training consisted of 3 or 4 sessions focused on self-management of advanced insulin therapy and technical aspects of pumps. They occurred in patients' homes using Skype™ for synchronous teleconferencing. After the training, two patients transitioned to the MiniMed 670G system, one to Omnipod and one to Accu-Chek Solo. Insulin pump informations and CGM data were remotely downloaded, and follow-up telemedicine visits were scheduled.

Results: As early as two weeks after the insulin pump has been implanted, a hypoglycemic episode reset was recorded in all patients and the time in range (TIR) was greater than 90% in three of the four patients. During one-year remote follow-up, all patients maintained a satisfactory %TIR and glycemic variability, with a limited number of hypoglycemic events. One patient had COVID-19 disease and one became pregnant: these conditions were well managed by telemedicine service.

Conclusions: These findings support the effectiveness of telemedicine for remote training, initiation, and follow-up of insulin pump therapy, ensuring a positive control of glycometabolic outcomes.

EP195 / #719

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

DIAHELP - A FREE SMARTPHONE APPLICATION DESIGNED TO HELP PEOPLE WITH DIABETES

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Background and Aims: Unexpected lack of diabetes supplies (diabetic loses, forgets it, supplies are stolen or he/she runs out at inconvenient moment) can be mediated by DiaHelp app. DiaHelp locates the diabetic in need and broadcasts request for supplies to DiaHelpers who are close. When in dangerously low or high, app offers SOS button. Request for help with location is broadcasted to predefined contacts via SMS and to DiaHelpers in a 1km radius. Diahelp app offers interesting information and education about diabetes enabling continuous motivation.

Methods: A survey was conducted among diabetics (n = 324) with the aim of determining the need for emergency supplies situations, frequency, and ways of resolving.

Results: The results showed that such situations occur to a statistically significant number of diabetics (81%) once every 1-2 years. For 63% of them the situation was very stressful or significantly stressful. The DiaHelp app was successfully launched in Croatia, BiH, Slovenia, and Serbia on 7/2021. There are circa 3.000 users and we have recorded circa 300 requests for help in this period.

Conclusions: Diabetes management is better with motivation, education, and peer support as it is a chronic, complicated to manage, and overwhelming disease. The stress of taking care of many supplies and medications and the fear of hypo as one of the important factors influencing the regulation of diabetes can be reduced. Location data allows easier access to the ambulance and family in case of hypo and DKA. Occasional calls for help will allow the individual social discharge and reduce the feeling of isolation.

EP196 / #724

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

HEALTHCARE PROFESSIONALS' THOUGHTS ON USING VIDEO CONSULTATIONS FOR TYPE 1 DIABETES PATIENTS TREATED WITH INSULIN PUMPS IN THE OUTPATIENT CLINIC

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Background and Aims: The Hospital of Southern Jutland has three diabetes mellitus (DM) outpatient clinics located in three of the four municipalities in the catchment area. However, all adult insulin pump patients attend the Department of Endocrinology in Sønderborg resulting in longer traveling times and more inconvenience for some patients. Hence, the hospital aims to conduct more outpatient clinic video consultations.

The aim of this study was to explore healthcare professionals'perspectives on video consultations for type 1 diabetes patients treated with insulin pumps in the outpatient clinic.

Methods: A qualitative design using semi-structured interviews was employed. Healthcare professionals involved in the treatment of type 1 diabetes patients with insulin pumps were included. Data were analyzed using inductive thematic analysis.

Results: Three doctors, three nurses and three clinical dietitians were interviewed. Preliminary results are grouped into three themes. 1) Flexibility with responsibility includes; less transportation time, flexible consultation plans and patients playing an active role in their treatment. 2) Pros and cons of video includes; benefits and limitations of video, video vs. phone and when to meet in person. 3) Variations in professionals' perspectives includes; varying degrees of interest in preforming video consultations reflected in professional roles, tasks and thereto-perceived possibilities for conducting consultations by video.

Conclusions: Healthcare professionals were generally positive about using video and its benefits. Doctors were more sceptical than nurses and dieticians. It is uncertain as to why one group of professionals displayed differences in their perspectives on the use of video consultations. Studies are ongoing.

EP197 / #744

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

NOCTURNAL GLUCOSE FLUCTUATIONS IN PATIENTS WITH TYPE 1 DIABETES: WHICH PATTERNS ARE ASSOCIATED WITH HYPOGLYCEMIA?

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Background and Aims: Nocturnal hypoglycaemia (NH) is a potentially harmful and underestimated complication of insulin therapy. In this study, we aimed to determine which patterns of nocturnal glucose dynamics are associated with NH in patients with type 1 diabetes (T1D).

Methods: We used a dataset of continuous glucose monitoring records obtained from 405 adult subjects with T1D. The NH was defined as an episode of interstitial glucose <3.9 mmol/L for at least 15 min between 0-6 a.m. The clustering was performed using a hierarchical clustering algorithm. The Ward distance was chosen as the metric responsible for the distance between classes. After excluding records with missing data (>10%), 2797 intervals, including 316 with NH, were analyzed.

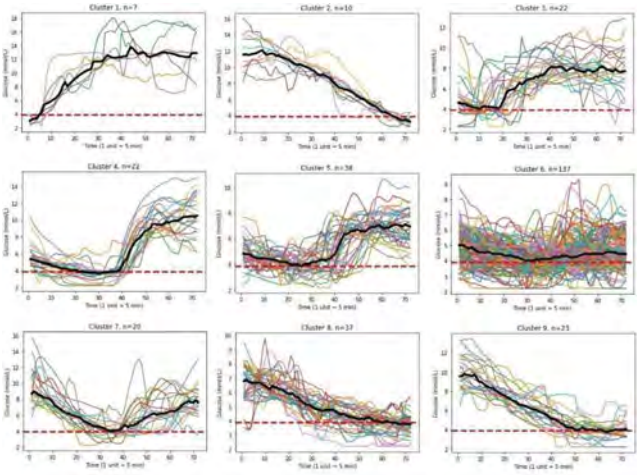

Fig. Clusters of nocturnal glucose with hypoglycemia

Results: Fourteen clusters without hypoglycemia and nine clusters with NH were identified (Figure). In 7 cases only, NH was observed at the beginning of the nocturnal interval (0-1 a.m., cluster 1). Mostly, it was observed at 2–4 a.m. in clusters with initially normal glucose and downtrend (clusters 3-6, n = 219). If glucose was initially elevated, NH was recorded more frequently at 4–6 a.m. (clusters 2, 8, 9, n = 70). The rate and amplitude of the rise in glucose levels after hypoglycemia varied significantly between clusters, affecting glucose levels at the end of the night.

Conclusions: The results demonstrate that clustering of nocturnal glucose dynamics could be a promising approach for identification of T1D subjects at high risk of NH. **Grant support:** The study was supported by RSF (grant #20-15-00057).

EP198 / #747

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

LAUNCHING OF THE RENACED-DT1 PERSONAL PLATFORM FOR PATIENTS LIVING WITH TYPE 1 DIABETES

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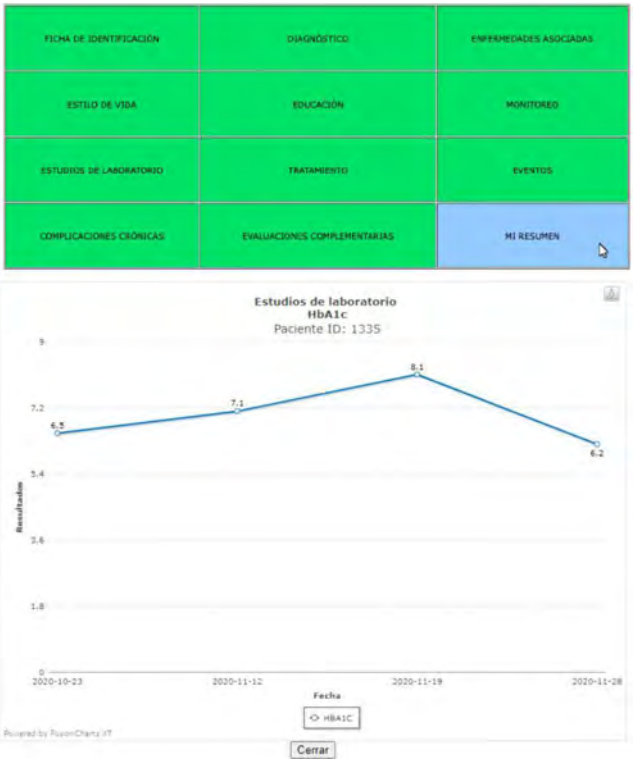
Background and Aims: There is little information regarding the real prevalence of type 1 diabetes (T1D) in Mexico. In an effort to have longitudinal data regarding clinical and metabolic variables, treatment practices and complications in patients with T1D, we created RENACED-DT1, a T1D national registry. Since its launch in 2014, 49 physicians have joined the registry and 1718 patients have been registered. We hypothesize that creating a platform for patients to self register, might be of help in knowing the real prevalence of T1D In Mexico.

Methods: We built a secure and robust platform, using the national identification number to avoid duplicates. There are 11 sections (Fig.1): personal data, diagnosis, associated diseases, lifestyle, education, glucose monitoring, laboratory results (an A1c graph can be obtained-Fig2), treatment, acute events, chronic complications, and complementary evaluations. Also a one page summary can be printed with the answers to all the sections.

Results: We tried the platform with influencers living with T1D and implemented most changes suggested for easier reading and understanding, and faster use. We launched the platform in November 2021 via a FaceBook live conference and round table, with experts in the field and leading members of the T1D community. Ten days after launching, 970 persons watched the video. RENACED-DT1 physicians are encouraging other T1D community members to join the registry.

Conclusions: We expect that this platform will allow active patient participation and enrich the information from RENACED-DT1 registry. The involvement and education of individuals living with T1D will help have reliable information and to achieve better outcomes.



EP199 / #767

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

AN EVALUATION OF VIRTUAL CARE FOR GESTATIONAL DIABETES USING THE QUADRUPLE AIM FRAMEWORK: ASSESSMENT OF PATIENT AND PROVIDER EXPERIENCE, COST AND CLINICAL OUTCOMES

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Background and Aims: The objective of this study was to evaluate the impact of virtual care for gestational diabetes (GDM) in the context of the COVID-19 pandemic.

Methods: This mixed methods program evaluation used the quadruple aim framework. The impact on patient and provider satisfaction and costs was assessed with surveys and interviews. Chi-square tests of independence compared clinical outcomes before (April 2019-Feb 2020) to after (May 2020-March 2021) the shift to virtual care.

Results: 82 women completed a patient experience questionnaire. The majority rated their virtual care experience as good or excellent (93%) with a preference to continue visits in the future (84%). Most respondents felt virtual care saved them money (90%) and time (98%). Providers all felt the switch to virtual care was positive but there was concern about the loss of non-verbal cues and personal connections. Physicians noted increased efficiency however more difficulty with assessing glucose trends. Nurses noted an increased work load, concerns about adequacy of patient education and delays in insulin initiation. When comparing outcomes for women who received in-person and virtual care there were no significant difference in rates of insulin initiation, C-sections, macrosomia or NICU admissions. There was a decreased rate of missed appointments after the switch to virtual care (6.1% vs 1.1%, p-value < .01).

Conclusions: There has been high patient and provider satisfaction for virtual GDM care with no difference in clinical outcomes and less missed appointments. Virtual GDM care should remain an option in the future.

EP200 / #780

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

CURATION OF LAB BIOMARKER UNITS IN EMR DATA FOR PREDICTIVE MODEL BUILDING

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Background and Aims: Developing predictive models using data from Electronic Medical Records (EMRs) presents many challenges such as lab values that are in different or incorrect units. We selected Serum Albumin assay in the IBM Explorys

dataset* to demonstrate our approach. *Certain data used in this study were supplied by International Business Machines Corporation as part of one or more IBM Explorys Therapeutic Datasets Delivered. Any analysis, interpretation, or conclusion based on these data is solely that of the authors and not International Business Machines Corporation

Methods: In our effort to curate the Albumin data, we first plotted them to get an insight into the data distribution and variation. Simple statistics were other means to review the data. Knowing the expected range of data helped us decide whether or not some of the observations were outliers or in different units. For Albumin, we chose g/dL as the target unit with the range [0, 6]. We did a tally of all units that were in the data and focused on those with the most number of observations, and removed those with questionable or a small number of observations. We then converted other units to g/dL and discarded everything that was outside the normal range of [0, 6].

Results: After the data curation, we salvaged 956,601 out of a total of 1,000,000 Serum Albumin observations in 11 different units.

Conclusions: We successfully applied this method with a number of lab values to clean the data as a precursor step to model building.

EP201 / #805

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ONLINE COURSE - A NEW OPTION IN IMPROVING GESTATIONAL DIABETES MANAGEMENT THROUGH PATIENT AND DOCTOR EDUCATION

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Background and Aims: A successful pregnancy and birth outcome in women with gestational diabetes mellitus (GDM) requires a multidisciplinary approach with close collaboration between healthcare providers. One of the key elements for the successful management of GDM is the education of pregnant women and all the doctors who meet pregnant women. The aim or the study was to evaluate the role of online courses in the educational process of women with GDM, doctors and nurses.

Methods: Online course "100 questions about gestational diabetes" by endocrinologist Olga Derevyanko based on Guidelines of Russian Endocrinology Association, American Diabetes Association, The National Institute for Health and Care Excellence and Royal College of Obstetricians and Gynaecologists consist of 8 part e-Learning series wich provide health professionals and patients with an evidence-based approach to the care of women with GDM in a multidisciplinary environment. Both doctors and patients (38 and 29, respectively) were tested before and after the course. The questions included the topics of diagnosis, treatment, nutrition and physical activity in GDM, as well as questions about postpartum management. Patients also answered questions about the anxiety level and the feeling of understanding the current state before and after the course.

Results: Both doctors, nurses and patients improved their results in tests rated on a 100-point scale after the course - from 68 to 96 points (healthcare specialists) and from 27 to 91 (patients).

Conclusions: Online course is a great option in improving GDM management through the training of medical personnel and patients.

EP202 / #811

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

DETECTING THE RISK OF TYPE 1 DIABETES THROUGH CLUSTERING OF DATA COLLECTED DURING A SELF-ADMINISTERED CGM-BASED HOME TEST

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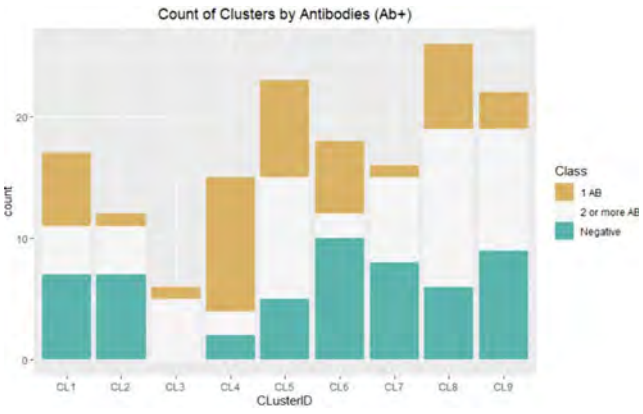
Background and Aims: Identifying factors contributing to the type 1 diabetes (T1D) risk and designing clinical tests for their assessment has been a challenge. Our aim is to explore whether the outcomes of a simple, self-administered continuous glucose monitoring (CGM)-based home test has the potential to distinguish between subjects at different levels of immunological risk to develop T1D as defined by the number of their positive islet autoantibodies (Ab+).

Methods: We use data from 55 healthy relatives to T1D having 0, 1, and 2 or more islet Ab, with mean ± SD age of 25.1 ± 10.9, HbA1c of 5.3 ± 0.3%, and BMI of 23.8 ± 5.7 (kg/m^2). All subjects consumed three caloric drinks instead of breakfasts (mixed meal tolerance tests (MMTT)). Fuzzy c-means (FCM) clustering was applied to 155 CGM traces of 3-hrs duration around each MMTT (1-hr pre– and 2-hrs post-MMTT). To assess the average compactness and separation of fuzzy partitions and reach an optimal number of clusters, the Compose Within and Between Scattering (CWB) index was used. Pearson's Chi-squared test was used to assess the association between CGM traces clusters and autoantibody classes.

Results: Nine clusters were identified by FCM and CWB validity index. A statistically significant relationship between the 9 clusters originating from the 44 (1 AB), 57 (2 or more AB), and 54 (Negative) autoantibodies, with a p–value = 0.0004 was observed as in the figure.



Conclusions: A new self-administered clustering technique based on home CGM traces in response to a Boost is a relevant method for assessing the immunological risk for developing T1D.

EP203 / #84

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

CLINICAL PRACTICE INSIGHTS DELIVERING CARE DURING COVID IN FIVE EUROPEAN COUNTRIES UTILIZING A PROFESSIONAL DIABETES MANAGEMENT ECOSYSTEM

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Background and Aims: Connecting in-person with patients is challenging during COVID, potentially undermining the frequency and quality of consultations with health care professionals (HCPs). Telemedicine offers a way to support patient-provider connectivity.

Methods: Survey data was collected from 22 HCPs from 20 institutions who then participated in one of four virtual meetings to share telemedicine insights using the professional version of OneTouch Reveal® (OTR Pro) ecosystem.

Results: Remote consultations increased 46% in these institutions during COVID, divided 52% and 48% between patients with type 1 and type 2 diabetes. Methods included telephone (60%), email (19%), video (10%), texting (3%), or combinations (8%). HCPs reviewed OTR Pro data during (45%) or before (25%) consultations, every 3 months (20%) or every 2 weeks (5%). 55% of HCPs said going forward, OTR Pro would become their standard of care, 30% for current or new patients, 10% during face-to-face visits and only 5% returning to face-to-face consultations without OTR Pro. For managing patients, HCPs ranked ''allows me to make treatment/therapy decisions,'' ''helps me schedule consultations/reminders,'' ''access 24/7 to status of my patients,'' as the top 3 benefits of OTR Pro. 95% of HCPs agreed OTR Pro identified patterns, trends and trouble spots for more meaningful conversations with patients, facilitating clinical practice during COVID.

Conclusions: The OneTouch Reveal® ecosystem supported telemedicine during the pandemic and will continue to play a valuable role beyond the pandemic.

EP204 / #85

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

ASSESSMENT OF BLOOD GLUCOSE READINGS OF PEOPLE WITH DIABETES IN AUSTRALIA WHO WERE USING THE CONNECTED CONTOUR® BGMS AND CONTOUR®DIABETES APP

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Background and Aims: Previously we presented profiles of people with diabetes in Australia, who were using connected CONTOUR® NEXT (CN) or CONTOUR® NEXT ONE (CNO) blood glucose monitoring system (BGMS) with CONTOUR®DIABETES App (further ''CDA system''). The objective is to assess the estimated frequency of blood glucose readings (BGRs) in various hypo- and hyperglycemic ranges in those patients who were using the CDA system for 210 days.

Methods: Anonymized BGRs were obtained from 7047 CDA system users who reported at least 5 BGRs within first 30 days (baseline) and between 180-210 days of CDA use. Data were partitioned into four groups called Events; Event A -**very low** BGR (≤54 mg/dL), Event B- **low** (≤70 mg/dL), Event C- **high BGR** (≥180 mg/dL) and Event D -**very high BGR** ((≥250 mg/dL). Odds ratios (ORs) were used to estimate expected changes in the frequency of all four events from baseline to 210 days.

Results: The more prominent increase in mean odds was observed in Event C (high), D (very high) and B (low) in Table 1.

Conclusions: The use of connected CN and CNO BGMS with CDA for 210 days was associated with a reduced frequency of expected events in below and above blood glucose target ranges. Further analysis will explore the assessed patient profiles. These results support that when people with diabetes are monitoring blood glucose levels and actively using CDA for at least 6 months, it may lead to improved glycemic control.

Table 1. Estimated mean Odds Ratio

Number of CDA system users= 7047				95% Confidence intervals		
Event	BGR levels	N of Odds Ratio	Mean Odds Ratio^	LCL	UCL	P-value*
A	≤54mg/dL	98	1.17	0.98	1.38	0.0372
B	≤70mg/dL	392	1.23	1.10	1.38	0.0000
C	≥180mg/dL	2390	6.50	4.90	8.68	0.0000
D	≥250mg/dL	871	5.58	3.64	7.95	0.0000

Blood Glucose Reading (BGR); Odds Ratio (OR) is Odds of Event in the first 30 days/Odds of Event in the last 30 days;
Lower Confidence Level (LCL); Upper Confidence Level (UCL);
*P-value <0.05 implies OR significantly different from 1
^Mean Odds ratio >1 implies the likelihood of event is greater in the first 30 days compared to 180-210 days of CDA system use

EP205 / #126

Topic: ***AS07-Insulin Pumps***

FEAR OF HYPOGLYCAEMIA BETWEEN PEOPLE WITH TYPE 1 DIABETES ON INSULIN PUMP VERSUS BASAL BOLUS INSULIN THERAPY

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Background and Aims: Type 1 diabetes mellitus (T1D) requires complex manipulations (daily glucose measurements and

multiple insulin injections) with a significant impact on the quality of patient's life. Thus, the aim of the present study was to evaluate the fear of hypoglycemia between people on insulin pump versus basal bolus insulin therapy.

Methods: The study involved 95 individuals (40 men, mean age: 47 ± 3.9 years) with a body mass index (BMI) of 27.1 ± 5.9 Kg/m^2, duration of diabetes 24.3 ± 11.1 years and HbA1c 7.7 ± 1.5%. of 56.8% used continuous glucose monitoring and 42.1% insulin pump therapy. 42.1% had hypertension, 61.1% dyslipidemia, 7.4% coronary heart disease, 31.6% retinopathy, 8.4% chronic renal failure and 17.9% peripheral neuropathy. Fear of hypoglycemia was assessed with the Hypoglycemia Fear Syrvey (HFS) questionnaire.

Results: Regarding HFS scale, people on insulin pump therapy had a lower overall score than those on basal bolus therapy (18.35 ± 6.09 vs. 26.36 ± 7.78, respectively, P = .03). No statistically significant difference was observed in the HFS scale between subjects in continuous glucose monitoring compared to those in subcutaneous ambulatory blood measurement. Multiple regression analysis in study population showed that HFS scale was associated positively with duration of diabetes (beta = 0.24, P = 0.01), and negatively with dyslipidemia (beta = -0.31, P = 0.002) and total daily insulin units (beta = -0.31, P = 0.001).

Conclusions: The results of the present study showed that people with T1D on insulin pump therapy had less fear of hypoglycemia than people on basal bolus insulin therapy, with duration of diabetes, dyslipidemia and total daily insulin units being the main determinants.

EP206 / #127

Topic: ***AS07-Insulin Pumps***

PREVALENCE OF EMOTIONAL STRESS AMONG PEOPLE WITH TYPE 1 DIABETES AND INSULIN PUMP VERSUS BASAL BOLUS INSULIN THERAPY

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Background and Aims: Type 1 diabetes mellitus (T1D) requires complex manipulations with a significant impact on the quality of patient's life. The aim of the present study was to evaluate the emotional burden associated with diabetes between individuals with insulin pump versus people on basal bolus insulin therapy.

Methods: The study involved 95 individuals (40 men, mean age:47 ± 13.9 years) with a body mass index (BMI):27.1 ± 5.9 Kg/m^2, duration of diabetes 24.3 ± 11.1 years and HbA1c:7.7 ± 1.5%. 57.9% was on basal bolus, 42.1% on insulin pump, 56.8% used continuous glucose monitoring. 42.1% had hypertension, 61.1% dyslipidemia, 7.4% coronary heart disease, 31.6% retinopathy, 17.9% neuropathy. Diabetes-related emotional burden was assessed using the Problem Areas in Diabetes Scale (PAID).

Results: 30% of patients on insulin pump had PAID score ≥40. The corresponding rate in subjects on an intensified insulin regimen was 45.5% (P = 0.09). Logistic regression analysis showed that PAID scale was related to BMI [relative risk (RR):1.12, 95% confidence interval (CI):1.01-1.21], duration of diabetes (RR:1.08, 95% CI:1.02-1.14), HbA1c (RR:1.50, 95% CI:0.96-2.34), presence of coronary artery disease (RR:0.04, 95% CI:0.01-0.73), chronic kidney disease (RR:4.96, 95% CI:0.74-3.87), insulin pump (RR:0.14, 95% CI:0.04-0.56), continuous glucose monitoring (RR:4.13, 95% CI:1.21-5.41) and hypoglycemic events (RR:1.01, 95% CI:1.01-1.02).

Conclusions: The results of the present study showed that people with T1D on insulin pump had less emotional stress associated with diabetes compared to individuals on basal bolus insulin therapy. BMI, duration of diabetes, HbA1c, presence of coronary artery disease, chronic kidney disease, use of insulin pump, continuous glucose monitoring and hypoglycemic events were the main determinants of emotional stress.

EP207 / #153

Topic: ***AS07-Insulin Pumps***

EVALUATION OF A HYBRID CLOSED-LOOP SYSTEM INITIATION PROTOCOL FOR ADULTS WITH TYPE 1 DIABETES ON MULTIPLE DAILY INJECTIONS THERAPY

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Background and Aims: The 10-day onboarding protocol from multiple daily injections (MDI) to MiniMed 670G hybrid closed-loop (HCL)system demonstrated effectiveness in the pediatric age group. We aimed in this study to assess this protocol for adults with type 1 diabetes (T1D) to achieve glycemic targets.

Methods: We included individuals aged 18-65 years with T1D on MDI in an open-label, single-arm, single-center, clinical research following a structured protocol: 2-days, HCL system readiness; 5-days, HCL system training (2-hours sessions in 5 consecutive days with groups of 3 to 5 candidates); 3-days, Manual Mode use of HCL system; 84-days, Auto Mode use of the HCL system, cumulating 10 days from MDI to Auto Mode.

Results: 24 individuals (13 females), aged 28.8 ± 9 years with T1D for 12.1 ± 7.4 years were enrolled. Only 23 participants completed the study as one participant became pregnant during the study. The participants had a median sensor usage of 86% of the time and spent a median of 83% in Auto Mode. The mean HbA1C improved from 8.9 ± 1.4% (74 ± 15.3 mmol/mol) at baseline to 7.5 ± 0.8% (59 ± 9.3 mmol/mol) by the end of the study (P = 0.0001). Time in Range (3.9-10 mmol/L) increased from 48.96 ± 17.9% on MDI to 67.22 ± 13.2% on Auto Mode (P = 0.0003). These were accomplished with time below 3.9 mmol/L of 3.6%. No severe hypoglycemia or DKA episodes were noted during the study.

Conclusions: A structured 10-day initiation protocol was a successful strategy to commence the HCL system for adults with T1D on MDI.

EP208 / #247

Topic: ***AS07-Insulin Pumps***

EVALUATION OF HYBRID CLOSED-LOOP INSULIN DELIVERY IN PATIENTS WITH TYPE 1 DIABETES IN REAL-LIFE CONDITIONS: PREVIOUSLY USED THERAPY MATTERS ?

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Background and Aims: Hybrid Closed-loop(HCL) has shown potential to improve glycaemic control in people with type 1 diabetes(T1D). This study aims to establish the efficacy of HCL in people with T1D, and compare outcomes with standard therapy for T1D used before start with HCL.

Methods: It was a 1 year multicenter, observational study in patients with T1D, in Argentina. Enrolled individuals all ages with T1D >1 year, using intensive insulin therapy (multiple daily injections or insulin pump) after a run-in period wiht diabetes and carbohydrate-counting education, HCL system was initiated, patients were followed at 1, 3, 6, 9 and 12 months, HbA1c was obtained and data collected.

Results: 60 patients (age 31.7 ± 15.6 years), 38(59.62%) were females initiated HCL. They used as prior therapy 18% minimed 640, 10% minimed 754, 33% MDI , 15% Accuchek combo, 21% minimed veo and 1.6% minimed 715 . HbA1c decreased from 7.8 ± 1.4% at baseline, to 6.7 ± 0.5% at 3 months(p = 0.02) and remained stable to 7.1 ± 0.6% at 12 months (p = 0.02) Time in range(70-180 mg/dL) increased 56.9% baseline to 71.9% at 1 month and remained above 70% during the 12 months of HCL use(p = 0.01) Time below range (> 70 mg/dL) decreased from 5% at the first month to 2.6% at 3 month and remained under 3% during the 12 months of HCL use(p = 0.01) in all groups of prior technology used.

Conclusions: HCL in patients previously treated with MDI or insulin pump improves HbA1c, TIR, TBR at the first month. The improved was maintained the 1 year following Auto Mode initiation regardless of prior therapy.

EP209 / #264

Topic: ***AS07-Insulin Pumps***

INSULIN PUMP AND AHCL RESULTS FROM A TERTIARY LEVEL DIABETES HOSPITAL

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Background and Aims: To describe patients characteristics and clinical results of all adult type 1 diabetes (T1D) patients treated with continuous subcutaneous insulin infusion (CSII) in a tertiary level diabetes hospital.

Methods: Cross-sectional study from all adult T1D patients treated with CSII in Ciudad Real General University Hospital (Ciudad Real, Spain). Data were gathered from previous visit to CSII initiation and compared with data from last visit in 2021. Main endpoint was change in HbA1c from the beginning to the end of the follow-up.

Results: One hundred and fourteen patients (female 62%). Mean age was 42.2 yrs. (range 22-62 yrs.). Mean T1D duration was 24.7 ± 9.1 yrs. and patients were on CSII treatment for 8.7 ± 4.4 yrs. Main indications for CSII were: HbA1c >7%, 41%; severe, unaware or frequent hypoglycemia, 16%; high glycemic variability, 16%; pregnancy or programmed pregnancy, 13%; others, 14%. Aspart (51%) and faster aspart (26%) were the most frequent insulin used. Real-time continuous glucose monitoring was used by 68% of the patients, and 35% was treated with an advanced hybrid closed loop system (aHCL). We detected a -0.6% (CI 95, -0.9, -0.3, $P < 0.001$) reduction in HbA1c during the follow-up. Patients using aHCL showed inferior HbA1c in the last visit compared with those using other electronic devices (6.9 ± 1.0% vs. 7.8 ± 1.1% ; $P = 0.03$).

Conclusions: CSII was associated with a better glycemic control in adult T1D patients , this benefit was greater in those patients using aHCL.

EP210 / #288

Topic: ***AS07-Insulin Pumps***

SELF-MANAGEMENT OF INSULIN PUMP SETTINGS AND DATA UPLOAD ARE ASSOCIATED WITH LOWER HBA1C

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Background and Aims: The effect of insulin pump therapy is dependent on appropriate tuning of pump settings. We present associations between insulin pump self-management and HbA1c.

Methods: Adult insulin pump users (18+) with type 1 diabetes from the Capital Region of Denmark completed an online questionnaire covering aspects of insulin pump self-management including use of insulin pump functions, carbohydrate counting, data upload and insulin pump adjustment behaviors. Clinical data (HbA1c) and demographics were collected from respondents' electronic medical records and national registries. Linear regression models were used to investigate associations between HbA1c and insulin pump self-management, adjusted for CGM use, sex, age, and educational level.

Results: In total, 770 individuals responded to the questionnaire. Most responders were female (60%); median age and HbA1c were 49 years and 56 mmol/mol, respectively. 36% reported uploading 2-5 times a year or more, 14% uploaded once a year or less, and 50% never uploaded data. Uploading 2-5 times a year or more was associated with lower HbA1c (-2 mmol/mol, $P = 0.049$) compared with never uploading. 32% of individuals mainly adjusted pump settings themselves, while 68% mainly let their health care professional do the adjustments. Self-adjusters had HbA1c 6 mmol/mol ($P < 0.001$) lower than those never

adjusting. Basal rate and insulin:carbohydrate ratio were the most frequently self-adjusted settings and associated with a 4 mmol/mol ($P < 0.001$) and 2 mmol/mol ($P < 0.002$) lower HbA1c, respectively compared with not adjusting these settings.

Conclusions: User-driven data upload and adjustment of insulin pump settings are associated with lower HbA1c.

EP211 / #340

Topic: ***AS07-Insulin Pumps***

THE INFLUENCE OF BOLUS TYPE IN GLYCAEMIC CONTROL OF TYPE 1 DIABETIC CHILDREN ON INSULIN PUMPS

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Background and Aims: Insulin pumps allow the use of other types of bolus (OTB) aside standard bolus, that can be adapted to the composition of the meal and are associated with lower postprandial glycaemic variability. The aim was to evaluate the impact of bolus type in glycaemic control in children with type 1 diabetes (DM1).

Methods: A retrospective study with pediatric patients with DM1 on insulin pump and with continuous or intermittent glucose monitoring, observed between July and September of 2021. We compared diabetics who made only standard bolus with those who also made OTB. Statistical analysis was made with SPSS® 22.

Results: A total of 107 patients were included, 55% were boys, with a mean age of 12,6 ± 3,8 years. The age at diagnosis was 6,5 ± 3,7 years, with a disease duration of 5,3 (0,6-16,6) years and 2,6 (0,1-10,1) years of insulin pump therapy. The glucose readings per day were 10 (2-84), the mean glycemia was 175 ± 33,4 mg/dL. The total daily dose of insulin per kilo was 0,89 (0,3-1,74) units, with 35,3 ± 9,2% of daily basal dose and 64,7 ± 9,3% of daily bolus. Time in range was 48,9 ± 14,8%. The mean A1c hemoglobin was 7,5 ± 0,8%. Only 25% of patients (n = 27) made OTB, associated with a higher average bolus number per day 6,9 (4,1-13,9) *versus* 5,8 (2,6-12,4) ($p = 0{,}026$) and lower A1c hemoglobin 7,2 ± 0,8% *versus* 7,6 ± 0,7% ($p = 0{,}043$). There was no significant difference between groups in the remaining variables.

Conclusions: OTB seem to be more physiological and to contribute to better glycaemic control, so their use should be encouraged in patient education.

EP212 / #385

Topic: ***AS07-Insulin Pumps***

INFLUENCE OF TIME OF DAY ON PLASMA GLUCOSE RESPONSES TO CARDIOPULMONARY EXERCISE TESTING IN INDIVIDUALS WITH TYPE 1 DIABETES USING INSULIN PUMP THERAPY

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Background and Aims: To explore the influence of the time of day on plasma glucose dynamics during cardiopulmonary exercise testing (CPET) in individuals with type 1 diabetes (T1D) using insulin pump therapy.

Methods: Twenty-three adults with T1D (15 females [65%], HbA_{1c}: 7.4 ± 0.9% [56.9 ± 9.3 $mmol.mol^{-1}$], diabetes duration: 31 ± 14 years, age: 50 ± 12 years, BMI: 25.4 ± 3.5 $kg.m^{-2}$) using insulin pump or hybrid closed-loop therapy undertook an incremental CPET to volitional exhaustion on a cycle ergometer. Participants refrained from bolus insulin dose administration for at least 90 minutes prior to laboratory arrival. Venous-derived plasma glucose concentrations were obtained every 3 minutes during exercise, as well as at peak and recovery periods. Participants were retrospectively stratified into groups based on commencing exercise during the morning (<1200 [AM]) or afternoon (≥1200 [PM]). Data were compared using general linear modelling and independent t-tests with p values ≤0.05 accepted for statistical significance.

Results: There were no differences between groups in any anthropometric- or diabetes-related characteristics (all $p \geq 0.4$), nor were there differences in any cardiopulmonary responses to CPET. Plasma glucose levels remained equivalent to rested concentrations throughout testing regardless of time of day ($F[1,21] = 0.142$, $p = 0.71$. Figure 1 A). However, the small decline in glucose with afternoon exercise differed significantly to the rise observed during morning tests (PM: -0.3 ± 0.6 $mmol.L^{-1}$ vs. AM: +0.5 ± 1.1 $mmol.L^{-1}$, $p = 0.04$. Figure 1 B).

Conclusions: These data suggest that the expected change in glucose during CPET is neglectable, whether performed in the morning or afternoon. This information may serve useful for informing appropriate insulin therapy management ahead of CPET.

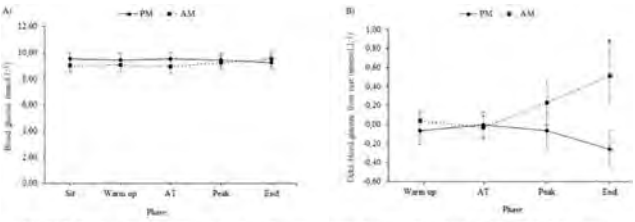

Figure 1. *Plasma glucose responses to cardiopulmonary exercise testing in individuals with type 1 diabetes using insulin pump therapy when expressed as A) the absolute plasma glucose concentrations at each work phase during the test and B) the change in plasma glucose at each phase of the test relative to rested concentrations immediately before exercise commencement. AT; anaerobic threshold. * denotes a significant difference of p≤0.05 between values.*

EP213 / #391

Topic: ***AS07-Insulin Pumps***

SEXUAL DIMORPHISM IN CARDIOPULMONARY BUT NOT GLYCAEMIC RESPONSES TO SUBMAXIMAL AND MAXIMAL EXERCISE IN ADULTS WITH TYPE 1 DIABETES USING INSULIN PUMP THERAPY.

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Background and Aims: To explore the influence of sex on glycaemic and cardiopulmonary responses to graded exercise testing to exhaustion in adults with type 1 diabetes (T1D) using insulin pump therapy.

Methods: Twenty-three adults with T1D treated with insulin pump therapy undertook an incremental cardiopulmonary exercise test (CPET) to volitional exhaustion on a cycle ergometer. Cardiopulmonary variables were obtained continuously whilst venous-derived plasma glucose concentrations were collected every 3 minutes during exercise as well as at peak and recovery phases. The anaerobic threshold (AT) was determined as the workload corresponding to the fixed rise in lactate of 1 mmol. L^{-1} from baseline equating to ~60% peak power. Participants were spilt into groups based on sex (Table 1a). Between group differences were compared via general linear modelling techniques and independent t-tests with p values of ≤0.05 accepted for statistical significance.

Results: There were no anthropometric- or diabetes-specific differences between groups (Table 1a). Plasma glucose remained comparable to rested concentrations throughout exercise regardless of sex (F (1,21) = 2.229, p = 0.150). Relative to males, females had lower O_2, O_2 pulse, (Table 1b) and power output (Table 1c) at both submaximal and peak workloads as well as an earlier time to reach the AT and exhaustion. Females had a lesser reliance on carbohydrates as the dominant fuel during submaximal workloads (Table 1b).

Conclusions: These data demonstrate equivalency in plasma glucose responses to incremental exercise testing in males and females with T1D. However, potential sexual dimorphisms in cardiopulmonary responses to CPET may need consideration for optimal exercise prescription and interpretation.

EP214 / #404

Topic: ***AS07-Insulin Pumps***

ANALYSIS OF A STRUCTURED EDUCATIONAL PROGRAM FOR CANDIDATES FOR THERAPY WITH SUBCUTANEOUS CONTINUOUS INSULIN INFUSION

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Background and Aims: Continuous subcutaneous insulin infusion (CSII) therapy allows people with diabetes to improve their metabolic control and quality of life. At the same time, the integration of technology could represent a challenge, so it is essential that people are trained and empowered in diabetes self-management and in interaction with devices (and the information they provide). Our aim is to evaluate a specific structured educational program in CSII for patients with type 1 diabetes mellitus (T1D)

Methods: Retrospective observational study. We analyze the duration of the educational process, the difficulty of visits and its association with the variables of the patients (criteria for starting therapy, age, sex, and educational level) in a sample of 76 subjects referred to start therapy with CSII.

Results: 71 patients (63,4% female) completed the specific CSII structured educational program in a total of 6,4 ± 1,6 visits. 5 patients (100% male) left the training process, these patients were referred to CSII therapy by the same criteria (variability and poor metabolic control). 11 patients (15%) needed reinforcement sessions. Greater length of education program was associated to elderly patients, lower education level, variability and poor metabolic control criteria and difficulties during process.

Conclusions: Although adherence to educational intervention was high, baseline characteristics which may slow down or discontinue the educational process must be considered.

EP215 / #420

Topic: ***AS07-Insulin Pumps***

THE IMPACT OF CONTINUOUS INSULIN INFUSION AND SGLT2-I ON GLYCAEMIC CONTROL OF NIGHT-SHIFT WORKERS WITH TYPE 1 DIABETES

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Background and Aims: Background: Night-shift workers (NSW) exhibit poorer metabolic health than daytime workers, which is related to circadian system disruption. In patients with type 1 diabetes (T1D), shift-work may be associated with poor glycaemic control. **Aim:** To evaluate if patients with T1D working night-shifts (NSW) had improvement of glycaemic control with the use of continuous insulin infusion (CSII); and whether patients under adjunctive treatment with SGLT2-inhibitors (SGLT2i) are better controlled.

Methods: Methods: Retrospective analysis of T1D-NSW patients under CSII therapy followed at our department (N = 28). We collected data from continuous glucose monitoring (CGM-90 days) and HbA1c before and after being under CSII (CGM data before CSII not available for most patients). Patients under SGLT2i (N = 6) were compared to those without (N = 22).

Results: Results: 18 females (64.3%), mean age 33.5 ± 9.6 years, duration of diabetes 21.3 ± 10.4 years, age at the beginning of CSII 26.1 ± 9.7 years. HbA1c was significantly lower after starting CSII (7.3% (6.9-7.8) vs 8.0% (7.1-8.7), p = 0.043). Patients under adjunctive treatment with SGLT2i had a higher *Time in range* (64% (58-74) vs 52% (43-61), p = 0.019) and lower *Time above range* (28% (18-36) vs 41% (34-51), p = 0.019), with no differences in *Time below range* or number of hypoglycaemias.

Conclusions: Conclusions: In our study, T1D-NSW patients had an improvement of glycaemic control with the use of CSII, which allows programming of different basal insulin rates throughout day and night and to switch between different basal patterns. Among CSII users, adjunctive treatment with SGLT2i may improve glycaemic control without increasing hypoglycaemias.

EP216 / #482

Topic: ***AS07-Insulin Pumps***

ACCURACY OF FAST BOLUS DELIVERY OF TWO INSULIN PUMPS

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Background and Aims: Insulin pumps are commonly used in the therapy of type 1 diabetes and often allow choosing between multiple bolus delivery speeds. In this study, fast bolus delivery accuracy of two insulin pumps was assessed.

Methods: Using a microgravimetric method based on IEC 60601-2-24, fast bolus delivery accuracy (delivery speed: 15 U/min)) of the patch pump Medisafe With [MSW] and the durable pump MiniMed 640G [MM6] was assessed for bolus sizes of 0.2 U, 1.0 U and 7.0 U. In 9 experiments comprising 25 or 24 bolus deliveries each, in total 225 (0.2 U and 1.0 U) and 216 (7.0 U) boluses were delivered with both pump models. Deviations greater than 15% were considered relevant.

Results: The results for fast bolus delivery accuracy are shown in the table.

Conclusions: Median deviation from target was comparable among both pumps. However, median deviation was greater and variance was larger at smaller bolus doses. Compared to previous tests, these results indicate that the bolus delivery speed has no considerable influence on bolus accuracy.

Bolus volume [U]	n	Median deviation [%] (2.5th percentile; 97.5th percentile) [%]		Percentage of boluses within ±15% of target [%]	
		MSW	MM6	MSW	MM6
0.2	225	+4.2 (-2.6; +10.0)	+5.7 (-4.9; +15.2)	100	96.4
1.0	225	+2.6 (-0.4; +5.5)	+2.0% (-2.1; +5.6)	100	99.6
7.0	216	+0.8 (-1.4; +3.2)	+0.0 (-2.7; +1.8)	100	100

EP217 / #488

Topic: ***AS07-Insulin Pumps***

DELIVERY ACCURACY AND OCCLUSION DETECTION TIME OF SIGI™, A NOVEL PATCH PUMP TO BE USED WITH STANDARD 1.6 ML INSULIN PREFILLED PUMP CARTRIDGES

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Background and Aims: Insulin pumps are commonly used to treat type 1 diabetes. Therefore, sufficient accuracy and reliability are important. In this study, basal rate and bolus accuracy and occlusion detection time of prototypes of a novel patch pump were assessed.

Methods: Basal rate accuracy for 1.0 U/h, bolus accuracy for 0.2 U and 1.0 U and occlusion detection time at 0.1 U/h and 1.0 U/h were assessed for the Sigi™ patch pump. Experimental testing was based on EN 60601-2-24. In addition to the total basal rate deviation after 72 h, accuracy of separate 1-h-windows was assessed. One bolus experiment comprised 25 consecutive individual deliveries whose deviation from target was calculated. Occlusion detection time was determined by occluding the pump's cannula with a surgical clamp and measuring the time until an occlusion alarm occurred. Each test scenario was repeated 6 times.

Results: After 72 h, the pump showed a mean basal rate deviation of -0.3 ± 2.0%. 97.7% of separate 1-h-windows deviated less than 5% from target. Mean bolus deviation was 1.8 ± 2.5% at volumes of 0.2 U and 0.3 ± 2.4% at a bolus size of 1.0 U. Mean occlusion detection time was 29 min at a basal rate of 0.1 U/h and 10 min using a basal rate of 1.0 U/h.

Conclusions: In this first prototype study Sigi™ showed delivery accuracy comparable to published data of the most accurate commercially available insulin pumps tested in similar settings. Occlusion detection time was markedly shorter than of insulin pumps currently available on the market.

EP218 / #496

Topic: ***AS07-Insulin Pumps***

A SUCCESSFUL EXPERIENCE OF CSII WITH HCL SYSTEM IN A 10 MONTHS-OLD CHILD

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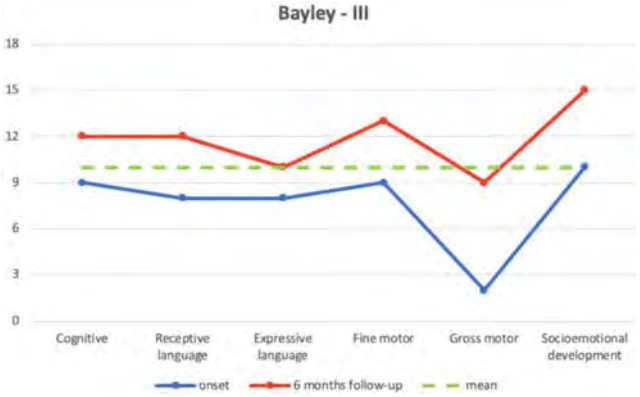
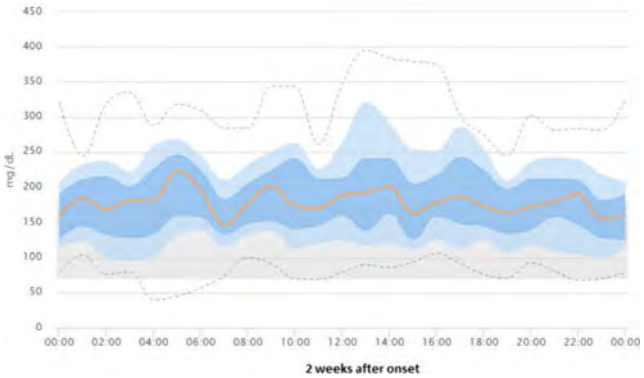
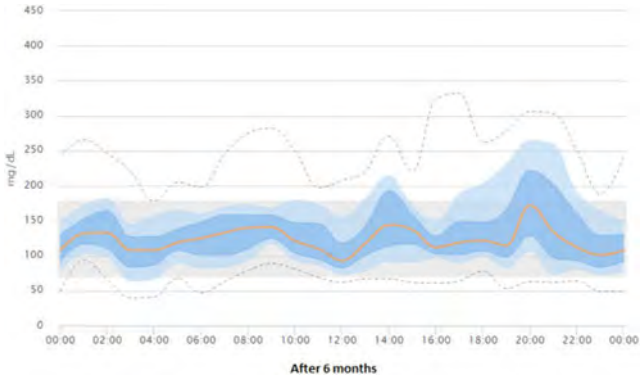
Background and Aims: Data on HCL systems in young children with T1D are limited. We aim to describe a case of a severe DKA in a ten months-old child, treated firstly with PLGS and then with HCL.

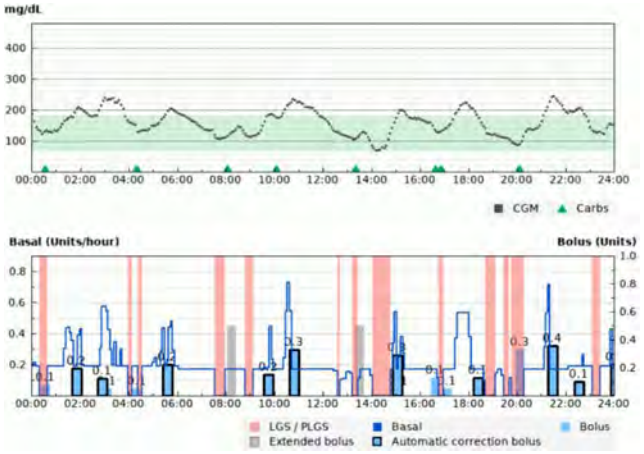
Methods: After a previous admission in ED, he was taken again arriving in cardiac arrest. ROSC after 3 minutes, pH 6,95, pCO2 24 mmHg, HCO3- 5,3 mmol/L, BE -26, glycemia 685 mg/dl, K corrected 2,63 mmol/L, ketonemia 7,4 mmol/L. He was intubated and received fluid resuscitation. A new episode of bradycardia regressed with <1 minute CPR. Transferred in PICU, he received transfusions of plasma because of hypovolemic shock and multi-organ failure. DKA was corrected and insulin was started. Genetic tests for neonatal diabetes were negative. Pancreatic autoimmunity was initially negative, repeated confirmed T1D. On day 2 placement of CGM Dexcom G6; on day 7 insulin was moved to subcutaneous and insulin pump was placed: Tandem t:slim X2 Basal IQ; after a week shifted on Control IQ mode. TDI was 0,9 U/kg/die, bolus for milk meals in extended mode. The Control IQ managed automatically meals up to 40 g of carbs.

Results:









No hypoglycaemic episodes were observed. After two weeks: TIR 52%, TAR 48%, TBR 0%. After six months: TIR 85%, TAR 12%, TBR 4% (1% <54 mg/dl). Neurocognitive Bayley-III scale was administered at onset and after six months with important improvements.

Conclusions: HCL systems, used in an experienced center, might be useful to manage diabetes from its very onset, also for toddlers. Specific studies are needed.

EP219 / #553

Topic: ***AS07-Insulin Pumps***

CONTINUOUS SUBCUTANEOUS INSULIN INFUSION IS ASSOCIATED WITH BETTER NAFLD INDICES IN PATIENTS WITH TYPE 1 DIABETES.

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Background and Aims: NAFLD is a raising concern also in type 1 diabetes (T1D) and is associated with micro and macrovascular complication. This study evaluated whether different ways of insulin administration (multiple daily injections [MDI] or continuous subcutaneous insulin infusion [CSII]) may affect NAFDL indices.

Methods: We performed a cross-sectional study on 658 patients with T1D (37 ± 13 years, 51% male, HbA1c 7.8 ± 1.2%, body mass index 25 ± 4 kg/m^2). who had no history of excessive alcohol consumption or other secondary chronic liver disease, regulrly attending Diabetes Unit of Teaching Hospital of Federico II University. NAFLD was assessed by the Fatty Liver Index (FLI) and Hepatic Steatosis Index (HSI). Anthropometric, biochemical, and clinical parameters were retrieved by electronic records. Differences in NAFLD indices between patients on MDI or CSII were evaluated by univariate analysis, adjusted for possible confounders.

Results: Patients on CSII (n = 259), compared with those on MDI (n = 399), differed for gender distribution (men: 47% vs 55%, p = 0.046), diabetes duration (22 ± 11 vs 18 ± 12; p<;0.001), prevalence of retinopathy (26% vs 18%, p = 0.018), and nephropathy (15% vs 10%, p = 0.035), respectively. According to univariate analysis adjusted for gender and diabetes duration, patients on CSII had a significantly lower HSI (36 ± 5 vs 37 ± 6; p = 0.003), FLI (20 ± 21 vs 25 ± 24; p = 0.003), waist circumference (85 ± 12 vs 87 ± 14 cm; p = 0.047), triglycerides (76 ± 44 vs 85 ± 60 mg/dl; p = 0.035), and insulin daily dose (0.53 ± 0.22 vs 0.64 ± 0.25 UI/kg body weight; p<;0.001).

Conclusions: Patients with T1D on CSII have better NAFLD indices. This is probably due to a more rational distribution of daily insulin dose contributing to better regulate lipogenic pathways.

EP220 / #558

Topic: ***AS07-Insulin Pumps***

IN-VITRO ACCURACY EVALUATION OF A NOVEL, AFFORDABLE INSULIN PUMP

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Background and Aims: Accuracy and precision of insulin delivery are imperative for the safety of patients and efficacy of CSII (Continuous Subcutaneous Insulin Infusion) therapy. Freckmann et al. (2019) report mean bolus delivery within ±5% of the programmed value (n = 225) for 10 commercial pumps. They are also reported to have a range of 81.2%-99.5% of 1-hour windows within ±15% of the programmed rate (n = 648) at a basal rate of 1U/hour.

In this work, we undertake in-vitro accuracy evaluation of a novel, affordable insulin pump, designed for type-1 diabetic patients in resource-constrained settings.

Methods: Accuracy of the pump under development (IISc. pump or ISP) was evaluated for a 10U bolus dose and at a basal rate of 1U/hour in accordance with the IEC 60601-2-24 standard.

Mean absolute error (MAE) for 2 runs of 12 successive 10U bolus deliveries (n = 24) was determined. Basal delivery accuracy at a rate of 1U/hour for individual 1-hour windows (n = 216) was measured for 3 runs of 72-hours each to plot a trumpet curve.

Results: MAE in the 10U bolus tests for the ISP was 1.2%, with 100% of individual boluses within ±15% of the programmed value. 93.5% of deviations from the programmed value in 1-hour windows, at a 1U/hour basal rate were within ±15%.

Conclusions: The trumpet curve of ISP when compared to Medtronic Paradigm Veo shows lower deviations at lower observation windows. Commercial pumps evaluated by Freckmann et al. (2019) report a better MAE as compared with ISP, however, ISP is well within the ±5% deviation band as reported in literature.

EP221 / #585

Topic: ***AS07-Insulin Pumps***

REAL LIFE EXPERIENCE: EVOLUTION FROM SAP TO HYBRID CLOSED LOOP SYSTEM IN PATIENTS WITH TYPE 1 DM

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Background and Aims: With the aim of achieving an improvement in the intensification of insulin treatment in patients with type 1 diabetes mellitus (DM1), it had been developed different intelligent systems to modify insulin infusion based on user monitoring data. In this study we compared systems with predictive low glucose suspend algorithm with their subsequent upgrade to closed loop systems.

Methods: We select a group of patients, Tandem T Slim X2 Basal IQ (TS-BasalIQ) users, they were matched with patients of the same sex and similar ages and time of evolution of diabetes, Medtronic MiniMed 640G (MM640G) users. Affiliation, anthropometric, clinical data and device data downloads were collected. We repeat this process after upgrading to Control IQ algorithm (TS-ControlIQ) and Medtronic MiniMed 780G (MM780G) respectively.

Results: We finally included 14 patients. Their characteristics are shown in Table 1.

Data from analysis of glycemic control parameters are shown in Table 2.

We found statistically significant differences in the comparison of TIR between TS-BasalIQ and TS-ControlIQ, (p = 0.028). There were not statistically significant differences between MM640G and MM780; neither between MM780G and TS-ControlIQ in our population of study.

Table 1 - Patient's characteristics. Mean ± SD.

	TS-BasalIQ	MM640G	TS-ControlIQ	MM780G
Women (n)	3	3	3	3
Age (year)	37.7 ± 11.2	38.4 ± 10.4	37,7 ± 11.2	38.1 ± 10.1
Diabetes duration (years)	26.0 ± 13.6	24.0 ± 9.5	26.0 ± 13.6	23.1 ± 10.5
Time with SAP (years)	4.1 ± 2.8	4.8 ± 3.4	4.1 ± 2.8	5.4 ± 3.7

Table 2 - Results of the analysis of glycaemic control parameters

	TS – BasalIQ	MM640G	TS – ControlIQ	MM780G
Total daily insulin dose (U)	38.5 ± 14.4	43 ± 11.7	36.8 ± 10.5	41.3 ± 7.7
Total daily insulin dose, units per kg (U/Kg)	0.52 ± 0.2	0.58 ± 0.1	0.52 ± 0.2	0.61 ± 0.2
Mean sensor glucose (mg/dl)	153 ± 29.6	145 ± 9.8	142 ± 12.8	135 ± 9.5
CV (%)	32.8 ± 3.4	33.3 ± 6.5	32.0 ± 1.8	35.5 ± 5.4
TIR 70 – 180 (%)	65.99 ± 10.6	75.35 ± 2.4	77.4 ± 5.9	80.1 ± 8.3
TUR < 70 (%)	4.8 ± 6.4	3.5 ± 2.4	2.9 ± 2.7	3.3 ± 2.0
TAR > 180 (%)	29.2 ± 14.6	21.2 ± 11.0	21.1 ± 8.8	15.1 ± 6.5
Estimated HbA1c (%) (GMI)	7.0 ± 1.0	6.7 ± 0.3	6.6 ± 0.4	6.6 ± 0.2

Conclusions: In our population, we obtained a superior result with a statistically significant difference in TIR between TS-BasalIQ and TS-ControlIQ. Without finding differences with statistical significance in the different parameters we have studied. Hybrid closed loop systems were shown to be effective in achieving desirable glycemic control goals. More studies will be necessary as we receive and test updates to these systems and new ones in real life situation.

EP222 / #598

Topic: ***AS07-Insulin Pumps***

A COMPARATIVE STUDY USING CONTROL-IQ CLOSED LOOP SYSTEM VS BASAL-IQ SYSTEM IN VERY YOUNG CHILDREN WITH TYPE 1 DIABETES (T1D): CLINICAL EFFECTIVENESS AND SAFETY

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Background and Aims: Background: Few data are available on the benefits and safety of the advanced hybrid closed-loop (AHCL) Control-IQ system and its relationship to glycemic outcomes, in very young children with type 1 diabetes (T1D). The aim of the study was to evaluate the impact of Tandem t:slim X2 Control-IQ system unselected-group of patients with T1D, compared to Tandem t:slim T2 Basal-IQ system.

Methods: Materials and Methods: We analyzed glycemic parameters, time in different glucose ranges (2-weeks sensor and pump data were downloaded) and rates of acute complications in very young children with T1D using Tandem Control-IQ system compared to Basal-IQ system.

Results: Results: Ten subjects with T1D were included (mean age: 4.6 ± 1.9 years, mean weight: 19 kg, mean height: 102.6 cm). Higher time in rage (TIR)% ($P = 0.05$) and less time above range (TAR >250 mg/dl)% ($P = 0.01$) were reported using Control-IQ system, compared to Basal-IQ system. Better glycemic variability indices in terms of mean standard deviation (SD) ($P = 0.01$) and coefficient of variation (CV) ($P = 0.002$) with similar glycemic mean were also seen in Control-IQ system.. No severe hypoglycemic events and DKA episodes were also reported.

Conclusions: Conclusions: Control-IQ system was associated in this group of young patients with a greater TIR%, lower TAR% >250mg/dl and better glycemic variability than the Basal-IQ system, with similar total daily dose of insulin and with very low dose of basal insulin between groups, without any problem of safety.

EP223 / #610

Topic: ***AS07-Insulin Pumps***

COMPARISON OF SAP VS MDI WITH CGM IN VERY YOUNG CHILDREN WITH NEWLY DIAGNOSED TYPE 1 DIABETES: CLINICAL EFFECTIVENESS AND LONG TERM BENEFITS.

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Background and Aims: *The <7% HbA1c target recommended by the ADA and ISPAD is attained by <20% of children with T1D. Advances in technologies for T1D aim to improve metabolic outcomes, life of quality, and reduce complications. These include sensor augmented pumps (SAP), continuous glucose monitoring (CGM), predictive low glucose suspension algorithms, and closed-loop systems. This study assesses the long-term outcomes of SAP therapy compared to multiple daily injections (MDI) initiated at onset in young children with T1D.*

Methods: 54 patients <4 years of age with T1D were enrolled over 9 years. 24 subjects started CSII within 3 months of diagnosis, and 30 subjects received MDI therapy from onset. BMI, BMI-SDS, HbA1c, and total daily insulin dose (TDD/kg) were collected from admission and every 4-6 months. HbA1cAUC >6%, rates of acute complications, glycemic variability indices and, glucometrics were recorded.

Results: Patients with CSII therapy had significantly lower estimated mean HbA1c values when compared to subjects receiving MDI therapy. CSII recorded lower mean HbA1cAUC >6%, TDD/kg, and higher BMI-Z scores. TIR reported higher in patients with CSII, and hyperglycemia events were lower. Better glycemic variability indices were seen with CSII therapy in terms of estimated mean glycemia, standard deviation, Coefficient of Variation, and HBGI. There was no statistically significant difference between frequency of severe hypoglycemia and diabetic ketoacidosis episodes between both groups.

Conclusions: Early initiation of CSII compared to MDI treatment determines better glycemic control with lower glucose variability and exposition of hyperglycemia in very young children with T1D, thus preventing long-term complications.

EP224 / #653

Topic: ***AS07-Insulin Pumps***

TIME IN RANGE IN CHILDREN WITH TYPE 1 DIABETES IN A PEDIATRIC UNIT

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Background and Aims: Continuous or intermittent glucose monitoring (CGM) is an important tool to evaluate and manage glycaemic control in diabetic patients. The aim was to evaluate time in, below and above range (TIR, TBR, TAR), in type 1 diabetic pediatric (DM1) patients and its relation with disease time and insulin bolus.

Methods: Retrospective study with pediatric patients with DM1 on insulin pump (IP) and with CGM, observed between July and September of 2021. A1C hemoglobin, demographic, CGM and IP data were studied. Statistical analysis was made using SPSS® 22.

Results: We included 107 patients (55% boys), with a mean age of 12,6 ± 3,8 years. Disease duration was 5,3 (0,6-16,6) years and IP therapy duration 2,6 (0,1-10,1) years. The readings per day were 10 (2-84), TIR was 48,9 ± 14,8%, TAR 43,4 ± 17,1%, TBR 5 (0-28)% and hypoglycemic events per day were 11 (0-56). Total daily dose of insulin per kilo (TDD/Kg) was 0,89 (0,3-1,74) units, 35,3 ± 9,2% of daily basal dose (%basal) and 64,7 ± 9,3% of daily bolus dose (%bolus). The number of bolus per day (bolus/day) was 6,0 (2,8-13,9). Disease duration was weakly correlated with TBR (r = 0,202), hypoglycemic events (r = 0,240) and A1C hemoglobin (r = 0,287). TDD/Kg was weakly correlated with TIR (r = -0,315). There was no significant correlation between bolus/day and any variable.

Conclusions: A higher number of bolus did not affect TIR. Longer disease time was associated with worse glycaemic control, which may justify the association between higher TDD to a lower TIR. Accessible closed-loop systems and CGM would be important towards improving TIR.

EP225 / #738

Topic: ***AS07-Insulin Pumps***

IMPACT OF NEW TECHNOLOGIES ON QUALITY OF LIFE AND GLUCOSE CONTROL IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Background: technological advances in glucose monitoring and continuous subcutaneous insulin infusion (CSII) should aim to improve glucose control and quality of life in type 1 diabetes (T1D). Aim: to compare different devices on glucose control and quality of life in T1D.

Methods: sixty-nine T1D patients (mean age 39 ± 12; 31 males) were recruited. 36 were on multiple daily insulin injections (MDI), 33 on CSII devices including Medtronic Minimed 640G and 670G, Theras Omnipod, Roche Insight and Movy Tandem. Glucose monitoring was performed with Dexcom-G6, Guardian sensor and Flash Freestyle Libre. The Diabetes Treatment Satisfaction Questionnaire (DTSQ), the Diabetes Specific Quality Of Life Scale (DSQOLS) and The Short Form (36) Health Survey (SF-36) were administered to test quality of life. HbA1c, time in range (TIR), time above the range (TAR) and time below the range (TBR) were investigated as glucose control parameters.

Results: patients in the CSII group had higher treatment-related satisfaction (84.8% vs 52.8%, p = 0.005), and better disease acceptance (84.8% vs 52.8%, p = 0.012) compared with patients on MDI, despite similar age (CSII mean age 41 ± 11.6, MDI 38 ± 12.5). No differences were observed among devices (p = ns). TIR resulted higher in the CSII group than in the MDI group (p = 0.001). The Dexcom G6 group had higher TIR values than the Freestyle (p = 0.03) group, but similar to the Medtronic (p = 0.12) group.

Conclusions: technological devices may improve quality of life over MDI treatment. Type of glucose monitoring system may also impact glucose control.

EP226 / #752

Topic: ***AS07-Insulin Pumps***

PERCEPTION OF QUALITY OF LIFE, DEGREE OF SATISFACTION AND GLYCEMIC CONTROL IN USERS OF YPSOPUMP®

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Background and Aims: Ypsopump® (Ypsomed) is an insulin pump available in Spain since 2018. The objective was to evaluate the impact of Ypsopump® on glycemic control, degree of satisfaction and quality of life in adults with T1D.

Methods: Ypsopump® users of at least 6 months participated in an online survey using Google Forms. Sociodemographic, clinical and biochemical data were collected. Perceived satisfaction was assessed with the ''Diabetes Impact and Device Satisfaction'' (DIDS) scale. The benefits and perceived barriers were assessed with the ''Insulin Pump Attitudes Questionnaire'' (IPA). The data were analyzed using SPSS

Results: 26 patients participated, 68.5% being women of 40 ± 12.5 years old using Ypsopump® 14 ± 5 months. The main indications for CSII were marked glycemic variability (37.5%) and high HbA1c despite intensified MDI (31.3%). Improved glycemic control and decreased hypoglycemic episodes were reported by 84% and 80% of the participants, respectively. Technical problems presented 11.5%. The DIDS scale showed a high degree of satisfaction (88%) for its ease of use (88%) and the feel of being more in control of their diabetes (92%). The main benefits perceived according to the IPA questionnaire were: more flexibility in their daily routine and that can do sports more spontaneously. The main barrier was that others could immediately see that they have diabetes. HbA1c before CSII therapy was 8.2 ± 0.6 and at 6-12 months was 7.1 ± 0.4 ($p < 0.01$).

Conclusions: A high degree of satisfaction in terms of glycemic control and improvement of QoL was observed among users of Ypsopump® alongside with a significant reduction in HbA1c.

EP227 / #774

Topic: ***AS07-Insulin Pumps***

COMPARISON OF INTENSIFIED INSULIN THERAPY IN COMBINATION WITH SELF-MONITORING BLOOD GLUCOSE, CONTINUOUS GLUCOSE MONITORING AND SENSOR AUGMENTED INSULINPUMP TREATMENT IN TYPE 1 DIABETIC PREGNANT WOMEN

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Background and Aims: Maternal and fetal complications are still high in type 1 diabetes. Since 2020 the continuous glucose monitoring (CGM) system is reimbursed in Hungary. We expect to achieve a more balanced blood sugar during pregnancy, a lower variability and less complication.

Methods: 36 type T1D women data were analyzed, 8 of them delivered 2 times during the examined period. We enrolled 22 pregnant women using intensified insulin therapy (ICT) with self-monitoring blood glucose and 19 pregnant women using CGM. In 9 of the 19 pregnancies with CGM, fractional human insulin therapy was used and 10 patients were on insulin pump therapy. We enrolled pregnant women less than 12 weeks of pregnancy.

Results: HbA1c levels were significantly higher during the first trimester in the ICT+SMBG group than in the ICT+CGM group, but there was no difference during third trimester. HbA1c improved significantly between the first and third trimester in the ICT+SMBG group. Comparing the three groups there were no difference in maternal complications. In the SAP group birth weight was higher than in the traditional ICT group. Insulin dose were significantly higher in the ICT+ SMBG group during the first trimester than in the SAP group, but in the third trimester difference diminsed.

Conclusions: Patients in the CGM groups started with a better carbohydrate metabolism. There was no preterm birth in SAP group, while in the SMBG group, 3 children were born at 34th weeks. The improvement in HbA1c between the first and third trimesters underscores the role of close control in the SMBG group

EP228 / #775

Topic: ***AS07-Insulin Pumps***

EFFICACY AND SAFETY OF SENSOR-AUGMENTED PUMP THERAPY EVALUATED BY TIME IN RANGE IN AN OLDER ADULT POPULATION WITH TYPE 1 DIABETES.

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Background and Aims: The literature supports less stringent glycemic targets in older adults with type 1 diabetes (T1D), although the evidence for this recommendation is limited. Our objective is to describe the efficacy and safety of sensor-augmented pump therapy (SAPT) in a population of older adults with T1D.

Methods: Descriptive, cross-sectional, observational study that included patients with T1D older than 60 years, treated with SAPT. CGM data were analyzed considering time in range (TIR%), time above range (TAR%), time below range (TBR%), coefficient of variation (CV%) and use. sensor, as well as information related to geriatric assessment and sociodemographic characteristics.

Results: 45 patients were included (53.3% men, mean age 67.1 years and A1c 7.47% with IQR 6.5-8.12). The TIR% was $75.4\% \pm 9.9$, TAR% 19.7 ± 7.4 and TBR%<70 mg/dL and <54 mg/dL were $2.4\% \pm 2.3$ and $0.47\% \pm 0.81$ respectively. The CV% was $33.1 \pm 6.13\%$ and the use of the sensor was 86.7%. Most of the patients did not meet criteria for functional dependence, risk of malnutrition, or neurocognitive disorder. 7.03% and 4.9% of the patients met the criteria for frailty and sarcopenia, respectively. We found that the lower the muscle mass, the higher the CV%.

Conclusions: Our older adult population mostly meets the criteria for good metabolic control with the goals for young adults, without increasing TBR%. This is explained by a low prevalence of frailty and sarcopenia. Patients with lower muscle mass had significantly higher glycemic variability, which is explained by the known association between sarcopenia and poorer metabolic control.

EP229 / #794

Topic: ***AS07-Insulin Pumps***

FIRST EXPERIENCES OF PATCH PUMPS IN ARGENTINA: PILOT STUDY IN 25 TYPE 1 DIABETIC NAIVE INSULIN PUMPS TREATMENT.

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Background and Aims: To analyze metabolic laboratory and statistics data from Smart pix software parameters of the Accu-chek Solo administrator, three months before and after the patch pump placement, in patients with type 1 diabetes who were previously undergoing intensified treatment with multiple doses of insulin.

Methods: Data was collected anonymously and with the prior informed consent of the patient.T1DM patients older than 18 years,not pregnant or lactating women who had been on MDI for at least 6 months were included.A period of 90 days before and after the placement of the patch pump Accu-Chek Solo was analyzed.

Results: Data from 25 adult patients with T1DM who met the inclusion criteria were analyzed, from January 2020-agust 2021.10 men and 15 women were included.The mean age was 35,4 (CI 19-54) years and the mean years since diagnosis was 12 (CI 3-30). The average and SD were: A1c pre-13% ± 1.8, post 8% ± 0.95; BGM test/day pre 3.4 / d ± 1.5, post 4.5 / d ± 0.97; Glucose Average pre 198mg / dl ±49, post 171mg / dl ±31; GV % pre 42 ± 7,7, post 41 ± 7,3; PIR (70-180mg / dl) pre 45% ± 16, post 56% ± 13; LBGI pre 2,1 ± 3,1 post 1.7 ± 2,5.

Conclusions: After 3 months of patch pump treatment, patients showed significant metabolic changes, greater adherence, and a greater percentage of measurements in range, with a significant percentage of hypoglycemia reductions. Prospective studies will be necessary to analyze the continuity of these long-term results.

EP230 / #120

Topic: ***AS08-New Medications for Treatment of Diabetes***

EFFICACY AND SAFETY OF GLUCOLO PLUS IN TYPE 2 DIABETES MANAGEMENT (GLEEN STUDY): A DOUBLE-BLIND, RANDOMISED, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER TRIAL.

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Background and Aims: Diabetes is a chronic disease associated with many comorbidities and a higher risk of mortality. Patients are constantly in the lookout for Complementary and Alternative Medicines (CAM) that are safe and efficacious.

Methods: This double-blind randomised placebo-controlled trial evaluated the effects of daily GlucoLo Plus, a newly formulated CAM for diabetes type 2. The primary outcome was to evaluate the effect of GlucoLo Plus on HbA1c and the secondary outcome was it's effect on bodyweight.

Results: Of 64 individuals assessed for eligibility, 61 (mean HbA1c 6.98% [52.8 mmol/mol], mean age 67.3 years [SD 9 · 5], 26 [43%] women, mean diabetes duration 3.2 years, and mean body-mass index 27 · 9 kg/m^2) were randomly assigned to GlucoLo Plus (n = 32 [53%]), or placebo (n = 28 [47%]). 1 participant was lost to follow up. At 12 weeks, GlucoLo Plus decreased HBa1c by 0.83% (P = 0.0131) while placebo reduced it by 0.12% (p = 0.6151). GlucoLo Plus arm had a mean 1.84 lbs weight loss while the placebo arm had a 0.21 lbs weight gain. The most frequent adverse events with GlucoLo Plus were mild and transient gastrointestinal events including nausea (9.3% vs 3.5%) and dyspepsia (15.6% vs 10.7%).

Conclusions: GlucoLo Plus significantly lowered the HbA1c, had a positive effect on bodyweight and had a minimal side effect profile. These results suggest that GlucoLo Plus could be an alternative and adjunct to type 2 diabetes in people who are reluctant to initiate or add new antidiabetic agents.

EP231 / #133

Topic: ***AS08-New Medications for Treatment of Diabetes***

REAL-WORLD EFFECTIVENESS OF IGLARLIXI THERAPY IN OUTPATIENTS WITH TYPE 2 DIABETES: THE SOLO RETROSPECTIVE COHORT STUDY

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Background and Aims: Background: The effectiveness and safety of iGlarLixi for treatment of people with T2D has been demonstrated in randomized clinical trials, but data on the use of iGlarLixi in real-life setting is needed **Aim:** To evaluate the effectiveness and safety of iGlarLixi use in a daily clinical practice to manage T2DM outpatients.

Methods: SOLO is a retrospective multicenter cohort study conducted in Moscow (Russia). T2DM adults with an HbA1c ≥7% were eligible in case of availability of medical records during at least 180 days before the start of fixed-ratio

combination of glargine 100 U/ml and lixisenatide (iGlarLixi) treatment - Index Date (ID), and 1 valid HbA1c record within 150-210 days after ID.

Results: Medical records of 383 T2DM adults were included (mean age 59.9 ± 8.3 years; mean BMI 36.4 ± 6.3 kg/m^2; mean HbA1c 9.14 ± 1.08%). At ID 65% of participants were receiving oral antidiabetic drugs (OADs) alone; 31.3% -OADs with basal insulin (BI). There was significant decrease of HbA1c by 1,38 ± 0.93 and 1,74 ± 0.90 % after 6 and 12 months ($p < 0.001$), and a significant decrease of body weight by 1.96 ± 4.03 kg at month 6 and by 3.13 ± 4.71 kg at month 12 ($p < 0.001$). Overall, 4 participants (1.04%) reported symptomatic hypoglycemia (glycemia ≤3.9 mmol/L); no severe hypoglycemia episode was reported.

Conclusions: In a real-world setting in Russia, initiation of iGlarLixi in adults with T2DM suboptimally controlled on OADs alone or combined to BI resulted in an improved glycemic control and body weight change with a reduced risk of hypoglycemia.

EP232 / #144

Topic: *AS08-New Medications for Treatment of Diabetes*

POPULATION PHARMACOKINETIC MODELING OF DASIGLUCAGON IN SUBJECTS WITH TYPE I DIABETES MELLITUS

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Background and Aims: Zegalogue® was recently approved by FDA for the treatment of severe hypoglycemia in pediatric and adult subjects with diabetes aged 6 years and above. Dasiglucagon is the active ingredient in Zegalogue® and the first physically and chemically stable analog of human glucagon. To quantify the impact of subject covariates on pharmacokinetics (PK) of the novel, ready-to-use glucagon analog dasiglucagon, we developed a population PK model.

Methods: PK profiles (n = 337) of dasiglucagon following subcutaneous administration (0.1-1.0mg) were obtained from subjects with T1DM across six clinical trials and used for the model development. Nine covariates were evaluated in the population PK analysis using NONMEM version 7.4.3/PsN.

Results: Dasiglucagon pharmacokinetics was dose-linear in the tested dose range (0.1 to 1.0 mg) and was adequately described by a 1-compartment model with first-order absorption and elimination, including an absorption lag-time and standard allometric scaling by body weight. The final model included injection site and age as covariates on bioavailability and predicted lower exposure following thigh, buttocks, and deltoid vs. abdomen injection and in pediatric vs. adult patients. MDRD eGFR and sex were included as covariates on apparent clearance and absorption rate constant, respectively, predicting higher exposure with lower eGFR and faster absorption in female patients. The model also accounted drug content at end-of-shelf-life storage.

Conclusions: The model-predicted effects of PK covariates on dasiglucagon exposure generally fell within the observed exposure from the analysis population receiving 0.6 mg dasiglucagon and observed across the trials to result in reliable recovery from hypoglycemia. Overall, the model reliably predicted the observed data.

EP233 / #216

Topic: *AS08-New Medications for Treatment of Diabetes*

THE PODOCALYXIN AND LIPID METABOLISM INDICATORS LEVELS IN PATIENTS WITH TYPE 1 DIABETES MELLITUS AND DIFFERENT LEVELS OF ALBUMINURIA

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Background and Aims: Currently a special emphasis is being placed on the study of the disorders development pathogenetic mechanisms at the diabetic nephropathy preclinical stages, which will not only allow diabetic complication early diagnosis, but will also can help to establish primary kidney damage early biomarkers. The aim of this study was to establish the podocalyxin level in urine and lipid metabolism indicators in the blood serum of patients with type 1 diabetes mellitus and different levels of albuminuria.

Methods: Reproductive age 56 men with T1DM divided into 2 groups: 24 patients with albuminuria A1 stage (A1 group) and 32 patients with albuminuria A2 stage (A2 group). The control group consisted of 28 healthy men. Enzyme immunoassay and spectrophotometric methods were used.

Results: Higher podocalyxin values were found in A1 (p = 0.003) and A2 (p = 0.004) group compare to control group. According to the results, A1 group had higher median values of total cholesterol (TC) (p = 0.005), triacylglycerides (TG) (p = 0.007) and very low-density lipoproteins (VLDL) (p = 0.006) relative to control. A2 group also differed from the control values with higher values of TC (p = 0.001), TG (p = 0.022), VLDL (p = 0.026).

Conclusions: Regardless of the level of albuminuria, men with T1DM had podocalixin and lipid metabolism parameters significantly increased levels. Data of this study can be used as the basis for the potential strategies of diabetic nephropathy development prevention and early treatment.

EP234 / #224

Topic: *AS08-New Medications for Treatment of Diabetes*

DUAL GIP-GLP-1 RECEPTOR AGONIST TIRZEPATIDE IMPROVES GLUCOSE CONTROL AND INSULIN SENSITIVITY IN MIXED MEAL TESTS IN PEOPLE WITH TYPE 2 DIABETES

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Background and Aims: Tirzepatide, a dual GIP and GLP-1 receptor agonist, produced superior glycemic control and body weight reductions as compared with selective GLP-1 receptor agonists in type 2 diabetes (T2D) clinical trials. We explored the effects of tirzepatide on glucose control and on measures of insulin sensitivity during standardized mixed-meal tolerance testing (sMMTT).

Methods: Within a randomized, double-blind, Phase 1 trial including placebo, tirzepatide-15mg, and active comparator semaglutide-1mg in T2D, sMMTT was conducted at baseline and 28-weeks, with measurement of blood glucose and insulin. Insulin sensitivity indices were calculated (Matsuda, OGIS and Stumvoll).

Results: At 28-weeks, tirzepatide reduced HbA1c by 2.05% and body weight by 11.2kg. Reduction of glucose total AUC 0-240 min was significantly greater with tirzepatide (41%) than with semaglutide (34%) or with placebo (increased by 1%) at 28-weeks (both $p \leq 0.002$). Greater glucose AUC reduction with tirzepatide was paralleled by greater reduction in fasting glucose ($p \leq 0.006$), while incremental AUC was not significantly different between tirzepatide and semaglutide ($p = 0.11$). The three sMMTT insulin sensitivity indices improved more with tirzepatide than with placebo or semaglutide. For instance, Matsuda index increased by 164% with tirzepatide vs 14% with placebo and 77% with semaglutide (both $p < 0.001$).

Conclusions: Treatment with tirzepatide substantially improved glucose control and sMMTT insulin sensitivity in people with T2D, consistent with hyperinsulinemic-euglycemic clamp M-values. Insulin sensitivity improvement is a likely factor contributing to the better sMMTT glucose control seen with tirzepatide than with semaglutide.

EP235 / #327

Topic: ***AS08-New Medications for Treatment of Diabetes***

EARLY DEESCALATION WITH IDEGLIRA IN PATIENTS WITH TYPE 2 DIABETES USING SHORT-TERM HUMAN BASAL-BOLUS THERAPY TO CORRECT SEVERE HYPERGLYCEMIA

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Background and Aims: In selected patients with T2DM complex insulin regimens initiated for correcting severe hyperglycemia and applied at least for 3 months can be safely deescalated with IDegLira. As basal-bolus therapy (BBT) can reverse glucotoxicity in a few days we hypothesized that deescalation can be performed much earlier, even within the first week after the initiation of insulin treatment. We examined prospectively the efficacy and safety of early deescalation with IDegLira in patients with T2DM applying short-term human BBT for correcting severe hyperglycemia.

Methods: Human BBT initiated for severe hyperglycemia (HbA1c>11% or HbA1c>9% with clinical symptoms of hyperglycemia and/or fasting glucose >13.9mmol/L or random glucose >16.7mmol/l) was switched to IDegLira after reaching a blood glucose range below 10 mmol/l usually on the first week of therapy if the previously insulin-naive patient had a c-peptide value >1.1ng/ml, the daily dose of BBT was <60IU and insulin requirement was <0.6IU/kg. Patients are controlled in every 4 months.

Results: Between february 2020 and september 2021 early deescalation was performed in 44 patients. The first 4-month control has so far been performed in 24 patients (62% newly diagnosed T2DM, mean age 57.5 ± 12 years, mean BMI $30.93 \pm 5.08 kg/m^2$). During the follow-up HbA1c decreased from $12.16 \pm 1.69\%$ to $6.14 \pm 0.66\%$ ($p < 0{,}0001$), body weight decreased from $88.95 \pm 16.93 kg$ to $86.93 \pm 18.15 kg$ ($p = 0{,}17$) and mean daily insulin dose changed from 40.7 ± 9 IU to 21.8 ± 6 units. Mild hypoglycemia occurred in 2 patients.

Conclusions: Early deescalation with IDegLira in selected patients with T2DM applying temporary human BBT to correct severe hyperglycemia is safe and results in significant glycemic improvement in the short-term.

EP236 / #368

Topic: ***AS08-New Medications for Treatment of Diabetes***

PORTABILITY OF NASAL GLUCAGON FOR THE RESCUE OF SEVERE HYPOGLYCEMIA: STABILITY AND PERFORMANCE EVALUATION ACROSS A BROAD RANGE OF TEMPERATURES

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Background and Aims: Nasal glucagon (NG) is a ready-to-use, drug-device combination therapy for treatment of severe hypoglycemia. Portability is key, as NG should be carried by persons with diabetes at all times. In designing for portability, medication must allow for exposure to a broad range of temperatures without significant adverse effect on product quality/performance. We evaluated the stability and performance of NG at temperatures -20 to +30°C to mimic real-world situations.

Methods: Testing focused on characterization of drug product (glucagon amount) and combination product performance (consistent delivery to nasal cavity). Critical quality elements, including chemical purity and content, particle size, actuation force, delivered dose, shot weight, spray pattern and plume geometry, were evaluated after being exposed to temperatures -20 to +30°C, a range broader than room temperature storage [e.g; 15° to 25°C] for products such as glucagon for injection.

Results: All testing demonstrated that 100% of critical quality elements were satisfied. NG could be exposed to frozen (-20°C), refrigerated (2 to 8°C), and up to 30°C conditions for the 2-year shelf life from the date of manufacture. Degradation of glucagon followed Arrhenius kinetics (i.e. slower degradation rates at lower temperatures). Temperature cycling studies showed no significant changes in the chemical/product performance attributes.

Conclusions: These analyses indicate no adverse impact to NG from a chemical and physical perspective when exposed to frozen, refrigerated, and up to 30°C conditions. Stability across a broad range of temperatures facilitates portability of NG as a rescue medication for severe hypoglycemia.

EP237 / #461

Topic: ***AS08-New Medications for Treatment of Diabetes***

USE OF BASAL INSULIN-GLP1 COMBINATION FOR THERAPEUTIC SIMPLIFICATION IN TYPE 2 DIABETIC PATIENTS WITH A BASAL-BOLUS OR BASAL PLUS SCHEME

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Background and Aims: Basal insulin-glp1 has been a treatment option with benefits as an intensification strategy. However, the evidence these combinations as a tool in therapeutic simplification has been not complete studied. Therefore, this study aimed to study the efficacy and effect of the use of basal-glp 1 insulin as a simplification terapy.

Methods: Observational study of a cohort of patients with basal-bolus or basal plus scheme at the Foundation Santa Fe de Bogotá Diabetes Center from January 2019 to July 2021 with a basal-glp1 insulin combination (Degludec-Liraglutide or Glargine-Lixisenatide) as a therapeutic simplification strategy. Changes in HbA1c, weight, insulin dose, and hypoglycemia were measured.

Results: Enrolled 28 patients, 15(53%) men, mean age of 70 years, and diabetes for 19.3 years. Metabolic control 15(53%) and hypoglycemia reduction 9(32%) were used as Indication for change. Follow-up time of 16.8 months, 3 (10,7%) patients discontinued (adverse effects, poor control, and change to oral medication). There was a significant decrease in HbA1c (0.8%), weight loss (2.1 kg), and lower insulin dose requirement (Table 1). No level 2 or severe hypoglycemia occurred. Seven patients required rapid insulin. Table 1.

	Baseline	Final monitoring	Wilcoxon/ T paired p-value
	Mean (SE)	Mean (SE)	
Basal-plus n:7(25%)	34.1 / 12.2	0	0.032
ID:(basal/bolus)			
Basal-Bolus n:21(75%)	28.1 / 24.4	0	
ID:(basal/bolus)			
Combination dose (IU)	0	22.7 (1.7)	
HbA1c(%)	8.0 (0.4)	7.2 (0.2)	0.011
Weight(Kg)	76.1 (2.8)	74 (2.9)	0.004
Fast acting ID	21.2 (2.6)	4.5 (1.9)	<0.001

*ID: insuline dose IU

Conclusions: The basal-glp1 insulin simplification strategy decreases Hba1c, weight and insulin dose in selected patients.

EP238 / #464

Topic: ***AS08-New Medications for Treatment of Diabetes***

EFFICACY AND SAFETY OF LIRAGLUTIDE IN AN INDIAN ADOLESCENT POPULATION WITH T2DM AND OBESITY: A SINGLE CENTRE EXPERIENCE FROM EASTERN INDIA

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Background and Aims: To investigate the safety, and efficacy of liraglutide in Indian adolescents with type 2 diabetes and obesity. This would be the first real world study from Indian subcontinent investigating the efficacy and safety of Liraglutide in this population, since the approval of Liraglutide in adolescent T2DM

Methods: This was an observational prospective trial. Thirty-one subjects, age between 12-17 years , with obesity (body mass index [BMI] corresponding to both a BMI ≥95th percentile for age and sex and to a BMI of ≥30 kg/m2 for adults were initiation with liraglutide to receive 12 weeks of treatment with liraglutide (0.6 mg with weekly dose escalated to a maximum of 1.8 mg for the last 4 weeks.

Results: All participants receiving liraglutide up to 1.8 mg, and only 4 had at least 1 treatment emergent side effect (TEAE). The most common TEAEs were gastrointestinal disorders. No severe TEAEs, TEAE-related withdrawals, or deaths occurred. No severe hypoglycemic episodes were reported. The HbA1c decreased significantly from 8.06 ± 1.79 % to 6.07 ± 0.98 %, $p < 0.001$. The body weight also decreased from 69 ± 1.14 kgs to 64.9 ± 2.32 kgs, $p < 0.001$ with a corresponding drop in the BMI from 27.87 ± 1.18 kg/m2 to 25.17 kg/m2. The HOMA-IR was reduced significantly from 3.14 to 2.34, $p = 0.017$ with a simultaneous increase in insulin sensitivity from 34.52 to 45.45, $p = 0.014$.

Conclusions: In Indian T2DM adolescents with obesity, liraglutide demonstrated a similar efficacy and safety profile compared with adults when administered to T2DM adolescents with obesity, with no unexpected safety/tolerability issues.

EP239 / #516

Topic: ***AS08-New Medications for Treatment of Diabetes***

SEARCH FOR NONCONVENTIONAL TREATMENT FOR DIABETES: ANTIDIABETIC, ANTIDYSLIPIDAEMIC, ANTIOXIDANT, SIALOGLYCOCONJUGATE, HAEMATOPOETIC AND WOUND-HEALING EFFECTS CONFER ON ANOGEISSUS LEIOCARPUS A TARGET FOR FURTHER TECHNOLOGICAL STUDIES.

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Background and Aims: *Anogeissus leiocarpus* modulated sialic acids as predictive, potent diagnostic biomarker with prognostic value in alloxan-induced diabetic dogs. Hence its antidiabetic, antidyslipidaemic, wound-healing and antioxidant activities were investigated in alloxan-induced diabetic dogs and rats.

Methods: Four groups of 3 dogs and four groups of 9 wistar rats were assigned nondiabetic (ND), diabetic untreated (DU), diabetic insulin-treated (DI) and diabetic extract-treated (DE). All dogs were assayed for fasting blood glucose, hepato-renal disease biomarkers, electrolytes, triglycerides, total cholesterol, low- and high-density lipoproteins (LDL, HDL). Internal organs of the rats were assayed for oxidative stress biomarkers, malondialdehyde, superoxide dismutase, catalase, glutathione and fasting blood glucose. Another four groups of 3 dogs, surgically

wounded, 14 days after established hyperglycaemia, were non-diabetic (NDW), diabetic untreated (DWU), diabetic insulin-treated (DWI) and diabetic extract-treated (DWE). Data were subjected to ANOVA with GraphPad Prism ® statistical package and Tukey's post-hoc tests; $P < 0.05$ is significant

Results: Severe aberrations of varying significance ($P < 0.05$; 0.01; 0.002; 0.001) occurred in the blood and organs of DU dogs and rats. The hyperglycaemia, induced anaemia, hepato-renal disease, electrolytes, dyslipidaemia and antioxidant biomarkers of oxidative stress were restored to normal by oral administration of ethanolic extract of *A. leiocarpus* at similar significant levels, without reversal of hyperglycaemia after withdrawal. The extract produced moderate to complete granulation and epithelial tissue formation with fully developed scar on day 21 post skin-wound.

Conclusions: *A. leicarpus* is potent nonconventional treatment for diabetes and complications from dyslipidaemia, oxidative stress and delayed wound-healing.

EP240 / #562

Topic: ***AS08-New Medications for Treatment of Diabetes***

RESULTS OF THE AUTOLOGOUS MESENCHYMAL STEM CELL TRANSPLANTATION IN PATIENTS WITH TYPE 1 DIABETES MELLITUS AND TYPE 2 DIABETES MELLITUS

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Background and Aims: Recent clinical studies have shown a promising stem cell role in the treatment of type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM). We evaluated the effect of autologous mesenchymal stem cell transplantation (AMSCT) on carbohydrate metabolism in T1DM and T2DM patients.

Methods: We examined 7 patients (5 male, 2 female, aged 20-42) with T1DM and 6 patients (4 male, 2 female, aged 37-57) with T2DM, who underwent AMSCT (cells were obtained from the patients' iliac crest and cultivated for 3-4 weeks) by intravenous infusion. The quantity of autologous mesenchymal stem cells infused was from 95 to 97×10^6. We analyzed the daily insulin dosages, glycated hemoglobin (HbA1c), leptin, glutamic acid decarboxylase (GAD) antibody and Langerhans antibody levels in patients before,1, 2 and 3 months after the AMSCT procedure.

Results: In patients with T1DM, AMSCT led to decrease in daily insulin dosage levels from 58,8 ±13,71 Units to 47,5 ± 12,7 Units ($p = 0,04$) with trend to increase leptin levels and decrease HbA1c levels**,** from 7,73±3.5 ng/ml to 16,9 ± 8,31 ng/ml ($p = 0,046$) and 9,59 ± 1,73% to 8,65 ± 0,93 % ($p = 0,092$) after 1 month, respectively. GAD antibody and Langerhans antibody levels didn't change significantly after AMSCT. In patients with T2DM, AMSCT resulted in a decrease in HbA1C levels from 6,76±0,4 % to 6,4±0,415% ($p = 0.095$) after 3 months.

Conclusions: The AMSCT led to decrease of the daily insulin dosage and glycated hemoglobin levels with increase of the leptin levels after 1 month without increasing of the GAD and Langerhans antibody levels within 3 months in patients with T1DM.

EP241 / #595

Topic: ***AS08-New Medications for Treatment of Diabetes***

TYPE 1 DIABETES: IMPACT OF SGLT-2 INHIBITORS ON GLYCEMIC CONTROL

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Background and Aims: Background: The use of SGLT-2 inhibitors (iSGLT2) in patients with type 1 diabetes (T1DM) has been growing, with EMA approval. More evidence is needed to optimize their use. Aim: To analyze the impact of iSGLT2 on global glycemic profile in a group of T1DM

Methods: A retrospective longitudinal study conducted in people with T1DM, who initiated therapy with an iSGLT2 (dapagliflozin 5mg). The following data were collected, before and after 3 months, using AGP and libreview: GMI, CV, TIR, TAR, TBR, level of fasting glucose, pre-meal glucose and 2h post-meal glucose (lunch/dinner), total daily insulin dose (TDD), basal and prandial doses, and body weight.

Results: 17 patients; mean age 36.1 years (±11.1); 58.8% female; 64.7% under CSII. After introduction of dapagliflozin: overall glycemic improvement. Statistical difference was found in TIR, increasing from 50.9% to 60.2% ($p = 0.019$). Both the CV and GMI decreased from 43.7% to 40.7% ($p = 0.001$) and 7.6% to 7% ($p = 0.001$). TDD reduced from 53.9 U to 44 U ($p = 0.001$), as well as basal (30U to 25U) and bolus doses (24.7 to 20U). Median fasting glucose decreased from 161.9 to 144.9 ($p = 0.023$), as well as levels of pre and post-meal glucose, that reduced significantly. A reduction in TAR was also found, although with no statistical significance (41.5 to 32.2, $p = 0.058$). There was no statistical difference in TBR. There was a statistically significant reduction in weight (4.4 kg; $p < 0.001$).

Conclusions: Introduction of iSGLT2 improved glycemic control (GMI, CV, TIR) covering the pre- and postprandial periods. This was accompanied by a reduction in weight

EP242 / #693

Topic: ***AS08-New Medications for Treatment of Diabetes***

MENOPAUSAL HORMONAL THERAPY ALLOWS REDUCING DIABETIC NEUROPATHY SYMPTOMS IN POSTMENOPAUSAL WOMEN

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Background and Aims: The estrogens have some neuroprotective action and the estrogen deficiency in postmenopausal women can deteriorate nerve dysfunction. We hypothesized that Menopausal Hormonal Therapy (MHT) in these patients would prevent of metabolic disorders and progression of diabetic complications.

Methods: We examined 61 postmenopausal women with type 2 diabetes and diabetic sensorimotor neuropathy (SMN). We excluded women with contraindications to MHT. All participants were divided on three groups: the first group (27 patients) had received estradiol valerate 2mg/per day plus progestagen, the second one (18 women) had received estradiol valerate 1mg/per day plus progestagen, the third group (16 patients) had received placebo.

Results: The patients of the three groups had same age (52.6±2.71, 55.5±3.07 and 52.7±3.52 years respectively; p=0.57), duration of diabetes (11.8±3.88, 8.6±3.74 and 9.9±4.34 years respectively, p=0,57) and anthropometric parameters. The HbA1c levels were 8.0±2.29, 8.2±2.69 and 8.3±3.22% respectively (p=0.93). We found moderate or severe SMN in all patients. Confirmed/severe Cardiac Autonomic neuropathy (CAN) were observed in 71.2, 77.8 and 69.8 % respectively. MHT resulted in improvement of Neuropathic Disability Score (9.0±2.92 at baseline and 7.1±2.58 after treatment, p=0.04) as well as sural nerves conduction study (9.0±1.93 mV and 30.9±2.96 sm/sec at baseline and 14.2±2.97 mV and 39.8±5.30 sm/sec after treatment, p=0.04) for women in first group. No changes in the neurological examination were found for other participants. Moreover incidence of CAN regression was 70% for first group and 57% for second one after treatment.

Conclusions: MHT were followed by restoration of diabetic neuropathy parameters. It's effect depends on the dose of estrogen.

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Topic: ***AS08-New Medications for Treatment of Diabetes***

INHALED GLUCAGON, A NEW WELL-ACCEPTED THERAPEUTIC TOOL IN PEDIATRICS

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Background and Aims: The safety data obtained from these studies demonstrated that nasal glucagon is well tolerated as an emergency treatment of severe hypoglycaemia in adult and pediatric patients with diabetes 4 years of age and older. The most frequently reported adverse reactions in the adult population associated with its use were increased lacrimation (36%), irritation of the upper respiratory tract (34%), nausea (27%), headache (21%) and vomiting (16 %).

Methods: Evaluate the clinical experience in incorporating BAQSIMI into routine clinical practice. Methods: DM1 patients over 4 years old, enrolled in school, from the start of follow-up in specialty consultations at our center. Previous use of GLUCAGEN hipoKIT

Results: 68 children older than 4 years (35♂), mean age 9.5 to [4-17]. HbA1c (DCA): 7.7% [6.8-9.2], time to debut 3.8a [0.8-10.1]. 93% use of MDI, 5 pumps. 100% correct use of inhaled glucagon. There was no impediment due to medical inspection except in 1 case (belonging to another health area). Previous severe hypoglycemia with previous loss of consciousness in <5% of cases (0.03 patient / year cases). Number of recipes made 70. (67 unique +3 multiples). 3 episodes of severe hypoglycemia (loss of consciousness, crisis) (2 in the same patient) associated with exercise + incomplete intake and / or incorrect bolus calculation. The 3 cases in MDI.Recovery WITHOUT sequelae and almost immediately. Symptoms manifested: tearing (33%), irritation of the upper respiratory tract (33%), nausea (33%), headache (66%) and vomiting (33%). Paternal evaluation: excellent (3/3

Conclusions: our study demonstrates the efficacy of inhaled glucagon

EP244 / #86

Topic: ***AS08-New Medications for Treatment of Diabetes***

ASSESSMENT OF PATIENT SATISFACTION AND CLINICAL EFFICACY WITH SEMAGLUTIDE IN SUBOPTIMALLY CONTROLLED PATIENTS WITH T2DM: A STUDY BASED ON THE FLASH GLUCOSE MONITORING SYSTEM

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Background and Aims: To assess the metabolic effectiveness and patient satisfaction reported outcomes of once-weekly semaglutide compared to iraglutide in suboptimally controlled patients with T2DM.

Methods: We included suboptimally controlled patients with T2DM who had completed liraglutide for at least three months at baseline, then shifted to Semaglutide and followed up for the same period. Glucometrics data of FGM system (mean average glucose, glycemic variability, time above range (TAR) 1, and (TIR) for baseline and follow-up were compared. To assess the satisfaction with shifting, we used the valid Arabic version of the (DTSQs) and (DTSQc) while the injection device preference was assessed using the Diabetes Injection Device Preference Questionnaire (DID-PQ)

Results: The mean HbA1c level reduced significantly after Semaglutide initiation (7.79% vs. 8.07%, p<0.001). Compared to the AGP data at baseline, we observed a significantly improved mean average glucose, GV, TAR , and TIR 7 (p-value <0.001). Data from the DTSQs showed a lower level of patient-reported satisfaction with the previous once-daily liraglutide treatment, with a higher perceived frequency of hyperglycemia, with a higher level of satisfaction in males compared to females (P<0.001). At the end of follow-up, the overall patients reported a high level of satisfaction after shifting to once weekly semaglutide treatment in all of the DTSQc domains, with comparable levels of treatment satisfaction between males and females. All patients preferred/strongly preferred once-weekly Semaglutide over once-daily liraglutide in the majority of DID-PQ questionnaire domains.

Conclusions: Switching once-daily liraglutide insulin to once-weekly semaglutide led to improvements in both clinical measures of glycemic control and patient-reported satisfaction

EP245 / #445

Topic: ***AS09-New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices***

DOSE OPTIMIZATION STUDY (DOS): SIMPLIFIED 2X DOSE OF INHALED TECHNOSPHERE INSULIN PROVIDES SIGNIFICANT REDUCTION IN POST PRANDIAL GLUCOSE EXCURSIONS WITH NO NEW SAFETY CONCERNS

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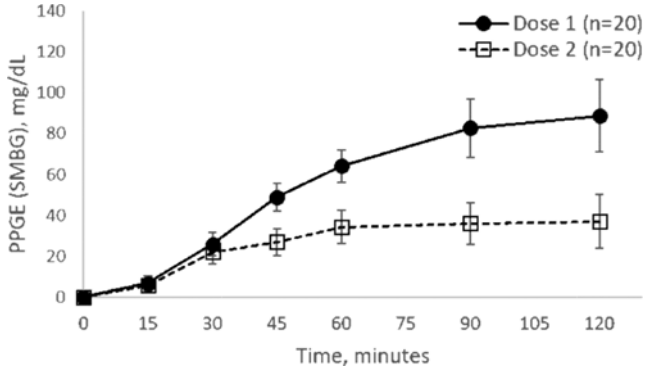
Background and Aims: Technosphere Insulin (TI), is an ultra-rapid-acting inhaled insulin approved for use in USA and Brazil, and available in 4U, 8U and 12U cartridges. This proof-of-concept study compared the efficacy of two different TI doses, by measuring mean change in post-prandial glucose excursion (PPGE) for an identical standardized meal. Secondary objective was to evaluate safety.

Methods: Twenty patients with T1D or T2D, on basal-bolus insulin therapy, received a pre-prandial dose of TI based on the current US label for switching from SC mealtime insulin (SCMI). At a subsequent visit, all subjects received a pre-prandial dose of TI calculated by doubling the SCMI dose and rounding down to the nearest TI dose. TI doses were administered immediately prior to consuming an identical standardized meal. SMBG was measured by Ascensia Contour™ meters.

Results: The simplified higher (~2x) dose provided significant reductions in PPGE from 45 to 120 minutes post-meal (48.9 vs 27.0 mg/dL @ 45 min, $P < 0.01$; 88.6 vs 36.9 mg/dL @ 120 min, $P < 0.001$). Peak glucose was reduced from 228.6 to 179.3 mg/dL ($P < 0.001$). Fourteen of the 20 subjects were also on CGM. The PPGE excursions measured by CGM in these 14 patients showed a significant reduction in PPGE from 60 to 120 minutes post-meal. There was no severe hypoglycemia, and no significant changes in FEV_1 were observed.

Conclusions: A simplified 2x pre-prandial dose of TI significantly reduced post-prandial glucose excursion vs. the current label recommended dose, as measured by SMBG or CGM, with no new safety concerns.



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Topic: ***AS09-New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices***

TIME-IN RANGE PATTERNS AROUND CLINIC VISITS AMONG PATIENTS WITH TYPE 1 DIABETES USING A SMART INSULIN PEN

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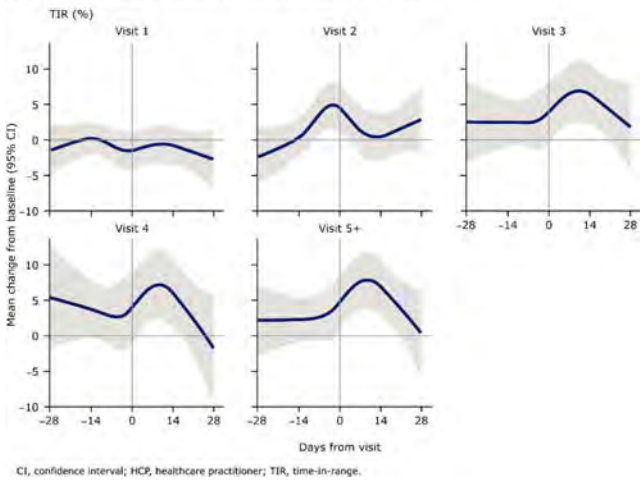
Background and Aims: In a single-arm, prospective, proof-of-concept study of patients with type 1 diabetes (T1D), smart insulin pen (NovoPen® 6) use was associated with improved glycaemic control and fewer missed bolus doses (MBD).[1] This *post hoc* analysis explored patterns of glycaemic control and injection behaviour around the time of patients' visit at the diabetes clinic.

Methods: Data from NovoPen®6 and continuous glucose monitoring (CGM) devices were uploaded at each routine visit at the clinic and used during the consultation by the patient and healthcare practitioner (HCP). Patients could not access complete injection data between clinic visits. Glycaemic control was measured as time-in-range (TIR; 3.9–10.0 mmol/L) over 180 days (mean value). Uploaded data were paired with the closest visit, ±28 days, and analysed using a cubic spline linear mixed model.

Results: Data from 87 patients were analysed. While TIR generally increased over the study, TIR peaked during the first 14 days after each visit and subsequently decreased to day 28 post-visit, from Visit 3 onwards (Figure). A similar trend was observed for the number of MBD.

Conclusions: Smart pen data may support qualified discussions at HCP visits, improve TIR, and reduce MBD. Our analysis suggests that there is a need for tools that maintain these improvements between HCP visits. These tools could be smart phone applications that provide injection data overviews, and virtual HCP visits, which may play an important role in the digital health space.

Figure. Mean change in TIR from baseline to each HCP study visit.



CI, confidence interval; HCP, healthcare practitioner; TIR, time-in-range.

EP247 / #226

Topic: ***AS10-Devices Focused on Diabetic Preventions***

HEALTH ECONOMIC IMPACT OF POSITIVE AIRWAY PRESSURE TREATMENT IN PATIENTS WITH SLEEP APNEA AND TYPE 2 DIABETES: A DIFFERENCE-IN-DIFFERENCE ANALYSIS

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Background and Aims: The clinical benefit of positive airway pressure (PAP) therapy has been demonstrated in patients with both type 2 diabetes (T2D) and sleep apnea.The aim of this study was to determine the health economic impact of PAP therapy in this patient population.

Methods: A retrospective analysis of Medicare and commercial claims data from 2016-2018 was conducted. Patients with T2D and newly diagnosed sleep apnea were enrolled into two groups based on the use of PAP therapy. We used difference-in-difference approach to compare the total healthcare costs in the 6-month period before and after the diagnosis of sleep apnea.

Results: Our study identified 18,028 patients with T2D and newly diagnosed sleep apnea, of whom 3,706 (20.6%) were PAP users. After adjusting for for age, gender, CCI (Charlson Comorbidity Index), region, payer type, and index date, at the end of 6 months after the diagnosis of sleep apnea, we found a significant reduction in total healthcare costs of $1,896 in the PAP group compared to the non-PAP group (a 23% reduction, $p < 0.0001$). The total healthcare costs reduction was $2,336 in commercial patients and $1,292 in Medicare Fee-For-Service patients (33% and 19% reduction, respectively, $p < 0.0001$). Compared to the non-PAP group, healthcare costs of PAP treatment group decreased by 94% in outpatient, 67% in inpatient, and 57% in office setting($p < 0.0001$).

Conclusions: Our findings suggest that PAP usage can produce significant healthcare costs reduction in the 6-month period after the initiation of the PAP therapy in patients with T2D and newly diagnosed sleep apnea.

EP248 / #284

Topic: ***AS10-Devices Focused on Diabetic Preventions***

DEMPOWER STUDY: EVALUATION OF THE EFFECT OF A PATIENT EMPOWERMENT AND COMMUNICATION DIGITAL TOOL ON METABOLIC CONTROL IN T2DM PATIENTS

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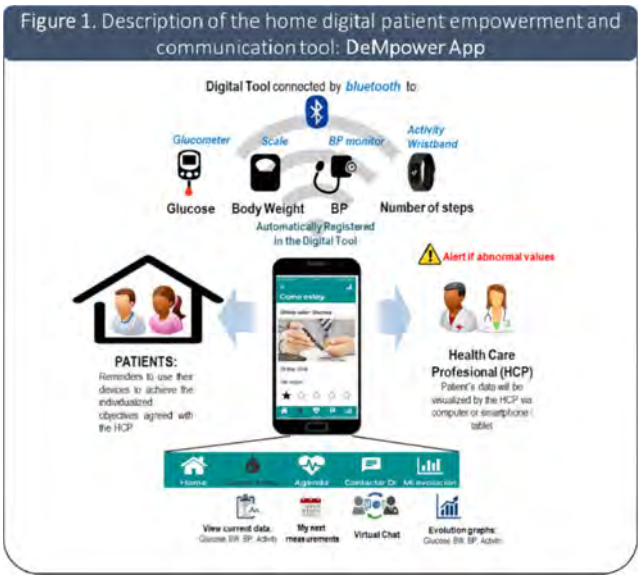
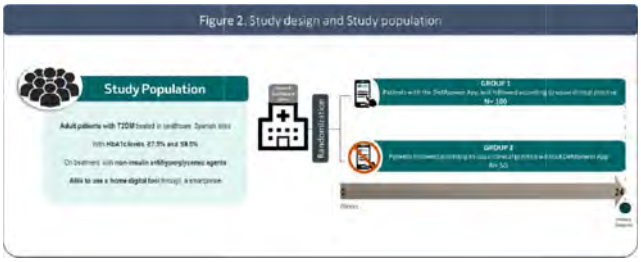
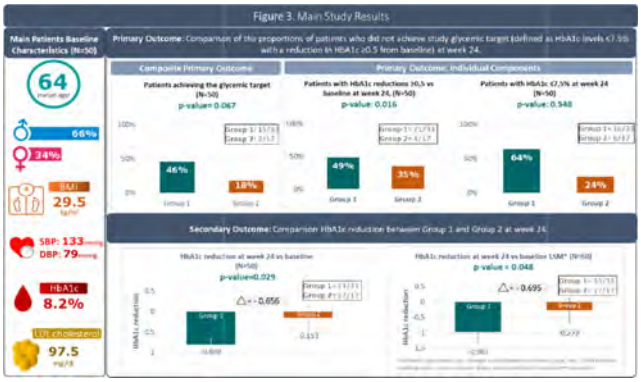
Background and Aims: There is still a high number of inadequately controlled T2DM patients. Therefore, it is essential to develop innovative solutions to improve patient's empowerment by increasing patient-physician communication and their self-management. The aim of this study was to analyze the effect of a home digital patient empowerment tool (Figure 1), on metabolic control in T2DM patients.

Methods: Multicentric, randomized prospective clinical trial including adult T2DM patients without adequate glycemic control treated according to usual clinical practice across Spain. Figure 2 summarizes the study design and study population. The primary endpoint was the comparison of the proportion of patients who did not achieve the study glycemic target (defined as HbA1c levels ≤7.5% with a reduction in HbA1c ≥0.5 from baseline) at week 24 between groups 1 and 2. It was also performed a comparison of mean HbA1c changes from baseline to week 24 between groups 1 and 2.

Results: The COVID-19 pandemic led to a premature study closure since patient's enrollment and follow-up were active during the 2020 lockdown. In total, 50 patients completed week 24 visit. Figure 3 shows the main study results. 46% patients from group 1 achieved study glycemic target vs 18% in group 2







($p = 0.067$), whereas the difference in the HbA1c reduction between group 1 and 2 was -0.66% ($p < 0.05$).

Conclusions: Our results suggest the patient empowerment through a home digital tool might allow an improvement in metabolic control and consequently a more effective management of T2DM.

EP249 / #436

Topic: ***AS10-Devices Focused on Diabetic Preventions***

PHASE 3 TRIALS OF PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH DIABETIC RETINOPATHY (DR) WITH OR WITHOUT DIABETIC MACULAR EDEMA (DME)

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Background and Aims: DR, including DME, is a main cause of blindness in adults of working-age. Treatments that lessen treatment burden of anti-vascular endothelial growth factor (VEGF) intravitreal injections while maintaining their clinical benefits are needed. The Port Delivery System with ranibizumab (PDS) is an innovative drug delivery system for continuous delivery of the anti-VEGF ranibizumab into the vitreous. PDS 100mg/ml was approved by the US FDA for the treatment of neovascular AMD in adults who have previously responded to at least 2 anti-VEGF injections. The designs of two ongoing, multicenter, randomized phase 3 trials to evaluate efficacy, safety, and tolerability of PDS 100mg/mL in DR with and without DME are described.

Methods: Pavilion (NCT04503551; $\sim n = 160$) will evaluate the prophylactic effects of PDS with refill-exchanges every 36 weeks (Q36W) versus clinical observation in moderately severe-severe non-proliferative DR without DME. Pagoda (NCT04108156; $\sim n = 545$) will evaluate the tolerability of PDS with refill-exchanges Q24W and its efficacy versus intravitreal ranibizumab 0.5mg Q4W injections in DME.

Results: The primary endpoint of Pavilion is the proportion of patients with a ≥2-step improvement from baseline on the Early Treatment Diabetic Retinopathy Study (ETDRS) Diabetic Retinopathy Severity Scale at week 52. The primary endpoint of Pagoda is change from baseline in best-corrected visual acuity (ETDRS letters) averaged over weeks 60 and 64. Both trials will report incidence, severity, and duration of adverse events and patient experience questionnaires.

Conclusions: These trials will inform on the safety and efficacy of PDS in DR with and without DME.

EP250 / #439

Topic: ***AS10-Devices Focused on Diabetic Preventions***

PREVALENCE OF ANXIETY AMONG TYPE 2 DIABETES PATIENTS IN A TUNISIAN POPULATION

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Background and Aims: Anxiety is associated with decreased functioning and quality of life. It may have added importance in diabetes for its potential adverse effects on regimen adherence and glycemic control. **Objective:** To estimate the prevalence of clinically significant anxiety in adults with diabetes.

Methods: We performed a cross-sectional study in 200 patients with type 2 diabetes consulting in endocrinology of kairouan hospital in Tunisia. The prevalence of anxiety was estimated using the Hospital anxiety and depression scale assessment.

Results: The rate of anxiety among our population was 35 %. Factors found to be associated with anxiety were hypertension, complications (nephropathy and neuropathy, foot amputation) , low physical activity, high BMI, insulin use and hypoglycemia. Frequent Blood glucose self monitoring was also found to be associated with anxiety ($p = 0{,}03$). Age, gender, glycemic control, coronary artery disease and stroke were not associated to anxiety in our study.

Conclusions: Since the prevalence of anxiety was greater among T2DM patients , public health initiatives are needed to prevent and treat this disorders in T2DM patients, specifically those with the above mentioned risk factors.

EP251 / #46

Topic: ***AS10-Devices Focused on Diabetic Preventions***

EFFECT OF EDUCATION ON KNOWLEDGE, ATTITUDE AND NUTRITIONAL BEHAVIOR OF PATIENTS WITH TYPE 2 DIABETES

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Background and Aims: Background: Nutrition and medical care prevents the incidence and increase of complications in patients with diabetes. There are controversial believes about the effect of education on the knowledge, attitude and practice of patients with type 2 diabetes. This study aimed to assess the effectiveness of education on knowledge, attitude and nutritional behavior of type 2 diabetic patients.

Methods: Methods: In an interventional study, 80 patients with type 2 diabetes were selected from the Tehran Abouzar Clinic (Iran) and allocated randomly in two intervention and control groups. Data collection was conducted before and 3 months after the intervention using a questionnaire including two sections, demographic information and questions assessing the knowledge, attitude, and nutritional behavior. The intervention was nutritional care education during two group discussion-based sessions in 30 minutes and by a two week interval

Results: Results: After the educational program, knowledge increased significantly in both intervention and control groups, which was probably due to the routine education program in that center. But significant increase in attitude and behavior was only observed in the intervention group.

Conclusions: Conclusion: Appropriate educational programs should be performed in type 2 diabetes clinics to promote attitude and behavior as well as knowledge of the patients.

EP252 / #477

Topic: ***AS10-Devices Focused on Diabetic Preventions***

MICROBIOME CHARACTERIZATION IN TYPE 2 DIABETES MELLITUS – RELATION TO VITAMIN D LEVELS

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Background and Aims: The human microbiome plays a very important role in the functionning of normal metabolic and immune system. Vitamin D helps in maintaining healthy intestinal microbiome and thus it improves glucose homeostasis in diabetes. The objective of our study was to characterize the composition of the microbiome in patients with type 2 diabetes mellitus (T2DM) in comparison to controls with normal glucose tolerance and to correlate the levels of Vitamin D with the changes in the microbiota.

Methods: The complex gut microbiome was analysed by the new generation sequencing method (GANZIMMUN Diagnostics AG) in 17 patients with T2DM and 16 disease-free controls; the groups were subdivided according to the levels of Vitamin D.

Results: A significant increase in butyrate-producing bacteria was found in controls with higher Vitamin D levels, as well as in controls compared to T2DM in subgroups with normal Vitamin D levels. Percentage of Eubacterium spp. significantly increases with normalization of Vitamin D in diabetic group. There is an increased amount of Bilophila wadsworthia in patients compared to controls in both subgroups - twice in the group with normal Vitamin D and 4 times in the group with low Vitamin D levels. The results showed 4 times higher amount of Enterobacter spp., Escherichia spp. and Pseudomonas spp. in patients compared to controls. After normalization of Vitamin D levels, the amount of Escherichia spp. significantly reduced.

Conclusions: The changes of microbiome are good targets for modulation in T2DM. **Acknowledgement**: The study was supported by BSNF Grant NoКП-06-H33/10, 2019.

EP253 / #478

Topic: ***AS10-Devices Focused on Diabetic Preventions***

USING MHEALTH FOR TYPE 2 DIABETES RISK REDUCTION IN URBAN AND RURAL INDIA – A PILOT STUDY

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Background and Aims: Mobile health (mHealth) applications are being used to reduce type 2 diabetes (T2D) risk. We created two novel diabetes prevention apps, which were assessed in parallel to two commercially available apps. Changes in anthropometric and clinical parameters associated with T2D were assessed.

Methods: The novel apps developed in-house were BUD.D [(BD) a chatbot] and Sweet Hack [(SH) a gaming app], and the commercially available apps were HealthifyMe (HM) and Google fit (GF). Participants aged 25-60 years, at high diabetes risk assessed by fasting blood sugar and the Indian Diabetes Risk Score were randomised to one of the five arms in urban (4 apps and control) or 3 arms in the rural areas (2 apps and control), as commercial apps were not available in local language. The intervention period was 3-4 months in the urban and approximately 2 months in the rural area.

Results: 400 urban and 210 rural participants from TamilNadu, India were recruited, with preliminary data from 100 urban and 192 rural participants reported in the table below. The median age was 39 (range: 23-60) years and 50% were males. Weight improved in SH groups in urban and rural areas. Blood pressure improved significantly in GF and HM groups.

Conclusions: With study completion, a complete dataset of primary and secondary outcomes will be available by March 2022. The results of this randomised controlled trial will help establish the benefits of mHealth apps on reducing risk of T2D within urban and rural populations in India.

Table 1: Percent change (%) from baseline to post intervention

	Urban Area (n=100)					Rural Area (n=192)		
Apps	BUD.D	Sweet Hack	GoogleFit	HealthifyMe	Control	BUD.D	Sweet Hack	Control
Variables	n=19	n=17	n=20	n=22	n=22	n=70	n=67	n=55
Weight (Kg)	1.5	-0.9	0	0.3	2.1	1.5	-0.4	0.3
BMI (Kg/m2)	3.3*	-0.9	0.7	1.4	2.5	1.3	-0.4	1.3
Systolic BP (mm/Hg)	-3.9	-2.4	-3.9*	-5*	-0.1	-0.8	-0.1	-0.4
Diastolic BP (mm/Hg)	-1	1.3	-3.7	1.4	No Change	-1.6	0.1	-1.5*
Fasting Blood Sugar (mg/dL)	0.5	14.8	23.5*	2	11.7	-1.5	-3.3*	-5.7*

*Paired t-test: p<0.05

EP254 / #498

Topic: ***AS10-Devices Focused on Diabetic Preventions***

ACCEPTABILITY OF TWO NOVEL MHEALTH APPLICATIONS FOR DIABETES PREVENTION IN URBAN AND RURAL INDIA

H. Ranjani[1], P. Avari[2], S. Nitika[1], N. Jagannathan[1], J. Valabhji[2], J. Chambers[3], V. Mohan[4], N. Oliver[2], R.M. Anjana[4]

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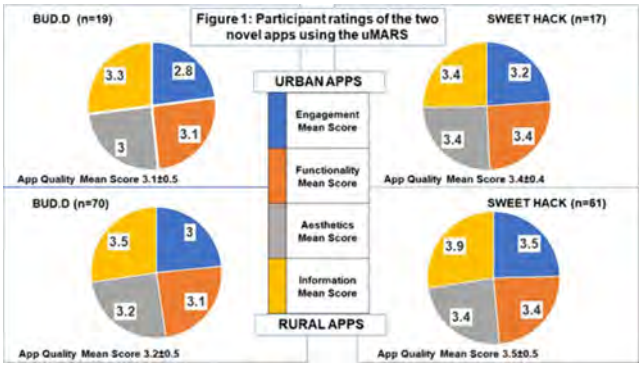
Background and Aims: A recent report states that healthcare applications (apps) have low retention rates (31%). We aimed to assess the acceptability of two recently developed novel apps for diabetes risk reduction, in urban and rural India.

Methods: We designed two novel apps: BUD.D (a chatbot embedded with artificial intelligence [AI]) and Sweet Hack (a gaming app with each level providing educational material on diabetes prevention). The apps were tested on 400 urban and 210 rural participants (aged 25-60 years, at high risk for diabetes) in a randomized controlled trial. Both apps were bilingual (English/Tamil). Acceptability and engagement were assessed using uMARS (User Mobile App Rating Scale). The intervention period was 3-4 months in the urban and approximately 2 months in the rural area.

Results: Acceptability and engagement data (preliminary) of 100 urban and 186 rural participants are reported in the figure below. Overall, the median age was 39 (range: 23-60) years and 50% were males. uMARS scores showed that the app quality mean score for both the apps were acceptable (3 and above) in urban and rural settings. SH rural scored high on each of the uMARS subscales along with overall quality followed by SH urban and BD rural. BD (urban and rural) scored low on engagement.

Conclusions: The novel mHealth apps (chatbot and gaming apps) were acceptable in urban and rural India and could therefore play a role in prevention of diabetes by creating awareness about healthy lifestyle practices.



EP255 / #500

Topic: ***AS10-Devices Focused on Diabetic Preventions***

USING MHEALTH APPS FOR BEHAVIOUR CHANGE IN URBAN AND RURAL INDIA –A PILOT STUDY

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Background and Aims: mHealth Applications are being used to modify behaviour for diabetes prevention. We aimed to assess changes in diet and physical activity after an mHealth intervention in urban and rural India.

Methods: Four mHealth apps for diabetes prevention were assessed: two novel apps developed in-house were BUD.D [a chatbot embedded in artificial intelligence (AI)] and Sweet Hack (a gaming app), and the two commercially available apps in India were HealthifyMe (HM) and Google fit (GF). Participants aged 25-60 years, at high diabetes risk assessed by fasting blood sugar and the Indian Diabetes Risk Score were randomised to one of the five arms in urban (4 apps and control) or 3 arms in the rural areas (2 apps and control), as commercial apps were not available in local language. The intervention period was 3-4 months in urban and approximately 2 months in the rural area.

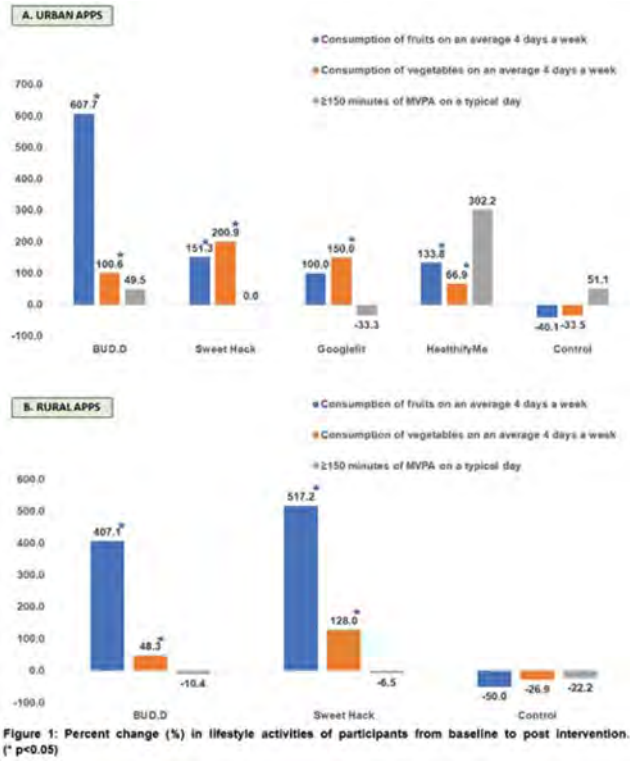

Figure 1: Percent change (%) in lifestyle activities of participants from baseline to post intervention. (* p<0.05)

Results: 400 urban and 210 rural participants from Tamil Nadu, India were recruited, with preliminary data from 100 urban and 192 rural participants reported in the figure below. The median age was 39 (range: 23-60) years and 50% were males. All intervention group participants showed an increase in the consumption of fruits and vegetables compared to control in both urban and rural areas. Urban participants showed an improvement in moderate to vigorous physical activity (MVPA).

Conclusions: Mobile health applications can have a positive effect on dietary and physical activity behaviours in urban and rural Indians at high risk for diabetes.

EP256 / #503

Topic: ***AS10-Devices Focused on Diabetic Preventions***

CHIC-D - CARDIOVASCULAR HEALTH IN CHILDREN WITH TYPE 1 DIABETES - EARLY DETECTION, CARDIOVASCULAR PREVENTION AND TREATMENT MONITORING

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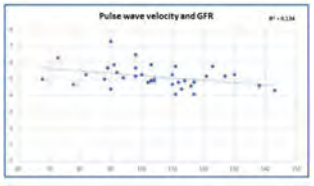
Background and Aims: We aim to determine the time course of vascular changes in children with T1D and the impact of metabolic control and blood pressure on changes in the arterial wall. Our objective is to establish a highly sensitive method of cardiovascular risk evaluation and treatment monitoring for paediatric patients with T1D.

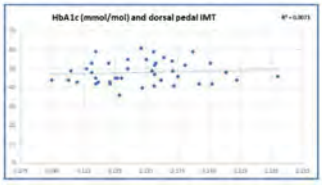
Methods: Children (6-15,99yr) with T1D duration of ≥5 years were randomly selected from the pediatric diabetes registry SWEDIABKIDS. We use ultra-high frequency ultrasound, enabling separate visualization of the layers in the arterial wall combined with measurements of pulse wave velocity (PWV), endothelial function and blood pressure. 50 children with T1D and 29 healthy controls have been included this far.

Results: Preliminary results show an approximately 11% increase in dorsal pedal (DP) intima- media thickness (IMT) among the children with type 1 diabetes (p = 0.05). A tendency towards increased intima- thickness (IT) in the radial artery and media-thickness (MT) in DP among the children with T1D was also seen (p = 0.09, p = 0.09) as well as a negative correlation between DP IMT and GFR (-0.32 p = 0.05) and a positive correlation between DP IMT and aortic PWV and HbA1c (0.38 p = 0.01, 0.32 p = 0.04).

Conclusions: Increased DP IMT in this well treated cohort of children with T1D (HbA1c 48.1 ± 5.9 mmol/mol) may be an important marker for early vascular impact. The correlation between DP IMT and HbA1c further supports the importance of metabolic control. The correlation between PWV and GFR indicates a connection between micro-and macro vascular impact. Using our sensitive methods preventive treatment strategies may be tested in the future.

	T1D patients n=46	Healthy controls n=26	p- value
Age (years)	12.0 ± 2.3	11.2 ± 2.7	0,156
Weight (kg)	48.3 ± 14.3	45.1 ± 14.6	0,358
Height (cm)	156.4 ± 14.8	151.6 ± 17.6	0,230
T1D duration (years)	7.7 ± 1.8	---	---
HbA1c (IFCC mmol/mol)	48.1 ± 5.9	30.6 ± 2.5	<0.001
HbA1c (DCCT %)	6.6 ± 0.5	4.9 ± 0.2	<0.001
Time in range%(B-glc 4-10 mmol/mol)	64.0 ± 8.5	---	---
Time in target%(B-glc 4-7.8 mmol/mol)	42.6 ± 9.8	---	---
SBP (mmHg)	105.8 ± 6.9	103.5 ± 8.3	0,217
DBP (mmHg)	65.4 ± 4.0	62.1 ± 5.4	0,004





EP257 / #702

Topic: ***AS10-Devices Focused on Diabetic Preventions***

GLUCOSE REDUCTION IN EMPLOYEES WITH DIABETES AFTER LONG-TERM ONE DROP USE

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Background and Aims: It is critical for mHealth interventions to demonstrate sustained long-term outcomes. The present study tests the effectiveness of One Drop for employer-sponsored members with diabetes participating in the program for 6 months or more and 1 year or more.

Methods: This retrospective study evaluated change in weekly average blood glucose (BG) for employer-sponsored members with type 1 or 2 diabetes and BG above target, defined as estimated hbA1c ≥ 7% (eA1c) participating in One Drop's multicondition program for 6 months or more. The first and most recent week of BG logging in the One Drop app were averaged and compared after 6 and 12 months of participation using Wilcoxon signed-rank tests.

Results: Of the 97 participants, 50% were male, 62% were 40 to 60 years old, and use ranged from 6 to 28 months. Those using One Drop for 6 months or more experienced a significant average BG reduction (-26.5 mg/dL, p < .001; -0.9% eA1c). Those who participated for 1 year or more (N = 29) similarly experienced a significant average BG reduction (-35.2 mg/dL, p = .011; -1.2% eA1c).

Conclusions: Achieving long term success in maintaining health changes is a priority for digital health programs. The current study demonstrated sustained clinically and statistically significant reductions of average BG from employees using One Drop after 6 months and 1 year. Moreover, implications of reduced BG have further long-term health benefits.

EP258 / #783

Topic: ***AS10-Devices Focused on Diabetic Preventions***

MEASUREMENT OF CENTRAL AUTONOMIC NERVOUS SYSTEM DYSFUNCTION (ANSD) BY A NOVEL DEVICE: MITIGATING ANSD BY INTERVENTION ENHANCES GLUCOSE HOMEOSTASIS IN TYPE 2 DIABETES

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Background and Aims: All living organisms have built-in mechanisms that modulate organic functions in an adaptive response to the environment with the aim of supporting survival. This process maintains homeostasis. The autonomic nervous system (ANS) is responsible for homeostasis, including glucose homeostasis. ANS dysfunction (ANSD) is held to be an important contributor to type 2 diabetes (T2D). A novel device allows to measure central ANSD by measuring an elevated pressure pain sensitivity of the chest bone (PPS). Further, a non-pharmacological intervention guided by daily PPS measurement has consistently been shown to reduce PPS and thus reestablish a disrupted ANS. The study aims to test the claim that this intervention would reintroduce glucose homeostasis during six months of intervention.

Methods: A randomized study of 112 persons with T2D.

Results: For persons with predefined a reduction of PPS by at least 15 arbitrary units (defined as responders), the homeostatic response measured as the coefficient of correlation (r) of change of HbA1c relative to baseline reached r = 0.75 (N = 52) (intragroup

P < 0.0001), compared to r = - 0.04 for the non-responder group (N = 60) (between group P < 0.0001). When active and control groups were compared, the odds ratio of being a responder was 5.2 (P = 0.0001) (95 % confidence limits 2.3-11.6).

Conclusions: Using a novel device for the measurement of ANSD, demonstrates that ANSD is associated with disruption of glucose homeostasis, and that this condition may be reversed by a non-pharmacological reduction of ANSD.

EP259 / #146

Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

THE ROLE OF EXTRACELLULAR MATRIX PROTEINS DURING IN-VITRO DIFFERENTIATION OF DEFINITIVE ENDODERM (DE) IN 3D CULTURE SYSTEMS

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Background and Aims: Three-dimensional (3D) culture of human embryonic stem cells (hESCs) provides a suitable system for upscaled manufacturing of cells with therapeutic potential such as insulin-producing beta cells. Although it is well established that different components of the extracellular matrix (ECM) play a pivotal role in determination of cell fate, little is known about the composition and dynamics of these components during 3D differentiation.

Methods: A systematic analysis was conducted to determine the expression patterns of the ECM proteins vitronectin, fibronectin and laminin and their corresponding integrins during *in vitro* 3D cultured differentiation of hESCs towards definitive endoderm (DE), the first stage generating beta cells. We next assessed whether the addition of exogenous vitronectin influences DE patterning analyzing specific markers expression via flow cytometry, immunostaining and qPCR.

Results: Upregulation of ECM proteins and integrins specific for DE formation (ITGAV/A5) and vitronectin binding (ITGAVB3) was observed during DE differentiation. Vitronectin supplementation resulted in an increased percentage of cells expressing high levels of the DE marker FOXA2, indicating a positive influence on differentiation towards beta-cells.

Conclusions: This study shows the potential role of vitronectin in differentiation towards DE and indicates that stage specific integrins may serve as markers to purify the desirable cell type used for beta-cell differentiation. Furthermore, these results illustrate the importance of understanding the role of microenvironment during *in vitro* differentiation to better mimic the *in vivo* developmental processes and therefore, enhance differentiation efficiency and specificity.

EP260 / #160

Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN THE POSTOPERATIVE MANAGEMENT OF HYPERGLYCEAMIA AFTER PANCREATICODUODENECTOMY – A COMPARISON WITH POINT-OF-CARE CAPILLARY TESTING

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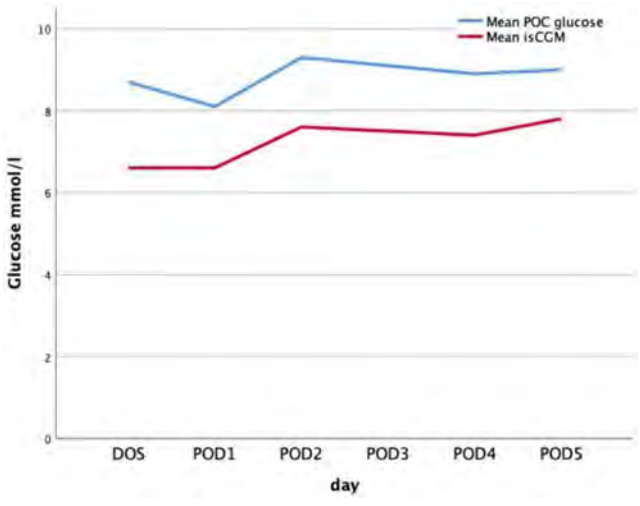
Background and Aims: Intermittently scanned continuous glucose monitoring (isCGM) systems have gained wide acceptance in diabetes care. However, the in-hospital use of these systems has not been thoroughly evaluated, and there are concerns about their accuracy and reliability during various conditions. Patients undergoing pancreaticoduodenectomy (PD) has an increased risk of hyperglycaemia after surgery which is aggravated by parenteral nutrition therapy. This study aims to evaluate accuracy and safety of Freestyle Libre isCMG system during insulin infusion in the postoperative management of hyperglycaemia, compared with point-of-care (POC) testing.

Methods: We prospectively included patients with a resectable pancreatic tumour. After surgery, continuous insulin infusion was initiated when POC glucose >7 mmol/l and titrated to maintain glucose between 7-10 mmol/l. Glucose was monitored both with isCGM and POC and median absolute relative difference (MARD), hypoglycemic events and major deviations were evaluated during five postoperative days.

Results: In total, 2346 paired POC-CGM values of 85 patients undergoing PD between 2017-2019 were evaluated. Mean daily POC was higher (8.8 ± 2.1 mmol/l) than isCGM (7.3 ± 2.3 mmol/l, p < 0.001), as shown in figure 1. Overall MARD was 17.9%, and higher for glucose <5.0mmol/l (MARD 29.6%). 4.5% of all CGM readings were <3.9 mmol/l, but only six events were confirmed with POC testing, none was severe (< 3.0 mmol/l).

Conclusions: isCGM could be useful to reduce the frequency of capillary POC testing during insulin infusion. However, isCGM underestimated glucose compared with POC and thus, a hybrid approach combining these two techniques is suggested.



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Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

CARBONYL STRESS PARAMETERS IN MEN WITH TYPE 1 DIABETES MELLITUS AND ALBUMINURIA DIFFERENT LEVELS

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Background and Aims: It has been shown that carbonyl compounds in diabetes mellitus can for long period accumulate in the organism, which together with other pathogenetic mechanisms leads to the kidneys serious dysregulation. Despite the available research data, there is still insufficient knowledge about the relationship between various renal damage factors and carbonyl stress indicators in the type 1 diabetes mellitus (T1DM) development. Therefore, the **aim** was to study the carbonyl stress parameters level in T1DM patients with albuminuria different levels.

Methods: 56 reproductive age men with T1DM divided into 2 groups: 24 patients with albuminuria A1 stage (A1 group) and 32 patients with albuminuria A2 stage (A2 group). The control group consisted of 28 healthy men. Enzyme immunoassay and spectrophotometric methods were used.

Results: Higher median methylglyoxal values compared to controls in patients of both A1 ($p = 0.0.31$) and A2 ($p < 0.001$) groups were found. Correlation analysis performed in A1 group showed a relationship between glomerular filtration rate (GFR) and creatinine ($r = -0.79$; $p = 0.0001$). A2 group was characterized by correlations between disease duration and albumin/creatinine ratio ($r = 0.47$; $p = 0.018$), GFR with blood creatinine level ($r = -0.44$; $p = 0.027$) and methylglyoxal level ($r = 0.64$; $p = 0.043$).

Conclusions: Thus, increased methylglyoxal concentration in the blood of T1DM patients with initial level of albuminuria may be the DM development unfavorable sign, whereas in A2 level conditions this index may reflect the carbonyl stress potential role in the diabetic nephropathy development.

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Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

IMPORTANCE AND UTILITY OF FIBROSCAN IN ASSOCIATION WITH FIB-4, FOR ASSESSMENT OF LIVER FIBROSIS IN T2DM FEMALE PATIENTS WITH NON-ALCOHOLIC FATTY LIVER DISEASE

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Background and Aims: The routinely used modalities (laboratory tests and ultrasonography), for the diagnosis of NAFLD, are unable to adequately determine the levels of steatosis and fibrosis. Aim of the study is to prove the utility of fibroscan with FIB-4 for early detection of cirrhosis of liver in NAFLD with T2DM female patients

Methods: We assessed liver fibrosis - transient elastography using FibroScan ($n = 42$), with Fibrosis-4 (FIB-4) scores in female patients with T2DM with NAFLD. Stages of fibrosis were (F0 1 - 6, F1 6.1 - 7, F2 7 - 9, F3 9.1 - 10.3, and F4 ≥ 10.4)

Results: Mean age and duration of diabetes was 62 (±9.2, range 38-77) and 12 (±6.8, range 0-25) years, respectively. Mean stiffness score, fibrosis score were 11 (±7.2, range 3.5-34) kPa, 1.9 (±1.4, range 0.48-7.5), respectively. Nineteen (45%) had advanced fibrosis (>F2). Mean platelet (232 ± 67 k/μL), serum ALT (27 ± 18 U/L), serum AST (30 ± 16U/L), were normal. There was significant positive correlation between age and fibrosis score ($r = 0.32$, 95% CI 0.018 to 0.56, $p = 0.038$). Difference in stiffness score was significant in >F2 (16.94 ± 6.72) Vs F2 or less (5.97 ± 1.41); $p < 0.0001$. Duration of diabetes (years) was higher in >F2 (10.89 ± 5.81) Vs F2 or less 5.97 ± 1.41); $p = 0.003$.

Conclusions: Fibroscan with FIB-4 appears to be useful for the diagnosis of fibrosis and mitigates the need for liver biopsy. The high prevalence of fibrosis (asymptomatic for NAFLD) in women with Type 2 Diabetes is alarming.

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Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

TIME ABOVE RANGE EMERGED AS VALUABLE PREDICTOR OF ALBUMINURIA IN PATIENTS WITH LATENT AUTOIMMUNE DIABETES AFTER FOLLOW-UP PERIOD

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Background and Aims: Continuous glucose monitoring (CGM) provides information about glucovariability, considered to be better related to diabetes complication comparing to glycated haemoglobin (HbA1c). The aim was to find out association of time in range (TIR) as important glucovariability metric with metabolic parameters and retinopathy (DR).

Methods: In patients with latent autoimmune diabetes (LADA) aged 49 ± 10.7 yrs. and diabetes duration 10 ± 8.13 yrs. TIR, HbA1c, albumin/creatinine ratio (ACR), estimated glomerular filtration (eGF), lipids and presence of DR were determined and followed after 6 month period. According to consensus TIR was define as the percentage of time spent within glucose range 3.9-10.0 mmol/L. Time above range (TAR) and time below range (TBR) were also considered. All patients underwent adequate education for usage of CGM system. $\alpha = 0.05$ was considered statistically significant.

Results: Among tested variables logistic procedure pointed out diabetes duration as statically significant predictor for retinopathy OR = 1.187, 95%CI (1.024, 1.376),AUR = 0.856. Regression stepwise procedure pointed out TAR ($R^2 = 0.255$) as significant predictor for albuminuria. Hba1c correlated significantly with TIR, TAR and TBR ($p < 0.05$). At the end of tested follow-up period TIR was statically increased (67.63 ± 20.06 - 74.23 ± 15.83, meandiff = -6.60, $p = 0.04$), whereas TAR was decreased (24.20 ± 16.40 - 19.30 ± 16.11, meandiff = 4.9, $p = 0.07$).

Conclusions: TAR emerged as important predictor of ACR. Decrease in TAR, as a metric of glucovariability at the end of the study, pointed at importance of glucovaribility and postprandial hyperglycaemia reduction for prevention of microalbuminuria and microvascular complication.

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Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

AN ARTIFICIAL INTELLIGENCE-POWERED SYSTEM TO ASSESS NUTRIENT INTAKE IN HOSPITALIZED OLDER PATIENTS

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Background and Aims: Malnutrition among older people with chronic diseases, such as diabetes, can lead to muscle loss, impaired wound healing, and increased mortality rates. Real-time, accurate and cost-efficient dietary assessment is of utmost importance not only to tackle malnutrition, but also to manage the therapy of older people with diabetes and thus prevent the onset of hypoglycaemic events. Our aim was to validate an Artificial Intelligence (AI)-powered system to assess the nutrient intake of geriatric patients, who generally have a higher prevalence of malnutrition.

Methods: We validated the newly introduced system in hospitalized older patients. The system requires as an input an RGB and a depth image of the patients' meal tray captured on a standardised mount, before and after meal consumption. The images are then analysed by advanced algorithmic approaches to output the nutrient intake automatically and in real-time.

Results: The system's performance was compared to visual estimations of nutritionists and the standard clinical procedure. It achieved a mean relative error of 11.64% for the energy and <15% for the macronutrients (carbohydrate, protein, fat) intake compared to the visual estimations of nutritionist experts. The errors of the nurses following the standard clinical procedure were >30%, and thus, significantly higher than those of the system.

Conclusions: AI-powered dietary assessment can be potentially integrated in the processes of assessing the nutrient intake and allow better glycaemic control in geriatric patients.

EP265 / #619

Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

METHOD OF THE HIGH-FREQUENCY ULTRASONIC DOPPLEROGRAPHY CAN BE USED FOR ASSESSMENT OF THE CARDIAC AUTONOMIC NEUROPATHY IN DIABETIC PATIENTS

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Background and Aims: Cardiac autonomic neuropathy (CAN) is the reason for early morbidity and mortality on diabetic patients. We estimated the parameters of skin microvascular blood flow in accordance with CAN staging.

Methods: We included 76 patients with type 2 diabetes in the study (24 with resent-onset diabetes (Gr. 1), 26 with diabetic sensorimotor neuropathy (Gr. 2), 26 with history of diabetic foot amputation (Gr. 3)). CAN was detected using cardiovascular autonomic reflex tests and was separated on the groups: CAN 0 (no CAN), CAN 1 (early), CAN 2 (confirmed), CAN 3 (severe). Microvascular blood flow of fingers skin was valuated at rest and with cold impact by method of High-frequency Ultrasonic Dopplerography (HFUD) using the ''Minimax Doppler K'' device (St. Petersburg, Russia).

Results: CAN 1 was found in 8% Gr. 1 patients, 42 and 21% patients in Gr.2 and Gr. 3 respectively. CAN 2 was diagnosed in 27% Gr. 2 and 58% Gr. 3 patients. CAN 3 in 8% Gr. 2 and 19% Gr. 3. Microvascular blood flow at rest were significantly decreased in patients with CN 2-3 in comparison with CAN 0-1 ($Vam = 2.5 \pm 0.66$ sm/min vs. 4.4 ± 0.54 sm/min respectively; $p < 0.05$). The abnormal result of cold test was detected in 94% patients with CAN 2-3 and 26% patients with CAN 1. The predictors of CAN 2-3 were microvascular blood flow at rest (OR = -1.62, 95%CI 1.15-2.89; $p < 0.05$) and abnormal cold-stress vasoconstriction (OR = 3.6, 95% CI 1.15-9.26; $p < 0.05$).

Conclusions: Microvascular blood flow of skin decreased progressively in patients with different staging of CAN. HFUD allowed separating of CAN stages.

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Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

DUODENAL-JEJUNAL BYPASS LINER FOR TREATMENT OF TYPE 2 DIABETES AND OBESITY: FOUR YEAR OUTCOMES IN THE FIRST NATIONAL HEALTH SERVICE (NHS) ENDOBARRIER SERVICE

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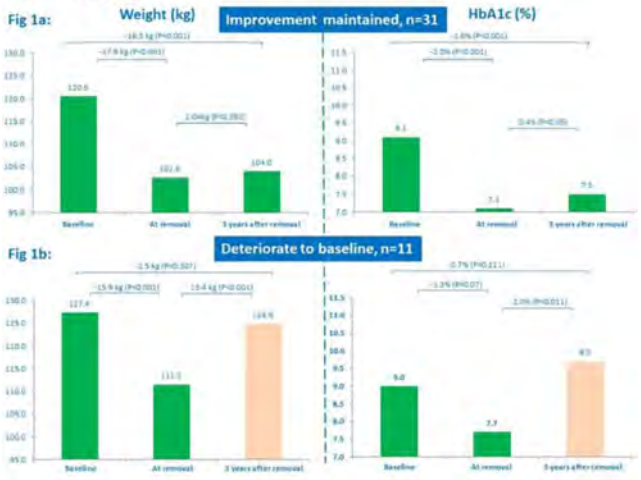
Background and Aims: EndoBarrier is a 60cm duodenal-jejunal bypass liner endoscopically implanted for up to one-year and designed to mimic the by-pass part of roux-en-y bariatric surgery. There is uncertainty concerning the extent to which improvements associated with EndoBarrier treatment are sustained post-removal. We therefore aimed to establish an EndoBarrier service for refractory diabesity and to continue to monitor the patients after EndoBarrier removal.

Methods: Between October 2014 and November 2017 we implanted 62 EndoBarriers in our NHS service with all removed by November 2018. Outcomes were monitored in a registry.

Results: As of October 2021, 60/62(97%) patients completed three-years post EndoBarrier removal and of these 42/60(70%)

Figure: The weight and HbA1c at baseline, at removal of EndoBarrier and 3 years after its removal in the 31/42 (74%) patients who maintained most of the improvement achieved in response to EndoBarrier treatment (Fig 1a), and the 11/42 (27%) who had deteriorated back to baseline by 3 years after its removal (Fig 1b).



(age 51.2 ± 7.2years, 55% male, diabetes duration 14.3(8-20)years, BMI 41.6 ± 7.3kg/m^2) attended follow-up. During EndoBarrier treatment, mean ± SD HbA1c fell by 1.8 ± 1.8% (20.2 ± 19.7mmol/mol), from 9.1 ± 1.7 to 7.2 ± 1.0% (75.7 ± 19.0 to 55.5 ± 11.2mmol/mol)($p < 0.001$), weight by 17.4 ± 9.2kg from 122.3 ± 29.4 to 104.9 ± 30.4kg(<0.001), systolic BP from 139.0 ± 14.5 to 125.4 ± 15.0mmHg(<0.001), cholesterol from 4.6 ± 1.0 to 3.8 ± 0.7mmol/L, serum alanine aminotransferase (a marker of liver fat) from 30.4 ± 17.6 to 19.0 ± 11.4U/L ($p < 0.001$). Median(IQR) total daily insulin dose reduced from 104(54-162) to 20(0-65)units($n = 27$,$p < 0.001$). 10/27(37%) insulin-treated patients discontinued insulin. Three-years post-EndoBarrier, 31/42(74%) maintained most of the improvement achieved with EndoBarrier whilst 11/42(27%) reverted to baseline (Figure). Of those deteriorating all had depression and/or bereavement and/or major health problems/disability. 10/62(16%) required early EndoBarrier removal for adverse events or symptoms; all 10 fully recovered after removal and most derived significant benefit.

Conclusions: Our data demonstrates EndoBarrier as highly effective in patients with refractory diabesity, with maintenance of significant improvement three-years after removal in 74%.

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Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

MOLECULAR PATHOGENESIS OF NASH THROUGH THE DYSREGULATION OF METABOLIC ORGAN NETWORK IN THE NASH-HCC MODEL MOUSE TREATED WITH STREPTOZOTOCIN-HIGH FAT DIET.

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Background and Aims: Non-alcoholic steatohepatitis (NASH) is an increasingly prevalent chronic liver disease. The multiple parallel hits hypothesis suggests abnormalities in adipocytokines, intestinal microflora, and endotoxins are intertwined, and could contribute to development of NASH. The STAM™ model which shows the same pathological progression as human NASH patients, has been widely used for pharmacological and basic research. However, analysis of the model has focused on the liver. Considering organ crosstalk, biological communication between organs, interactions between the gut and adipose tissue in the model should be clarified.

Methods: NASH was induced by a single subcutaneous injection of 200 μg streptozotocin solution 2 days after birth and feeding with a high-fat diet after 4 weeks of age followed by sacrificing at the NASH stage. Colon samples were snap-frozen in liquid nitrogen and stored at -80°C for tight junction-related protein analysis. Adipose tissue was prepared into paraffin blocks for HE staining. Blood adiponectin was analyzed to confirm changes in the adipocytokine profile.

Results: The data showed that expression of ZO-1 decreased with the progression of disease. Increased expression of endotoxin in the blood was also observed. HE staining of adipose tissue revealed hypertrophy of adipocytes. Adiponectin expression was decreased in STAM™.

Conclusions: Decreased expression of ZO-1 in the intestine of STAM™ mice suggests the occurrence of leaky gut, and abnormalities in adipocytokine secretion were also observed. Together with the liver, phenotypes in these organs are highly similar to human NASH patients, and might be involved in the pathogenesis of NASH.

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Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

USAGE OF METOBOLIC TRACKER DEVICE (LUMEN®) IMPROVES METABOLIC CONTROL IN ADULTS WITH PREDIABETES

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Background and Aims: Prediabetes is a risk factor for type 2 diabetes (T2DM), which can be reversed via lifestyle changes. Lumen® is a novel handheld CO_2 measurement device which was recently found to be in agreement with indirect calorimetry in providing an accurate assessment of metabolic fuel usage. The aim of the study was to examine the effects of Lumen usage alongside lifestyle intervention program on anthropometric and metabolic variables in prediabetic adults.

Methods: A 12-week single-arm intervention study was conducted with 27 participants, who received a Lumen device as a daily tool. Body composition and blood markers were measured at the start and end of study. Following the morning (fasted) Lumen measurement, participants received a depiction of their metabolic state (the degree of fat vs. carb oxidation). Participants were then provided with personalized guidance regarding their daily carbohydrate, fat, and protein intake, as well as recommendations to improve their daily lifestyle.

Results: revealed a significant decrease in body weight (5.99 kg, $p < 0.001$), resulted from significant decline in body fat

% (2.93%, $p < 0.001$), and waist circumference (6.23 cm, $p < 0.001$). Moreover, HbA1c% (0.27%, $p < 0.001$), triglycerides (0.45 mg/dL, $p < 0.001$), and systolic blood pressure (0.5 mmHg, $p < 0.05$) were all significantly reduced.

Conclusions: The short-term use of Lumen, an easily used noninvasive device, significantly ameliorated key metabolic parameters, demonstrating the potential of improving diabetes and metabolic syndrome outcomes.

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Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

THE IMPACT OF DIETARY BACKGROUND ON POST-ISCHEMIC MUSCLE RECOVERY

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Background and Aims: Metabolic abnormalities caused by high calorie intake lead to development of obesity, insulin resistance and macro- and microvascular diseases. Progression of hyperglycemia and macrovascular pathologies, such as peripheral artery disease, leads to muscle ischemia, necrosis and loss of function. Here we analyze how dietary-associated metabolic status influence post-ischemic muscle recovery and insulin sensitivity.

Methods: Male C57BL/6J mice were fed low-fat (LFD), high-fat (HFD) or grain-based diet (GBD) for 13 weeks prior hind limb ischemia and characterized by fasting blood glucose (FBG), insulin and glucose tolerance tests (ITT and GTT). Necrotic area of m.tibialis, macrophage infiltration were histologically evaluated. Glucose uptake in muscle was analyzed using [3H]-2-deoxyglucose; GLUT1 and GLUT4 expression were assessed by Western blotting.

Results: Animals fed different diets demonstrated distinct metabolic parameters: LFD had normal glucose metabolism, GBD had mild hyperglycemia and HFD had impaired glucose tolerance. Impaired metabolism in GBD and HFD was accompanied by decreased glucose uptake and low expression of glucose transporter GLUT4. Post-ischemic necrosis of m.tibialis and macrophage infiltration was higher in GBD and HFD compared to LFD group.

Conclusions: We conclude that dietary background and metabolic status influence the rate of post-ischemic skeletal muscle regeneration, metabolism and insulin sensitivity. We hypothesize that insulin resistance and hyperglycemia disturb energy supply of regeneration and activate latent inflammation. The most effective regeneration is supported by LFD, while the lowest rate of regeneration occurs on GBD. This work was supported by RSF grant #20-45-08003.

EP270 / #495

Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

DIGITAL MEAL LOGGING: MEAL COMPOSITION OF BREAKFAST, LUNCH, AND DINNER PREDICTS WEIGHT LOSS IN 11758 PATIENTS

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Background and Aims: To gauge the impact of meal composition (MC) on weight change, we analyzed meal logs from obese patients and identified MC that were associated with weight loss.

Methods: We performed retrospective analyses of ~1.8 million photo and label-based food logs and weight data (baseline & 12 +/- 2 weeks) from 11758 obese patients (female = 8194; mean baseline BMI = 37.3 kg/m^2, SD = 6.1; mean relative weight change at week 12 +/- 2 weeks = -3.51%, SD 4.19) that participated in blended-care weight loss interventions at a specialized nutritional care provider. Meal log pattern analysis via latent dirichlet allocation identified 30 frequent MC. Subsequently, their impact on weight loss was estimated using Bayesian linear regression.

Results: For breakfast, four MC yielded positive effects on weight loss (''cereals & dairy'', ''fruits'', ''fruits & cereals & dairy'', ''fruits & bread & dairy'', all probability of direction (pd) >0.95). For lunch, three MC yielded positive effects (''fruits'', ''soup & vegetables'', ''fish & salad'', all pd >0.95). For dinner, seven MC proved beneficial (all lunch MC; ''fish & vegetables'', ''red meat & vegetables'', ''salad & white meat'', ''white meat & vegetables'', all pd >0.95).

Conclusions: Results confirm the well-established influence of lower-carbohydrate MC on weight loss. More importantly, the observed association between the 30 MC categories and weight loss is a fundamental step for generating automated MC recommendations for optimal weight loss. Future research needs to hone the used weight loss prediction model by integrating quantitative information (e.g. meal size) and patient characteristics (e.g. dietary preferences).

EP271 / #530

Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

ARTIFICIAL INTELLIGENCE AND ITS ROLE IN ASSESSING MEDITERRANEAN DIET ADHERENCE: A FEASIBILITY STUDY

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Background and Aims: Mediterranean Diet (MD) eating patterns can play a major role in reducing the risks of non-communicable diseases, such as obesity and type-2 diabetes. We created an AI-based system and integrated it into an existing smartphone application (app) for providing professional nutrition care by dietitians. The system calculates a weekly MD adherence (MDA) score based on automatically recognised food items, their portions, and frequency of consumption. A feasibility study was conducted to evaluate the users' satisfaction with this newly integrated feature within the app.

Methods: A total of 24 weight loss patients (BMI >27 kg/m^2) enrolled in a long-term weight loss intervention led by dietitians were recruited to participate in the study. Information on their

dietary habits and socio-demographic data were collected with self-reported questionnaires. The users captured images of their meals for four weeks and a weekly report was sent to them including their MDA score and personalised suggestions to improve it. In the end, participants repeated the questionnaire and gave feedback regarding the new feature.

Results: Participants' as well as the team's dietitians' feedback was positive. More specifically, 21/24 participants reported that recording daily meals was straightforward and self-explanatory, 23/24 participants were satisfied with the weekly report, and 20/24 would be interested in using this new developed feature.

Conclusions: The introduced feature received positive feedback from the participants and the involved dietitians. Further studies are needed to understand the clinical impact of the AI-driven feature.

EP272 / #545

Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

LEPTIN, RESISTIN AND ANTIOXIDANT VITAMIN STATUS IN OBESE DIABETICS: A CASE-CONTROL STUDY

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Background and Aims: Obesity is associated with alteration of the antioxidant status. Our aim was to assess and compare the status of vitamins A and E, leptin and resistin in two groups.

Methods: A retrospective cross-sectional case-control study, including 33 obese diabetic women versus 30 healthy controls matched according to age and sex.

Results: The levels of antioxidant vitamin were significantly lower in obese diabetic women compared to the control group (0.55 ±, 31 mg / L versus 2.39 ± 0.86 mg / L; $p < 0.001$) for vitamin A and (7.66 ± 2.84 mg / L versus 12.19 ± 1.64 mg / L; $p < 0.001$) for vitamin E. The serum values of Leptin and Resistin were significantly higher in the obese diabetic group: (16.96 ± 5.03 ng / mL versus 4.24 ± 1.84 ng / mL; $p < 0.001$) for the leptin and (8.67 ± 2.79 ng / mL versus 3.49 ± 1.00 ng / mL; $p < 0.001$) for resistin. Inverse correlations were found between vitamin A l and leptine levels ($r = -0.602$; $p < 0.001$) and vitamin A and resistine levels ($r = -0.414$; $p < 0.017$). A statistically significant correlation was proved between vitamin A and vitamin E ($r = 0.586$; $p < 0.001$).The risk of developing obesity and insulin resistance would be higher with value beyond 0.63 mg / L for vitamine A and 9.74 mg / L for vitamine E.

Conclusions: The vitamins A and E have a protective role against obesity and insulin resistance, regulation of the secretion of leptin and resistin.

EP273 / #748

Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

INSULIN RESISTANCE IN OBESE CHILDREN

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Background and Aims: In recent years, there has been noted an increase in the prevalence of type 2 diabetes mellitus (DM) in children. THe pathogenesis of diabetes is based on insulun resistanse (IR). IR children is formed gradually, often against the background of obesity. The physiological IR of the puberty is an additional risk factor of diabetes. Aim: to assess the carbohydrate metabolism and the frequency in obese children.

Methods: Clinical and laboratory examination of 80 children with constitutionally exogenous obesity aged 5-17 years was perfomed. The children were divided into 2 groups:1st 5-11 years old, 2nd 12-17 years old.

Results: Fasting glycemic dosoders were recorded with the same frequency 7.5% and 12.5% in both groups. According to the glucose tolerance test (OGTT), by the end of the test 5% and 30% of cases of imparied carbohydrate tolerance were detected. An increase in average value of immunireactove insalin (IRI) was found against the background of the test, regadless of the severity of obesity in both groups. At 0 minute of the fraction, children with elevated IRI values were 13 people (32.5%) in the first group and 26 (65%) in the second group ($p = 0.0001$). By the end of the test, the number of children with elevated IRI in the both groups was 26 (55%) and 33 (65%), respectively ($p = 0.0001$).

Conclusions: obese children, including those of pe-puberty age, have disoders of carbohydrate metabolism. IR was detected woth a high freqensy (>50% cases regardless of age and severity of obesity.

EP274 / #768

Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

FACTORS ASSOCIATED WITH DIFFERENT PATTERNS OF WEIGHT CHANGE AFTER BARIATRIC SURGERY: A LONGITUDINAL STUDY

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Background and Aims: Bariatric surgery is the most effective treatment for obesity. During long-term follow-up, weight loss (WL) is variable between subjects. The aim of this study is to assess the change in percentage of total weight loss (%TWL) and excess weight loss (%EWL) and to describe the factors associated with greater or lesser WL over time.

Methods: Longitudinal study including patients treated with laparoscopic Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (LSG) and followed at Hospital Universitario San Ignacio, Bogotá (Colombia). Baseline data was recorded before surgery. Follow-up was performed at 3 ($n = 192$), 6 ($n = 190$), 9 ($n = 188$), 12 ($n = 186$), 24 ($n = 99$) and 36 ($n = 30$) months. Generalized Estimating Equation (GEE) analysis was used to assess the change in %TWL and %EWL over time.

Results: 196 patients were included (82.4% female, BMI 41.3 ± 5.2 kg/m2). The tendency to increase on %TWL (31.6 ± 6.6) and %EWL (80.2 RIQ 70.7-97.3) was evident in the first year, stabilizing after that. Nutritionist follow-up, baseline BMI >40 kg/m2 and WL ≥10kg before surgery were associated with an average higher increase of %TWL (2.39% $p = 0.014$, 0.41% p30 minutes/day after surgery reduced %TWL in 0.74% ($p = 0.009$). Similar findings were described on %EWL

Conclusions: Follow-up during the first year after bariatric surgery is critical to achieving %TWL and %EWL goals. This study suggests that modifiable factors such as nutritional follow-up, WL before surgery and time of physical activity are associated with a significant change in %TWL and %EWL during follow-up by a multidisciplinary team.

EP275 / #207

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

GLYCAEMIC CONTROL IN PATIENTS USING DIFFERENT INSULIN DELIVERY AND GLUCOSE SENSORING DEVICES: REAL-LIFE DATA FROM TAMPERE UNIVERSITY HOSPITAL

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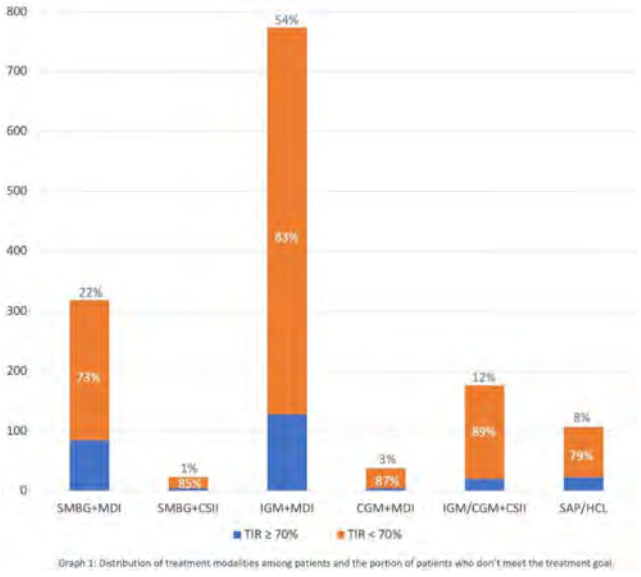
Background and Aims: Good glycaemic control requires optimal use of insulin delivery and glucose monitoring systems in patients with insulin deficiency. Since devices cause additional costs, we need information on the effectiveness of treatment modalities. Thereby, the aim of this study was to assess glycaemic control in ≥15-year-old patients with insulin deficiency treated in Tampere University Hospital.

Methods: The data included 1,464 patients (79% with T1DM). Glycaemic control was assessed according to HbA1c values, glucose determination values (time in range (TIR), below (TBR) and above range (TAR), and the mean and the coefficient of variation (CV) of glucose), and the incidence of acute complications. The analyses were stratified by age and by the combination of glucose determination method and treatment modality.

Results: In the conditional logistic regression model poor glycaemic control (TIR ≤70%) was associated independently with young age group (OR 4.70; 95% CI 2.42–9.13) and with high daily insulin dose per weight (OR 5.47; 95% CI 2.99–10.01). Furthermore, type 2 diabetes was associated with better balance (OR 0.46; 95% CI 0.28–0.81). Intermittent glucose monitoring with multiple daily injections (IGM+MDI) and continuous subcutaneous insulin infusion (CSII) with glucose sensor (IGM or continuous glucose monitoring, CGM; CSII+sensor) were independently associated with poor glycaemic control compared to sensor-augmented or hybrid closed-loop pump (SAP/HCL) which yielded the best results.

Conclusions: Good glycaemic control is associated with high age, type 2 diabetes, lower total daily insulin dose per weight and treatment modality, in which case the best glycaemic control was in the group with sensor-augmented pump or hybrid closed loop.



Graph 1: Distribution of treatment modalities among patients and the portion of patients who don't meet the treatment goal.

EP276 / #34

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

THE MINIMUM DURATION NEEDED TO ESTIMATE 24H TIME IN RANGE

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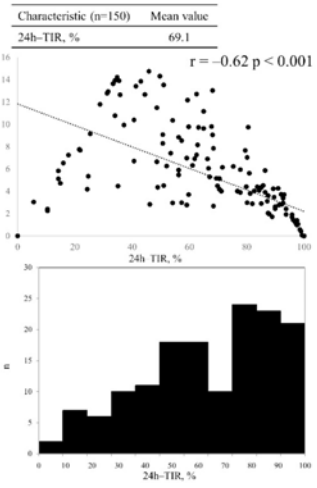
Background and Aims: It is useful for patients using a personal CGM to know the minimum duration [MD] from 0:00 needed to estimate ''time in range (70–180 mg/dL) [TIR] from 0:00 to 24:00'' (24h–TIR), to know appropriate intervention time to achieve target 24h–TIR.

Methods: In a cross-sectional study, we analyzed 24h glucose levels measured using CGM (iPro2) for 150 patients with type 2 diabetes. We calculated TIR, corresponding to 173 extracted durations (ED) [0:00–09:40, 0:00–09:45 … 0:00–24:00: 40–100% of 24h (40–100%)] (EDTIR). We arranged patients in descending order of 24h–TIR, ranking from 1 to 150. Then, 80 patients were selected 21 times as shown in table. MD needed to estimate 24h–TIR were provided by correlation coefficient analysis using $R^2 = 0.9$ as threshold, in all patients and corresponding to the 21 groups.

Results: The MD was 67.4% in all patients. 24h–TIR correlated to standard deviation (SD) of 173 EDTIR [SDEDTIR]. 24h–TIR for patients who had high SDEDTIR was mainly concentrated in the range (30%–70%), and patients whose 24h–TIR was in the range (0%–30%, 70%–100%) had low SDEDTIR. The number of patients increased as the patients' 24h–TIR increased. Mean of SDEDTIR (MSDEDTIR) correlated to MD ($r = 0.998$, $p < 0.001$) ($n = 21$). [Image]

Group number	Selected groups	MSDED TIR (%)	MD (% of 24h)
1	51–130	7.1	85.8
2	1–3, 54–129, 150	6.8	82.6
3	1–6, 57–128, 149–150	6.6	80.2
4	1–9, 60–127, 148–150	6.3	78.5
5	1–12, 63–126, 147–150	6.1	75.3
6	1–15, 66–125, 146–150	5.8	73.6
7	1–18, 69–124, 145–150	5.5	71.5
8	1–21, 72–123, 144–150	5.3	69.4
9	1–24, 75–122, 143–150	5.0	68.4
10	1–27, 78–121, 142–150	4.8	66.7
11	1–30, 81–120, 141–150	4.6	65.6
12	1–33, 84–119, 140–150	4.3	63.2
13	1–36, 87–118, 139–150	4.1	60.1
14	1–39, 90–117, 138–150	3.8	57.3
15	1–42, 93–116, 137–150	3.6	55.9
16	1–45, 96–115, 136–150	3.5	52.4
17	1–48, 99–114, 135–150	3.4	52.8
18	1–51, 102–113, 134–150	3.2	50.3
19	1–54, 105–112, 133–150	3.2	51.7
20	1–57, 108–111, 132–150	3.0	50.0
21	1–60, 131–150	3.1	50.3



Conclusions: As group number increased, it may be that 24h–TIRs between ranks varied more in bigger ranking numbers as well as SDEDTIR decreased more, that may have resulted in shorter MD. Patients should intervene to achieve target 24h–TIR by at least 16:00.

EP277 / #447

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

INTERFERENCE IN THE GLYCATED HEMOGLOBIN DETERMINATION BY HEMOGLOBIN VARIANTS: 4 CASES

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Background and Aims: Hemoglobinopathies are the result of alterations in the genes that encode the globin chains. The presence of any of these variants in the chromatogram could interfere with the measurement of HbA1c, quantified by High performance liquid chromatography (HPLC).

Methods: The measurement was made by HPLC- cation exchange in the automated analyzers Variant II Turbo and D-100 Hemoglobin Testing System, Bio-Rad Laboratories ®. Possible Hemoglobin variants were reprocessed in the D-10 analyzer and sent to the Hematology Service where it were studied by capillary electrophoresis (Minicap de Sebia®). The cases were sent to an external center for genetic study.

Results: The following Hemogloblin (Hb) variants are uncommon in our environment and their presence interferes with the determination of HbA1c. Hb *Le Lamentin* produces an underestimation of HbA1c. The genetic study shows the CCA> CAA mutation in codon 20 of the 1st exon of the Alfa2 gene. Hb *Stanleyville- II* carries an overestimation of HbA1c. The AAC> AAA mutation is found in codon 78 of the 2nd exon of the alpha2 gene. Hb *Niigata* produces a negative interference in the measurement of HbA1c. It presents the GTG> CTG mutation in codon 1 of the exon of the beta gene. Hb *Korle-Bu* is responsible of an underestimated HbA1c. The GAT> AAT mutation is found in codon 73 of the 2nd exon of the beta gene.

Conclusions: Chromatograms review is crucial to avoid reporting erroneous results in the determination of HbA1c. Although it is not common, there are hemoglobin variants that can interfere with the HbA1c results.

EP278 / #457

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

STRUCTURED SMBG AS A MEASURE OF GLYCEMIC VARIABILITY IN PERSONS WITH TYPE 2 DIABETES

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Background and Aims: India is a country with more than 77 million persons with diabetes(PwD) and limited resources. Assessing glycemic variability using CGM is expensive and impractical for most PwD. This study assessed structured SMBG(SSMBG) as a measure of glycemic variability in Indian setting.

Methods: In this retrospective observational study we compared SMBG values in/outside range(70-180 and 70-140mg/dl) with CGM values of time in, above and below range(TIR, TAR, TBR) in persons with T2D(PwT2D) who had undergone CGM using LibrePro, and were also performing SSMBG measuring fasting and three postprandial BG values on the same dates as CGM. SSMBG monitoring days with at least 3 SMBG values available were included in the study. Comparison was made for SMBG values in, above and below range (70-180mg/dl and 70-140mg/dl) and TIR, TAR and TBR measured by CGM.

Results: A total of 93 days data from 12 PwT2D was taken up for analysis. Of this, 4 daily SMBG values were available for 54 days and 3 daily values for 39 days. Average blood glucose(ABG) calculated by SSMBG was 170.83(±40.22) and had strong correlation with ABG calculated by CGM (149.06 ± 44.57) ($r = 0.81$, $p < .001$). TIR and TAR showed strong correlation with SMBG values in and above range (both 70-140mg/dl, 70-180mg/dl) which were statistically significant{SMBG(70-140)_IR & CGM(70-140)_TIR:$r = 0.61$,$p < 0.001$, SMBG(70-180)_IR & CGM(70-180)_TIR:$r = 0.68$,$p < 0.001$, SMBG(70-140)_AR & CGM(70-140)_TAR:$r = 0.61$,$p < 0.001$, SMBG(70-180)_AR & CGM(70-180)_TAR:$r = 0.73$,$p < 0.001$). Correlation between TBR values were not calculated as numbers were very few.

Conclusions: Structured SMBG values provide a simple measure of glycemic variability and appear to be good and economical alternative to CGM for measuring glycemic variability.

EP279 / #51

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

CONFIDENCE INTERVALS ESTIMATION OF PREDICTED HBA1C DERIVED FROM TIME-IN-RANGE FOR LINEAR REGRESSION ANALYSIS

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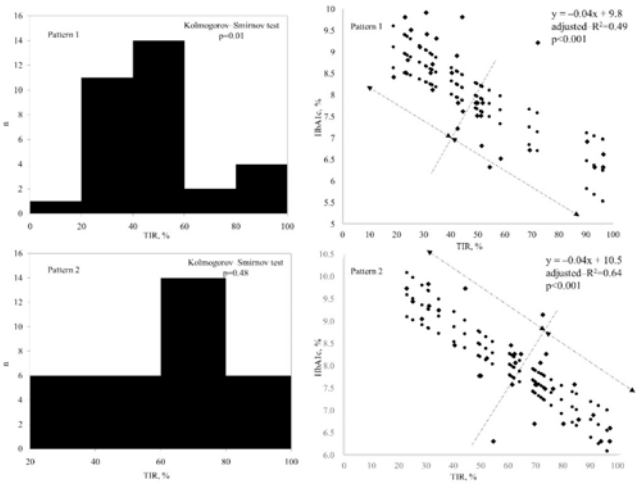
Background and Aims: We studied regarding confidence intervals estimation of predicted HbA1c derived from time-in-range (TIR) for linear regression analysis.

Methods: One hundred one outpatients with type 2 diabetes underwent HbA1c testing, wore a FGM (FreeStyle Libre Pro), and did not change diabetic treatments, on a hospital visit. TIR and mean glucose levels were calculated using FGM data over 24-h × 13 days. We selected 2 patterns of 32 patients, each comprising 8 patients with HbA1c of 6% level, 8 patients with HbA1c of 7% level, 8 patients with HbA1c of 8% level, and 8 patients with HbA1c of 9% level. Pattern 1 was selected for



achieving the following: Patients with low HbA1c had low TIR; ''The ratio of time-below-range (<70 mg/dL) to time-above-range (>180 mg/dL)'' (TBR <70/TAR >180) negatively correlated to HbA1c. Pattern 2 was selected to realize that ''TBR <70/TAR >180 did not correlate to HbA1c.

Results: In Pattern 1, HbA1c was distributed normally while TIR was not. TIR was negatively correlated with HbA1c. The center of curves for 95% confidence intervals estimation for predicted HbA1c derived from TIR ($C_{95\%\ CI\ curves}$) was situated on the lower TIR side of the center of the TIR distribution range. In Pattern 2, both HbA1c and TIR were distributed normally. TIR was negatively correlated with HbA1c. The $C_{95\%\ CI\ curves}$ was situated at the center of the TIR distribution range (Figure).

Conclusions: For linear regression analysis, the confidence interval estimation of predicted HbA1c derived from TIR may imply the degree of hypoglycemia occurrence for patients with low HbA1c.

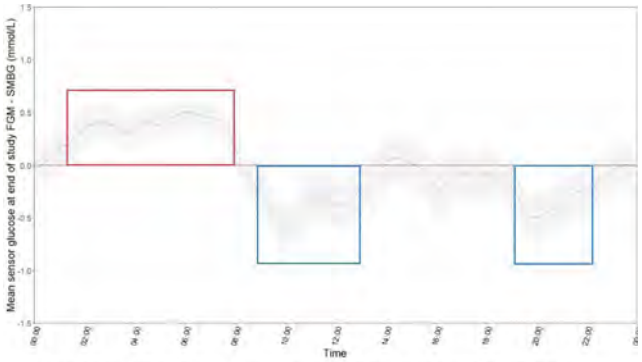


Fig 1: 24 hour profile of difference in mean sensor glucose in FGM – control groups at 16 weeks. Data are mean (95% CI) restricted by natural spline. Positive (red) and negative (blue) differences between treatment groups are shown.

EP280 / #527

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

FUNCTIONAL DATA ANALYSIS OF TEMPORAL GLUCOSE PROFILES IN FLASH GLUCOSE MONITORING VERSUS STANDARD BLOOD GLUCOSE MONITORING IN THE REDUCTION OF HYPOGLYCEMIA IN DIABETIC KIDNEY DISEASE

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Background and Aims: Use of Flash glucose monitoring (FGM) for 16 weeks resulted in reductions in time-in-hypoglycemia, but no significant differences in overall mean sensor glucose or time-below-range between patients randomized to FGM or self-monitoring blood glucose (SMBG). Fasting plasma glucose was significantly higher in the FGM group at 16 weeks with lower rates of nocturnal hypoglycemia. Dynamic glucose profiles may reveal between-group temporal differences not apparent from CGM metrics. We used functional data analysis (FDA) to compare changes in 24 hour CGM profiles in FGM vs SMBG groups.

Methods: Continuous glucose monitoring (CGM) data were collected from 90 CKD Stage 3b-5 patients randomized to either FGM (n = 45) or SMBG (n = 45) for 16 weeks. FDA was applied to the blinded CGM data collected at baseline and end-of-study to generate functional glucose curves.

Results: Despite similar reductions in mean glucose between two groups at the end of study (Adjusted mean difference -0.1 mmol/L (95% confidence interval CI -0.65 to 0.45, p = 0.71), FDA showed significantly lower post-prandial glucose in FGM versus SMBG group between 08:30 to 13:00 and 19:00 to 22:00 (Fig 1). Nocturnal glucose was higher between 01:00 and 0600 hours in the FGM group.

Conclusions: Use of FGM was associated with greater reductions in post breakfast and post dinner glucose but higher nocturnal glucose, as compared with SMBG. FDA may provide novel insight in analyzing CGM data through visualization and identification of patterns in conjunction with lifestyle and treatment.

EP281 / #540

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

EFFECT OF CALORIE RESTRICTED DIET VERSUS TIME RESTRICTED INTERMITTENT FASTING ON TIME IN RANGE IN INDIVIDUALS WITH TYPE 2 DIABETES MELLITUS: A PILOT STUDY

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Background and Aims: Background: Recent clinical data suggest that Glycemic Variability (GV) measured by Time in Range (TIR) is associated with micro-vascular as well as macro-vascular complications in Type 2 Diabetes Mellitus (T2DM), independent of HbA1c levels. To date, studies on the effect of anti-diabetic drugs in lowering the GV are present but studies on the effect of dietary intervention on GV are very scarce. Aims: A pilot study was undertaken with an aim to evaluate the effect of Calorie Restricted Diet (CRD) (daily caloric reduction by 500

CGMS Metric	CRD	95% CI	TRIF	95% CI	p value
Average blood sugar	115.7 ± 13.2 mg/dl	101.2-129	113.3 ± 21.5 mg/dl	90.6-135.9	0.86
Estimated HbA1c	5.6 ± 0.4 %	5.1-6.1	5.5 ± 0.7 %.	4.7-6.3	0.81
TIR	91.6 ± 3.6%	87.8-95.4	79.0 ± 4.9 %	73.7-84.3	0.0003*
TAR	5.6 ± 4.5%	0.8-10.4	10.6 ± 8.3 %	1.9-19.4	0.25
TBR	2.6 ± 2.5 %	0.04-5.2	10.3 ± 7.6 %	2.3-18.3	0.03*

from BMR with 4 meals) versus Time Restricted Intermittent Fasting (TRIF) (popular in India as 2 meal diet) in individuals with T2DM on TIR.

Methods: 6 participants were evaluated using - FreeStyle Libre-Pro Flash Glucose Monitoring System (CGMS) by Abbot and crossover design. 14 days CGMS data was studied to see the difference in TIR following the two dietary interventions.

Results: A significant increase of 12.6% in TIR, a significant decrease by 7.7% in Time Below Range (TBR) and a decrease of 5% in Time Above Range (TAR) was noted following CRD, indicating a statistically significant lower GV.

Conclusions: Evaluating based on HbA1C alone, it would be reasonable to continue the TRIF diet. However, the CGMS data reveals a different picture, showing elevated blood sugars after meals and hypoglycemia in between meals. A more detailed assessment using CGMS and TIR will enable us to assess the impact of the type of dietary intervention on GV, which can emerge as a useful tool to plan dietary guidelines for T2DM.

EP282 / #582

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

DIABETES IN AFRICAN-CARIBBEAN AND THE ROMFORD EXPERIENCE (DARE) STUDY: DISEASE CHARACTERISTIC AND CLINICAL PRESENTATION.

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Background and Aims: Type 2 diabetes is more prevalent among black people in Africa and other parts of the world as well as in the African diaspora communities and Afro -Caribbean compared to Caucasian European. The presentation of diabetes Afro-Caribbean may vary and can include Ketosis prone type 2 diabetes, diabetic ketoacidosis and Hyperosmolar Hyperglycaemic State (HHS). **Aims/Objectives** To present the disease characteristic and clinical presentation of diabetes in Afro-Caribbean patients from one of the East London Hospital

Methods: Retrospective audit/study and it set out to identify Afro-Caribbean patients who presented to Queens Hospital from 2016-2018. In total 52 case notes and discharge letters were identified. The demographic included age, gender and type of diabetes diagnosis or pre-existing diabetes

Results: The age of the patients ranged from 18-86 years. The average age was 46, 19 were female and 33 males. Clinical presentation included Pre-DKA 4% / Ketone Prone type 2 Diabetes, Hyperosmolar Hyperglycaemic state(HHS) 24%,DKA 39% and Acute Hyperglycaemia/Osmotic symptoms without DKA OR HHS 5%. Mixed DKA/HHS 2%, some of the patients presented with sepsis/perianal abscess 2%. 72% were type 2 diabetes, 16% type 1, diabetes 12% LADA

Conclusions: The cohort of Afro-Caribbean patients that present to London based district hospital were of different age and with variable manifestation as shown by data from this study. The presentation of diabetes in the Afro-Caribbean communities and African diaspora has greater variation than previously stated. Thus, it is imperative that healthcare professionals and wider scientific community have open mind and wider differential diagnosis when managing of these patients.

EP283 / #621

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

EFFECT OF HAND HYGIENE PRACTICE ON CAPILLARY BLOOD GLUCOSE AMONG THE FAMILY MEDICINE RESIDENTS IN JEDDAH, SAUDI ARABIA

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Background and Aims: Good glycemic control significantly reduces the incidence of diabetes-related complications; however, it depends greatly on the frequent and accurate monitoring of blood glucose levels. Hand hygiene may determine the accuracy of capillary blood glucose measurements, which may vary due to differences in hand hygiene practices. This study evaluated the impact of different hand hygiene practices on capillary blood glucose levels in Jeddah, Saudi Arabia.

Methods: observational cross-sectional study involving the collection of capillary blood samples for the measurement of blood glucose levels .The samples were collected before and after handwashing or after alcohol swab and hand sanitizer use.

Results: Of the 98 residents. No significant difference was observed in the capillary blood glucose levels of the residents who did not wash their hands compared to that of the residents who used hand sanitizer ($P = 0.785$) or alcohol swabs ($P = 0.487$). Similarly, the blood glucose levels of capillary blood samples from washed hands did not differ significantly from those of samples from unwashed ($P = 0.227$) or sanitized hands (0.270)

Conclusions: Capillary blood glucose levels obtained after using a hand sanitizer, alcohol swabs, or handwashing did not differ significantly from that of samples obtained from unwashed hands. However, a significant difference between the glucose levels in the samples obtained from the first and second drops from both washed and unwashed hands was observed. We recommend that patients perform hand hygiene measures and use the second capillary blood drop to obtain a more accurate assessment of blood glucose level. Additional larger studies are required to confirm these findings.

EP284 / #771

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

FACTORS AFFECTING GLUCOSE VARIABILITY IN PATIENTS WITH TYPE 1 DIABETES IN THE HOSPITAL SETTING

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Background and Aims: Glucose variability (GV) is supposed to be an independent risk factor for complications and therapeutic target in patients with diabetes. In this study, we aimed to identify factors associated with GV in hospitalized patients with type 1 diabetes (T1D).

Methods: We observed 400 adult subjects with T1D admitted to tertiary referral hospital to improve diabetes management. Daytime (06.00-23.59), nocturnal (0.00-5.59) and 24-hour time in range (TIR), time above range (TAR), time below range (TBR), coefficient of variation (CV), and mean absolute glucose (MAG) were derived from continuous glucose monitoring data.

Results: Patients with body mass index (BMI) ≥25 kg/m2, when compared to those with lower BMI, had higher 24-hour TAR and lower 24-hour MAG and daytime TBR. Patients with estimated glomerular filtration rate (eGFR) 15-59 mL/min/1.73m2 demonstrated lower 24-hour TBR and daytime MAG compared to those with higher eGRF. In ROC curve analysis, nocturnal and day-time CV in the upper quartile was associated with higher insulin dose. Lower BMI and waist circumference, higher daily insulin doses and HbA1c showed association with high (upper quartile) nocturnal and day-time MAG. In multivariate logistic analysis, duration of diabetes and eGFR were independent predictors of high CV. The duration of diabetes and HbA1c were associated with high nocturnal MAG; bolus insulin doses and HbA1c were predictors of high daytime MAG.

Conclusions: In patients with T1D, longer diabetes duration, higher insulin dose, HbA1c and eGFR, as well as lower BMI, are associated with high daytime and nocturnal GV. **Grant support:** The study was supported by RSF (grant #20-15-00057).

EP285 / #772

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

CORRELATION OF HBA1C AND TIME IN RANGE (SINGLE AMBULATORY GLUCOSE PROFILE REPORT) IN PERSONS WITH TYPE 2 DIABETES

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Background and Aims: Conventionally we use HbA1c to monitor glycemic control. Using continous glucose monitoring (AGP-libre pro 2) once in three months will give us information about glycemic pattern and variability. This paper is an attempt to study the correlation of TIR (time in range) derived from AGP with HbA1c.

Methods: A retrospective obsevational study was carried out at our diabetes clinic. All adults with type 2 diabetes whose CGM was done in our clinic were enrolled in this study between January 2021 to October 2021. 350 persons with type 2 diabetes were put on single time CGM (Libre Pro 2 AGP) as per clinical indication and their HbA1c was studied in the follow up visit after 3 months. The data was analysed to compare time in range values with the HbA1c results.

Results: The analysed patients were divided into 3 groups according to their time in range values. It was found that the mean HbA1c was 7.2 in patients whose TIR was more than 70%. For those whose TIR was between 50-70% ,the mean HbA1c came out to be 7.8%. For those whose TIR remained <50% the mean HbA1c was 8.5.

Conclusions: A single 14 day data of continuous glucose monitoring (by AGP libre pro 2) analysis is sufficient to predict the 3 months control of diabetes as more than 70% TIR correlates well with HbA1c.

EP286 / #784

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

GLYCEMIC VARIABILITY IN THE ICU AS A PROGNOSTIC MARKER FOR MORTALITY IN CRITICALLY ILL PATIENTS, BASED ON REAL WORLD EVIDENCE

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Background and Aims: Evidence suggests a role of glycemic variability (GV) in intensive care unit (ICU) mortality. Various metrics of GV for implementing glycemic control in critical patients, have been suggested and evidence is required to determine the most suitable metric. Coefficient of Variation (CV) of glucose has been suggested as a measure for glucose variability in ICU. This study investigated the CV in mixed type of ICUs, as a prognostic marker for mortality in critically ill patients.

Methods: CV derived as ratio of Standard Deviation (SD) over mean blood glucose was used to assess GV. We performed a retrospective cohort study using the Medical Information Mart for Intensive Care IV open access, anonymised database (MIMIC-IV), based on the data of 3639306 ICU admissions between 2008 and 2019 at Beth Israel Deaconess Medical Center, USA.

Image 1: GV as continuous variable (no binning)

ICU type	Variable	Odds Ratio	p-value	Conf. int. (2.5%)	Conf. int. (97.5%)
All ICUs (n = 3639306)	GV	1.147	<0.005	1.144	1.150
	Age	1.020	<0.005	1.020	1.020
	Gender (male)	0.837	<0.005	0.832	0.842
	SOFA (Sequential Organ Failure Assessment)	1.196	<0.005	1.195	1.197
	OASIS (Oxford Acute Severity of Illness Score)	1.040	<0.005	1.040	1.040
Medical (n = 1560905)	GV	1.111	<0.005	1.106	1.117
	Age	1.016	<0.005	1.015	1.016
	Gender (male)	0.798	<0.005	0.790	0.805
	SOFA	1.207	<0.005	1.205	1.208
	OASIS	1.052	<0.005	1.051	1.052

Image 2: GV split to two groups (threshold at 0.5)

ICU type	Variable	Odds Ratio	p-value	Conf. int. (2.5%)	Conf. int. (97.5%)
All ICUs (n = 3639306)	GV > 0.5	1.405	<0.005	1.389	1.421
	Age	1.020	<0.005	1.020	1.021
	Gender (male)	0.834	<0.005	0.829	0.838
	SOFA (Sequential Organ Failure Assessment)	1.198	<0.005	1.197	1.199
	OASIS (Oxford Acute Severity of Illness Score)	1.041	<0.005	1.040	1.041
Medical (n = 1560905)	GV > 0.5	1.399	<0.005	1.374	1.425
	Age	1.016	<0.005	1.016	1.016
	Gender (male)	0.794	<0.005	0.787	0.801
	SOFA	1.208	<0.005	1.206	1.209
	OASIS	1.052	<0.005	1.052	1.053

Logistic regression was performed, using age, sex, SOFA, OASIS and GV during ICU admission (thresholded at 0.5 for high) as predictors, and death in ICU as the target. The study protocol was approved by the respective Institutional Review Boards.

Results: The results of the analysis in two images:

Conclusions: An 1 SD increase in GV leads to a 1.147 increase in mortality odds (image 1). People in the high (>0.5) GV group have 1.405 times higher mortality odds (image 2). These results support, on a large number of ICU admissions compared with the existing literature, the evidence that GV (measured via the CoV metric) is associated with higher mortality in various types of ICUs.

EP287 / #801

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

THE OUTCOME OF CONTINEOUS GLUCOSE MONITORING IN TYPE 1 DIABETES: - AN AUDIT

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Background and Aims: Continuous subcutaneous glucose monitoring (CGM) supports children and young people (CYP) with Type 1 DM to gain better control of blood glucose levels. NICE (2015) recommends use of CGM to achieve better glycaemic control.It recommends to offer to children with type 1 DM who needed frequent blood glucose monitoring,poor glycemic control, frequent hypoglycaemia related seizure and for those children with neurodisabilities .To evaluate at the effectiveness of CGM in control of diabetes in CYP with Type 1 DM.

Methods: A retrospective audit between march 2019-2020. We have extracted information from our dendrite database and Dexcom clinical portal such as number of patients, hba1c at 0,3,6 and12 months.Kruskall Wallis test was used to compare the average glucose target range and the average DM related admission pre and post the introduction of CGM.

Results: Total 73 patients 6 were excluded due to lack of data. From the remaining 67 patients there was Median age of patients: 11 years (IQR: 7-13) , Median starting HbA1C: 8 (7.6-9.1) n = 56,Median at 12 months: 7.6 (7.2-8.2) n = 53.Comparing the distributions of HbA1C prior and after 12 months there is a significant difference p = 0.0229.Median % Glucose in target month one: 52% (44-64) n = 51 as compared to Median % Glucose in target: month twelve: 52% (41-65) n = 64. There was 5.2% DKA and 17.5% hypoglycaemia related admission post CGM.

Conclusions: CGM supports CYP with type 1 DM to gain better control of blood glucose levels, time in range and thereby reduce emergency admissions and complications which will reduce the cost of diabetes-associated healthcare.

EP288 / #104

Topic: ***AS14-Human factor in the use of diabetes technology***

USER EXPERIENCE OF THE OMNIPOD® 5 AUTOMATED INSULIN DELIVERY SYSTEM IN ADULTS WITH TYPE 2 DIABETES

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Background and Aims: While most studies of automated insulin delivery (AID) systems have focused on type 1 diabetes, adults with type 2 diabetes (T2D) should not be excluded from the benefits of technology. It is essential that AID systems are not only safe and effective, but also user-friendly and practical to implement into daily life, especially for people with T2D that may be less familiar with such technologies. We assessed the user experience of participants with T2D in an 8-week outpatient trial of the Omnipod 5 AID System.

Methods: In a prospective, single-arm trial, 24 adults with T2D and HbA1c >8% (64mmol/mol) previously using multiple daily injections (MDI) or basal-only injections used the AID system for 8 weeks at home. A subset of participants elected to also participate in a human factors follow-up interview including questions about their experience with the system and completion of the System Usability Scale (SUS) questionnaire (scores range from 0 [worst] to 100 [best]).

Figure. Single item responses on the System Usability Scale (SUS) questionnaire for adults with type 2 diabetes (N=14) using the Omnipod 5 AID System, with scores ranging from 1.0 (strongly disagree) to 5.0 (strongly agree)

Results: Fourteen participants, 57% female, aged 63.1 ± 7.6y (mean±SD) (range: 47.4-72.7y) with diabetes duration 19.0 ± 9.7y (range: 6.4-40.4y) were interviewed. Half were prior MDI users and 13 (92.9%) were insulin pump naïve. SUS results were 90.5 ± 13.5, demonstrating high perceived usability of the system (Figure). Factors driving the positive user experience included perceived health benefits (64%), convenience (57%), and improved confidence with diabetes management (36%).

Conclusions: The Omnipod 5 AID System was perceived as highly usable by adults with T2D, most of whom had never used an insulin pump, indicating the system's practicality as a treatment solution for this population.

EP289 / #129

Topic: ***AS14-Human factor in the use of diabetes technology***

HUMAN FACTORS INFLUENCE THE DESIGN AND USABILITY OF A DIABETES APP

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Background and Aims: To design a smartphone app supporting the self-management of Type-1 diabetes, placing priority on usability

Methods: Consideration of human factors during design

Results: Cognition and perception: Temporal data is presented in a scrollable bifocal diary (Spence & Apperley, 1982) to support both the understanding of quantitative data (e.g., blood glucose level during a selected day) and rapid perception of the qualitative representation of significant episodes occurring in adjacent days. **Change Blindness (**Rensink**,** 2005): an animated transition (Duration ∼500ms) between states is mandatory **Mental model** (''what a user believes they know about a user interface''Nielsen**,** 2010): is supported by easily remembered metaphors: for the bifocal diary (above) a band wrapped around two uprights and (right) four overlapping regions for personal data **Consistency:** The Icon -> touch -> tool -> touch -> icon scheme is universal and easily recall is anticipated. **Visible context** (Hinton, 2015): eases navigation as well as the planning of a meal or exercise in the viewable context of other factors that influence blood glucose level. **System response time:** if kept below 1 second supports decision making (Goodman & Spence, 1978) during a dynamic exploration of predicted changes in blood glucose level. **Attention** (Anderson, 2004)**:** is a limited resource so otherwise valuable visible context is rendered inconspicuous when of minimal importance, as in data entry

Conclusions: Design guidlines satisfied and human factors acknowledged

EP290 / #134

Topic: ***AS14-Human factor in the use of diabetes technology***

EXPERIENCES OF CAREGIVERS OF CHILDREN AND YOUNG ADULTS WITH TYPE 1 DIABETES RELATED TO SEVERE HYPOGLYCEMIA AND BEING PREPARED WITH NASAL GLUCAGON– A QUALITATIVE STUDY

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Background and Aims: The management of type 1 diabetes (T1D) in children and young adults can significantly impact the quality of life and psychological well-being of the patients and their caregivers. The present study aimed to understand caregiver experiences, including psychological distress, well-being, and social function regarding the child's risk for severe hypoglycemia and level of severe hypoglycemia preparedness, and assess the impact of nasal glucagon (NG) on these concerns.

Methods: This cross-sectional, non-interventional, qualitative study included adult caregivers of children or young adults with T1D. Eligible participants completed a semi-structured interview via telephone. The interview guide was developed in accordance with findings in existing literature. Participant characteristics were described using descriptive statistics and audio recordings were transcribed and qualitatively analyzed for themes.

Results: Caregivers (N = 32; mean age 45, SD ±7.7) of young people (mean age 13, SD ±4.7) were included in the analysis. There was a theme of proactivity by caregivers to prevent and prepare for severe hypoglycemia. Participants described experiencing 'social inhibition' (47%), 'acute distress from hypoglycemia' (47%), 'sleep loss/disruptions' (50%), and 'hypervigilance' about blood glucose getting too low (66%) due to hypoglycemia prevention, treatment, and worry. Many participants anticipated that NG would be easier to use than the original emergency kit, and it increased confidence in their and others' ability to administer it.

Conclusions: Overall, caregivers were hypervigilant about preventing severe hypoglycemia, and concerns about their child's severe hypoglycemia risk impacted their social and emotional well-being. NG appeared to increase caregivers' confidence in being prepared for severe hypoglycemia. Further research will quantitatively assess caregiver experiences.

EP291 / #158

Topic: ***AS14-Human factor in the use of diabetes technology***

UTILIZATION OF TIME IN RANGE IN REAL WORLD VARIES BY TYPE OF DIABETES

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Background and Aims: Previous studies have shown an association between Time in Range (TIR) and risk of microvascular complications. The present study aimed to assess the role of TIR when setting health goals and monitoring glucose data.

Methods: In an online survey in October 2021, 958 adults with diabetes and 44 caregivers of children and/or adults with diabetes were asked a series of questions related to personal diabetes-related goals and treatment metrics they review on their own and during visits with HCPs. Respondents received $10 USD for completing the survey.

Results: For the 86% of respondents who set personal diabetes health goals, consideration of TIR among one's top three goals was higher for those with type 1 diabetes (T1) (47%, n = 175) than those with type 2 diabetes (T2) (15%, n = 687). Among respondents who set TIR goals, 72% of those with T2 (n = 109) discuss TIR with their HCPs compared to 89% of those with T1 (n = 83). TIR was more likely to be identified as the most important diabetes metric by respondents who used CGMs (34%, n = 322) and respondents with T1D (30%, n = 201) compared to CGM non-users (2%, n = 676) and respondents with T2 (8%, n = 797).

Conclusions: This data highlights differences in TIR use between T1 and T2 populations and the lower levels of TIR use among people with T2 and CGM non-users. This study emphasizes opportunities for increased TIR use among T2 populations through increased CGM access.

EP292 / #167

Topic: ***AS14-Human factor in the use of diabetes technology***

USE OF FLASH GLUCOSE MONITORING (FGM) SYSTEM IN OLDER TYPE-2 DIABETICS

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Background and Aims: Self-monitoring of blood glucose is a key factor in the management of insulin-treated type-2 diabetes (T2 MDI). Elements of the treatment of diabetes are compliance with treatment and the self-monitoring of blood glucose, in which FGM is a useful, practical and non-invasive tool. The purpose of the study was to assess the efficacy of the FGM inT2 MDI older patients

Methods: In a retrospective longitudinal study, 204 patients, 129 men and 75 women, were examined. They were all treated at the Diabetes and Metabolic Diseases Unit Massa Carrara District and used the FGM system for 2 ± 0.5 years (average age 70.4 ± 3.5 years; duration of diabetes 18.2 ± 4.3 years).

Results: The data shows that the use of FGM improves blood glucose control in T2 MDI (HbA1c pre-FGM: 8.9 ± 0.9% vs HbA1c with FGM : 7.5 ± 1.4%, $p < 0.0001$). In patients between 65-74 years of age, we found an improvement that persists after 6 months and after 1 year ($p < 0.001$), stabilising 2 years from the start (1 year vs 2 years p = NS). In patients aged >75 years, a significant reduction in HbA1c was observed for the entire follow-up period. This improvement persisted 2 years from the start ($p < 0.005$). We did not record any episodes of severe hypoglycaemia or ketoacidosis.

Conclusions: Nowadays, patients need to keep track of their health and practice self-control thorough: medical guidance, self-motivation, or their carers' advice. The data shows that the use of FGM among elderly T2 MDI subjects is a valuable approach to manage their health as well as achieving their health-goals in a user friendly way.

EP293 / #171

Topic: ***AS14-Human factor in the use of diabetes technology***

RANKING OF IMPORTANT FACTORS IN RECOMMENDING DIABETES TECHNOLOGY BY PEDIATRIC AND ADULT ENDOCRINOLOGISTS: DATA FROM THE T1D EXCHANGE HEALTH EQUITY ADVANCEMENT LAB (T1DX HEAL) STUDY

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Background and Aims: Significant inequities exist in Continuous Glucose Monitors (CGM) and insulin pump use with lower use reported among Non-Hispanic Blacks and Hispanic patients compared to Non-Hispanic White patients. We aimed to understand the preference of diabetes providers in prescribing these technologies among providers in the T1D Exchange Quality Improvement Collaborative (T1Dx-QI) as part of the T1D Exchange Health Equity Advancement Lab (HEAL) Study.

Methods: T1Dx-QI is a learning network of forty-one US type 1 diabetes centers. Seven centers in the T1Dx-QI were invited to participate in this study. Adult (n = 35) and pediatric (n = 75) diabetes providers completed an online survey to rank the most important factors in recommending diabetes technology. Providers ranked the following factors from most important (#1) to least important (#7); insurance, race, income, patient preference, HbA1c, Patient Age, and self-management of blood glucose (SMBG). The results were analyzed by descriptive statistics and logistic regression models.

Results: Pediatric providers ranked patient technology preference (first), SMBG (second), and patient HbA1c (third) as the three most important factors before recommending any diabetes technology. Adult providers ranked patient technology preference (first), insurance type (second), and SMBG (third) as the three most important factors before recommending any diabetes technology. Race/ethnicity was consistently ranked to be the least important consideration in recommending diabetes technology by participating providers. There were differences in the ranking based on the type of diabetes technology (Insulin Pump vs CGM) for providers.

Conclusions: Identifying important factors for diabetes providers to recommend technology can help stakeholders develop targeted solutions addressing inequities in diabetes technology.

EP294 / #172

Topic: ***AS14-Human factor in the use of diabetes technology***

RACE-ETHNICITY MEDIATED BIAS IN RECOMMENDING DIABETES TECHNOLOGY: DOES IMPLICIT BIAS TRAINING MAKE A DIFFERENCE?

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Background and Aims: Inequities in the use of these diabetes devices persist with lower device use among Non-Hispanic Black and Hispanic patients compared to Non-Hispanic White patients. We examined the role of diabetes provider implicit bias mediated by patient's race in recommending devices.

Methods: Providers across seven US endocrinology centers electronically completed a Diabetes-Provider Implicit Bias (D-PIB) tool. This assessment contained a clinical vignette and ranking exercise. Providers were randomized and assigned identical case vignettes with different patient names as proxies of racial identity. Implicit bias was defined as providers recommending more technology for patients with an English-sounding name. Provider characteristics were analyzed using descriptive statistics and multivariate regression.

Results: Implicit bias based on patient race or ethnicity was observed among our sample (n = 37, 34%). There was no difference in the mean age of the providers (40.7 ± 10.3 years vs. 40.7 ± 10.7 years, p = 0.6), provider role, provider type (pediatric vs. adult), practice setting, or the number of practice years (8 ± 8.6 years vs. 7 ± 7.5 years, p = 0.8). In the biased group, 89% agreed with the statement 'I am able to recognize my own bias' compared to 61% in the non-bias group (0.001)''. The finding remained significant in a multivariate analysis accounting for age, provider's race, practice years as potential confounders (5.25, 95% CI [1.83,19.01]; P = .004). 62% of the providers in the biased group have received previous implicit bias training as compared to 51% in the non-biased group (P = 0.3)

Conclusions: Addressing implicit bias needs to extend beyond provider education to involve a deliberate approach rooted in racial justice and system changes.

EP295 / #187

Topic: ***AS14-Human factor in the use of diabetes technology***

ASSESSING EXPECTATIONS OF HYBRID CLOSED LOOP (HCL) INSULIN DELIVERY AMONG UNDERSERVED YOUTH WITH SUBOPTIMALLY CONTROLLED TYPE 1 DIABETES (T1D) AND THEIR CAREGIVERS

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Background and Aims: Significant disparities in access to and use of diabetes technologies exist among American youth with T1D. We aimed to evaluate expectations related to HCL insulin delivery among underserved youth with T1D and their caregivers to determine whether this influenced disparities in HCL use.

Methods: An ongoing study is recruiting 30 publicly insured, non-Hispanic Black (NHB) youth with T1D with $A1_C \geq 10\%$ and their caregivers to participate in a 6-month study of HCL use. The INSPIRE questionnaire measures positive expectations of HCL use. Scores range from 0-100; higher scores reflect greater positive expectations. Baseline characteristics were compared with the Tandem Control IQ pediatric pivotal trial cohort. INSPIRE scores were assessed using Welch's two sample t-test.

Results: Ten publicly insured NHB youth (M_{age} 14.1 ± 4.3 years, $M_{T1Dduration}$ 6.0 ± 6.0 years) with household incomes <$70,000 and suboptimal baseline glycemic control (M_{A1c} 11.8 ± 1.5%, Time in Range (TIR) 13.2 ± 11.6%) enrolled thus far. There was a trend towards higher INSPIRE scores among caregivers (M_{youth} 81 ± 11, M_{parent} 91 ± 12, p = 0.07). Comparatively, the Tandem pediatric Control IQ pivotal trial (n = 101 youth; M_{age} 11.2 ± 2.1 years, $M_{T1Dduration}$ 5.2 ± 2.8 years, M_{A1c} 7.7 ± 1.0) included no NHB participants (81% non-Hispanic White, 10% public insurance, 11% household incomes <$75,000). There were no significant differences in the INSPIRE scores between youth (76 ± 13, p = 0.23) or parents (85 ± 11, p = 0.18) in the two studies.

Conclusions: Positive expectancy of HCL systems was comparable among underserved youth with T1D and a predominantly non-Hispanic White, privately insured, high-income cohort. These findings suggest that differences in perceptions of HCL technology do not explain disparities in T1D technology.

EP296 / #214

Topic: ***AS14-Human factor in the use of diabetes technology***

REASONS FOR HESITANCY TOWARD NEW AUTOMATED INSULIN DELIVERY SYSTEM ADOPTION AMONG ADULTS LIVING WITH DIABETES IN THE UNITED STATES, CANADA, AND EUROPE

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Background and Aims: As diabetes technology continues to advance, multiple automated insulin delivery (AID), or closed loop, systems have already or will soon be launched. The present study aims to gain a deeper understanding of the reasons for patient unwillingness to adopt such new AID systems.

Methods: From March-June 2021, 5,226 adults living with diabetes in the United States, Canada, France, Germany, Italy, Netherlands, Sweden, and United Kingdom took an online survey in which they viewed the profiles of three new or upcoming commercial AID systems and selected their preferred system, if any. Respondents who selected ''none of the systems'' (n = 975) were asked to explain the reason for their choice. The subsequent 808 qualitative write-in responses (67% type 1, 59% female) were coded and analyzed.

Results: Overall, unwillingness to switch therapies (19%), unwillingness to use an insulin pump (16%), and distrust of technology (12%) were the top reasons for AID system adoption reluctance. Do-it-yourself hybrid closed loop (DIY HCL) users (n = 47) found the target ranges of the presented systems too restrictive (57%). Among non-DIY HCL pumpers (n = 160), distrust of technology ranked the highest (19%), followed by unwillingness to change current therapy (17%). Respondents on

MDI (n = 601) did not want to use a pump (20%). Respondents in the U.S. (n = 446) were more distrustful of technology (15%) than those in Canada and Europe (n = 336; 7%).

Conclusions: Reducing hesitancy toward AID system adoption would likely involve reducing insulin pump intrusiveness, increasing patient knowledge, and increasing system customizability.

EP297 / #295

Topic: ***AS14-Human factor in the use of diabetes technology***

HUMAN FACTORS INFLUENCING FREQUENCY AND ACCESSIBILITY OF BLOOD GLUCOSE SELF-MONITORING AMONG ADULTS WITH TYPE 2 DIABETES

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Background and Aims: Recent advancements in diabetes technology have been associated with increased self-monitoring of blood glucose (SMBG) and improved health outcomes. Despite these benefits, barriers to access exist, prohibiting patients from adopting technologies such as blood glucose meters (BGMs) and continuous glucose monitors (CGMs). The present study aimed to identify potential barriers to diabetes technology access among infrequent BGM users and non-BGM, non-CGM users with type 2 diabetes (T2D).

Methods: In September 2021, adults with T2D in the U.S. completed an online survey on their SMBG frequency. Respondents who use a BGM less than daily (infrequent BGM users) or do not use a BGM or CGM at all were asked to identify factors impacting their SMBG frequency and potential factors that could increase it. The resulting 798 responses were analyzed, and qualitative verbatims were coded.

Results: Among 748 infrequent BGM users, respondents cited forgetfulness (43%), pain with fingersticks (14%), disinterest in results (14%), and challenges with affordability (14%) as barriers to SMBG. Among 50 non-CGM, non-BGM users, 18% indicated that they do not know enough about diabetes technology and 14% reported feeling intimidated by its use. Both populations reported that improved affordability may increase technology use (38% and 20%, respectively), while non-technology users may also benefit from encouragement from HCPs (36%) and free trials (34%).

Conclusions: The present study identifies areas for improving the accessibility of diabetes technology. Future research should focus on methods to increase SMBG frequency, including technology-centric diabetes education and efforts to increase financial and emotional support.

EP298 / #297

Topic: ***AS14-Human factor in the use of diabetes technology***

TECH TRUTHS: REFLECTIONS ON TECHNOLOGY UTILIZATION FROM YOUTH AND THEIR PARENTS AFTER T1D DIAGNOSIS

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Background and Aims: A type 1 diabetes (T1D) diagnosis can have a profound impact on families, simultaneously coping with the psychosocial impact while also learning about both the challenges and benefits of technologies that can support the daily burden. We sought to better understand families' perceptions of technology use during the first year post diagnosis.

Methods: Focus groups were conducted via videoconferencing to examine the challenges and successes of technology utilization during the first year following diagnosis. Participants were 1 to 3 years post-diagnosis. Youth (ages 8-12, $n = 10$; 13-18, $n = 11$) and parents of youth under 8 ($n = 12$), 8-12 ($n = 15$) and 13-18 ($n = 12$) participated. Transcripts were analyzed using deductive coding and thematic analysis.

Results: All participants reported that CGM improved their ability to monitor glucose levels, decreased worry about out-of-range numbers, and was associated with occasional conflict surrounding site changes and notifications. Teens endorsed feeling annoyed by alarms. Parents expressed concern that the visibility of CGM/pump was associated with questions from others. Parents reported a sense of optimism for improved quality of life, improved sleep quality, and increased comfort in their child spending time away from home. Teens reported increased independence and opportunities for greater flexibility with food on pump therapy.

Conclusions: These findings reveal the benefits and unique challenges youth and their parents experience the first year following T1D diagnosis related to technology utilization. By understanding families' lived experiences, diabetes education may be altered to effectively address what information is shared at diagnosis to collaboratively overcome perceived barriers for ideal technology utilization.

EP299 / #298

Topic: ***AS14-Human factor in the use of diabetes technology***

DAILY PREDICTORS OF DIABETES SELF-MANAGEMENT IN ADOLESCENTS WITH TYPE 1 DIABETES (T1D) USING CGM

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Background and Aims: Understanding daily factors that influence adolescents' and young adults' (AYA) engagement in diabetes self-management (DSM) and goal attainment are important for supporting self-care behaviors.

Methods: Methods: 100 AYAs (mean 17.6 ± 2.6 yrs, 52% female, HbA1c 7.9 ± 1.4%, diabetes duration 8.8 ± 4.6 yrs) with T1D participated in a 2-week prospective study. Participants

chose a DSM goal to focus on during participation. On six quasi-random days, participants completed a 26-question morning ''predictor'' survey to assess current glucose level, sleep, mood, motivation, control beliefs, social support, illness, self-esteem, and help needs. An evening survey assessed goal attainment perceptions (average score of 3 questions). LASSO and mixed model regression determined items most predictive of perceived goal attainment, Time-in-Range (TIR), sensor mean glucose (SMG), number of insulin boluses, and hyperglycemia response (bolus within 30 minutes of high alert or glucose <200mg/dL within 2 hours).

Table: The variance in daily diabetes self-management, glycemia, and goal attainment explained by a 7-item and 10-item prediction model

Outcome		7-item model	10-item model
		1. Current glucose level on CGM? 2. I am planning on managing my diabetes today 3. I want to manage my diabetes today 4. Do you feel like skipping DSM activities because you feel fine? 5. I feel good about who I am 6. In general would you say your health right now is... 7. Do you think you could use some extra support for your diabetes management today?	Items 1-7 and 8. How sad are you feeling right now? 9. Do you feel accepted and cared for? 10. Do you feel that you are able to handle difficulties?
Number of Boluses	Marginal R^2	0.021	0.044
	Conditional R^2	0.583	0.594
Combined Hyperglycemic alert response	Marginal R^2	0.14	*
	Conditional R^2	0.342	*
% of high alerts followed by a bolus	Marginal R^2	0.089	*
	Conditional R^2	0.37	*
Sensor Mean Glucose (SMG)	Marginal R^2	0.181	0.186
	Conditional R^2	0.525	0.532
Time in Range (TIR) 70-180 mg/dL	Marginal R^2	0.167	0.175
	Conditional R^2	0.542	0.55
Goal attainment	Marginal R^2	0.287	0.29
	Conditional R^2	0.541	0.546

* model did not converge

Results: A 7-item and 10-item model (Table) were selected based on LASSO and theoretical considerations. While the conditional R^2 (entire model) predicted 37-59% of the variance in outcomes, the marginal R^2 (reflecting only fixed effects) predicted 14% of hyperglycemia response, 18% of SMG, and 29% of perceived goal attainment (Table). Both models included constructs related to glucose level, motivation, illness, and help-needs; the 10-item model also found mood, social-support, and control-beliefs to be predictive. Neither model identified sleep as a factor in DSM engagement.

Conclusions: A combination of daily predictors, including motivation, influence DSM engagement in AYAs. These models identify fulcrums for multi-factorial interventions to improve self-management and glycemic control.

EP300 / #302

Topic: ***AS14-Human factor in the use of diabetes technology***

AWARENESS OF TIME IN RANGE – OPPORTUNITIES FOR INCREASED ADOPTION

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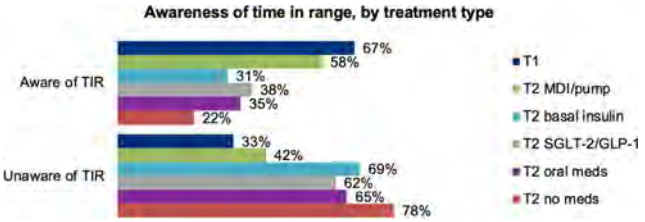
Background and Aims: Previous studies have shown a correlation between Time in Range (TIR) and risk for microvascular complications, but the level of TIR awareness among people with diabetes is unknown. This study aimed to assess the awareness of TIR among people with Type 1 (T1) and Type 2 (T2) diabetes and identify barriers to using the metric.



Methods: In an online survey in October 2021, 958 adults with diabetes and 44 caregivers of children and/or adults with diabetes were asked a series of questions related to their awareness of TIR, its value and ease of use, and barriers associated with using TIR. Respondents received $10 USD for completing the survey.

Results: 44% of respondents were aware of TIR. Awareness was higher among people with T1 (67%, n = 201) and T2 on MDI/pump therapy (58%, n = 195) compared to other people with T2 (33%, n = 606). 75% of CGM non-users (n = 680) were unaware of TIR compared to just 14% of CGM users (n = 322). Of those aware of TIR (n = 445), most believed TIR was valuable (88%) and easy to use (89%). Among TIR non-users (n = 559), 89% believed TIR would be helpful in diabetes management, and 66% identified education from their provider as a helpful resource for learning more about TIR.

Conclusions: This data highlights the varying levels of TIR awareness among people with diabetes and opportunities to increase TIR awareness among people with T2. Increased access to CGM and HCP education can help advance TIR awareness and adoption.

EP301 / #362

Topic: ***AS14-Human factor in the use of diabetes technology***

HUMAN FACTORS OF A FULLY IMPLANTABLE BIONIC INVISIBLE PANCREAS: PERCEIVED POTENTIAL BENEFITS AND BARRIERS OF PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: The EU project ''FORGETDIABETES'' (supported by H2020-FETPROACT, n.951933) aims at developing a fully implantable system for automated insulin delivery (AID). It will consist of an intraperitoneal pump and an implantable CGM sensor. The insulin pump will be refilled via an insulin pill and charged wirelessly. The aim is to provide fully automated diabetes management with minimal user interaction. To assess human factors associated with acceptance of the bionic invisible pancreas (BIP), we explored perceived benefits and barriers.

Methods: Three groups of people with type 1 diabetes were invited to complete a preliminary questionnaire on 9 potential benefits (e.g., flexibility, protection from long-term complications) and 10 potential barriers (e.g., implantation, loss of control) of

Figure 1. Comparison of perceived benefits and barriers across the three focus groups

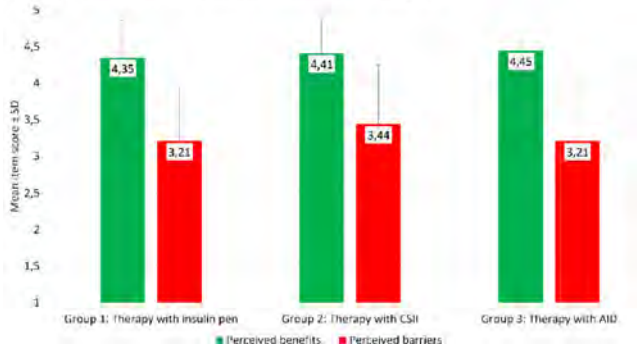
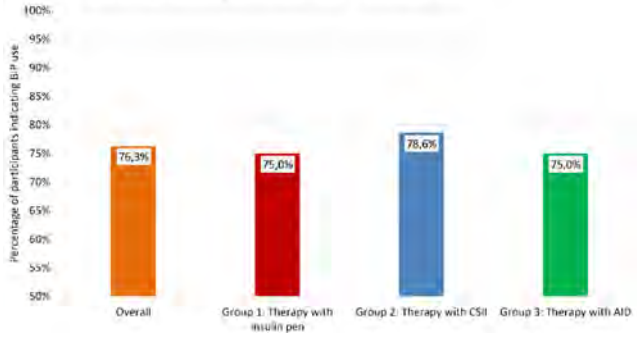


Figure 2. Percentage of participants indicating potential use of the bionic invisible pancreas



the BIP: 1) CGM and insulin pen therapy 2) CGM and insulin pump therapy 3) therapy with an AID system. All participants provided informed consent and were shown a video illustrating the components and functionality of the BIP. Questions were rated on a five-point Likert scale from 1-completely disagree to 5-completely agree.

Results: Data from 38 participants were analysed (Group 1: n = 12; Group 2: n = 14; Group 3: n = 12). Across groups, potential benefits were rather higher than barriers (mean item scores: 4.41 ± 0.45 vs. 3.29 ± 0.76; Cohen's d = 1.46). Interestingly, there were no between-group differences regarding benefits (p = 0.861) and barriers (p = 0.669). 76.3% of participants indicated that they would use the BIP. This high level of potential use did not differ between the groups (p = 0.969).

Conclusions: A fully implantable AID system was rated as highly beneficial across three groups with different diabetes-technology-use.

EP302 / #386

Topic: ***AS14-Human factor in the use of diabetes technology***

EVERSENSE AS THE FIRST CHOICE OF CGM TO IMPROVE QUALITY OF LIFE AMONG PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: **Background and aims:** In the past few years, continuous glucose monitoring systems (CGM) have been widely introduced among patients with type 1 diabetes (T1D). This technology has been shown to improve both glycaemic control and quality of life. However, there is less scientific evidence on implantable CGM such as Eversense, probably due to their cost, their greater insertion difficulty or because it is considered as a last option and only if the others CGM devices have failed. We aimed to assess whether the insertion of an Eversense as first CGM option among T1D patients increased satisfaction with treatment due to an increase in health-related quality of life and a decrease in fear of hypoglycaemia.

Methods: **Methods:** 10 patients with T1D (70% ♂, 29.6 ± 9.7 years) with an Eversense from three hospitals in the Balearic Islands, placed with criteria according to their doctor, were evaluated with a follow-up of three months. In order to assess unawareness or fear of hypoglycemia, Clarke test and FH-15 were administered respectively. Quality of life was administered using the Vida1 questionnaire and treatment satisfaction was evaluated by using The Diabetes Treatment Satisfaction Questionnaire (DTSQ-c).

Results: **Results:** All patients scored negative for Clarke test (1.4 ± 1) and showed no significant fear of hypoglycemia with FH-15 (19.2 ± 4.7). All domains of Vida 1 were above the mean score. Also, satisfaction with this treatment was good (16.8 ± 2).

Conclusions: **Conclusions:** Eversense as a first selection of CGM showed patients' satisfaction to treatment, a good health-related quality of life and positive results in hypoglycemia at short term.

EP303 / #392

Topic: ***AS14-Human factor in the use of diabetes technology***

EUROPEAN SURVEY ON ADULT PEOPLE WITH TYPE 1 DIABETES (T1D) AND THEIR CAREGIVERS: INSIGHTS INTO USE OF TECHNOLOGICAL DEVICES AND DIGITAL TOOLS

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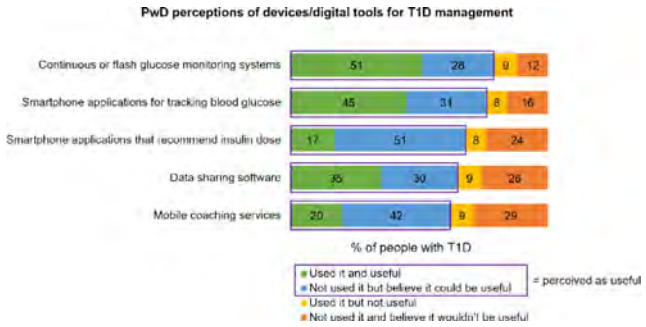
Background and Aims: T1D is a complex disease, in which technology can aid management. We aimed to survey the impact of diabetes on daily life, including use and perception of technology in T1D management.

Methods: Adults diagnosed with T1D or their caregivers living in France, Germany, Italy, Spain, or the UK were invited to complete an online survey on the Carenity platform (during July–August 2021).

Results: Responders included 458 people with diabetes (PwD; 54% female, 34% ≤ 40 years old, 43% 41–60, 23%> 60,



mean age at diagnosis 24.4 years) and 54 caregivers. Most PwD (64%) used insulin pens, 26% insulin pumps, and 7% smart insulin pens (3% did not know what they used). Smart insulin pen use was more common in those aged ≤40 years than older PwD. Classic glucose meters were used by 43% of PwD; 64% used continuous or flash glucose monitoring. Approximately half of responders (53% PwD, 56% caregivers) felt they lacked knowledge about T1D, especially devices/digital tools (24%,15%); however, most PwD believe current devices/digital tools are/could be useful (Figure). Relatives/friends (25%) and technology/devices (21%) were reported as the most helpful support for PwD. Most PwD (63%) felt that accessing data from T1D monitoring devices made life easier. Only 9% of PwD regularly used teleconsultation; 65% had never used teleconsultation, however two-thirds of those would have liked to.

Conclusions: People with T1D and their caregivers require more support and information on T1D management, and a majority of PwD believe devices/digital tools are/could be useful.

EP304 / #403

Topic: ***AS14-Human factor in the use of diabetes technology***

QUALITATIVE EVALUATION OF A TELEMONITORING SOLUTION FOR PEOPLE WITH TYPE 2 DIABETES ON INSULIN: A PILOT STUDY IN PREPERATION FOR THE DIAMONT TRIAL

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Background and Aims: People with type 2 diabetes (T2D) experience that mobile applications and monitoring devices are not always user-friendly. Thus, it is important to consider the user experience when designing a telemonitoring trial for people with T2D. This pilot study aimed to explore the user experience of a telemonitoring solution prior to a randomized controlled trial (The DiaMont trial (NCT04981808)).

Methods: A qualitative approach was applied. Five participants (age: 55-74, diabetes years: 0-20) used a telemonitoring solution for four weeks. The participants used an activity tracker, a continuous glucose monitor (CGM), and two smartphone applications at home, while lab technicians at the Department of Endocrinology at Aalborg University Hospital monitored their data. All participants were interviewed by the end of the study.

Results: Five themes emerged from the interviews: 1) Information overload, 2) User manuals, 3) Activity tracker, 4) CGM, and 5) The overall experience. Overall, the participants were very positive about the telemonitoring solution and found that it contributed to their glycemic control, self-management, and well-being. However, the heavy load of information and introduction to several devices at inclusion were found overwhelming. Some participants also experienced problems with the smartphone applications (unwanted alarms and poor usability).

Conclusions: Telemonitoring may add value to people with T2D in terms of improved glycemic control, self-management, and well-being. The heavy load of information and training should be considered when designing a telemonitoring trial for people with T2D.

EP305 / #411

Topic: ***AS14-Human factor in the use of diabetes technology***

IMPROVING TYPE 2 DIABETES MELLITUS PATIENT OUTCOMES WITH MINDFULNESS-BASED STRESS REDUCTION

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Background and Aims: Self-care management of Type 2 Diabetes (DM2) can be burdensome and stressful to patients. Stress, either physiologic or psychologic can contribute to negative outcomes for the person with DM2. Mindfulness-Based Stress-Reduction has been shown to reduce psychological distress, anxiety, and depression among patients with Type 2 diabetes. AIMS: Mindfulness-Based Stress Reduction (MBSR) intervention was effective for improving glycemic control in adult patients with Type 2 diabetes Participation in a MBSR program (8 weeks) prompted participants to incorporate mindfulness practice in their daily lives Sustainability of improved glycemic control was achieved when incorporating MBSR as adjunct treatment.

Methods: This was a quasi-experimental study using a pre post intervention design with follow up at 6 and 12 months. Biomarkers were measured: a) A1C was measured pre and post intervention, 6 months, 12 months b) glucose was measured using a Continuous Glucose Monitor (CGM) during the 8 week intervention. Psychometric testing using the Stress Visual Analog Scale (SVAS), the Perceived Stress Scale (PSS) and the Mindfulness Awareness Scale (MAAS) were administered to test for change in levels of stress.

Results: One-tailed t-tests showed that PSS scores were significantly reduced between pre and post intervention, while A1C was moderately but not significantly reduced. Using multilevel modeling, we found significant reductions in glucose (-14.0%) and SVAS (-2.93 points on a scale from 0 to 10) between before and after sessions. Throughout the intervention, glucose decreased (-1.2% per week) –although non-significantly – while SVAS significantly decreased (-0.15 points per week).

Conclusions: Findings support MBSR for stress management of DM2.

EP306 / #434

Topic: ***AS14-Human factor in the use of diabetes technology***

AGE-BASED DISPARITIES IN PATIENT-PROVIDER DISCUSSION OF DIABETES TECHNOLOGY: A CALL FOR DISMANTLING AGEISM IN DIABETES CARE

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Background and Aims: Continuous glucose monitoring (CGM) and insulin pump technologies provide glycemic and quality-of-life benefits for people with diabetes (PWD) of all ages. Healthcare providers' (HCP) implicit biases about the ability of older PWD to use technology may limit adoption for PWD ages 65+.This study assessed age-based differences in patient reports of HCP-initiated discussions of CGM and insulin pump technology.

Methods: In June 2021, 5,435 people living with type 1 (T1D) and type 2 (T2D) diabetes in the United States completed an online questionnaire. Non-CGM users (n = 2,630) were asked whether their HCP has ever initiated a conversation about CGM, and PWD taking multiple daily injections (MDI) (n = 1,078) were asked whether their HCP has ever initiated a conversation about pump technology. Health and demographic information were collected.

Results: Older age was a predictor of lower likelihood of technology discussion when adjusted for A1c, income, insurance status, race, HCP type, and diabetes type. Non-CGM users ages 65+ were less likely to report a discussion about CGM (8%) compared to those ages 18-35 (53%) and 36-64 (13%). Those on MDI ages 65+ were less likely to report a discussion about pumping (31%) compared to those in the 18-35 (81%) and 36-64 (51%) age groups. Age-based differences were present within T1D and T2D subpopulations.

Conclusions: These results suggest that providers may be less likely to suggest technology options to older patients. This study calls for a focus on ageism in diabetes care as a barrier to technology adoption.

EP307 / #455

Topic: ***AS14-Human factor in the use of diabetes technology***

IMPROVED TIME IN RANGE ASSOCIATED WITH A CONTINUOUS GLUCOSE MONITORING SYSTEM'S AUTOMATED NOTIFICATION AND RETROSPECTIVE ANALYSIS FEATURES

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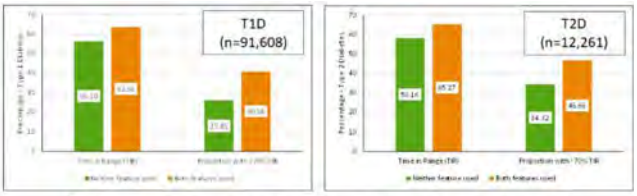
Background and Aims: The G6 Continuous Glucose Monitoring (CGM) System (Dexcom, Inc., San Diego, CA) includes CLARITY, which allows users to receive automated ''push'' notifications on compatible smart devices and which also provides comprehensive, device-independent reports of retrospective CGM data. We examined whether use of these features was associated with differences in time in range (TIR, 70-180 mg/dL) or the likelihood of achieving >70% TIR.



Association between push notification and retrospective analysis feature utilization, time in range, and likelihood of achieving >70% TIR

Methods: Anonymized data from a convenience sample of US-based G6 users with known diabetes type (T1, n = 91,608 or T2, n = 12,261) that were uploaded in the 6 months ended 31-OCT-2021 were analyzed. Data included estimated glucose values (EGVs), the opt-in status for push notifications, and the history of CLARITY login(s). Users who changed settings in the observation window were excluded.

Results: The T1 cohort was younger than the T2 cohort (mean age 37.4 vs. 60.0 years), had more EGVs <70 mg/dL (2.51 vs. 1.05%), and higher glycemic variability (CV, 35 vs. 30%, respectively). Regardless of diabetes type, use of push notifications together with logins for retrospective analysis (''Both features used'') was associated with higher TIR and higher proportions of individuals meeting the consensus recommendation of >70% TIR than use of neither feature (''Neither feature used'') (Figure).

Conclusions: In this sample of real-world G6 users with known diabetes type, use of CLARITY push notification and retrospective analysis features was associated with higher mean TIR and higher prevalences of users meeting the >70% TIR goal.

EP308 / #471

Topic: ***AS14-Human factor in the use of diabetes technology***

ANALYSIS OF DIABEFLY® DIGITAL THERAPEUTICS PLATFORM FOR ENHANCING BEHAVIOURAL SELF-MANAGEMENT IN DIABETES BASED ON PERFORMANCE IN MOTIVATION AND ATTITUDE TOWARDS CHANGING HEALTH (MATCH) QUESTIONNAIRE

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Background and Aims: Diabetes management involves long-term effort to follow a healthy regimen. In India, there are few studies on motivation levels of patients for effective diabetes management. The aim of this study is to evaluate effectiveness of Diabefly® digital therapeutics program to improve motivation towards behavioral change in people with type 2 diabetes.

Methods: 60 participants (51.66 % females, average age: 48.78 ± 12.34 years) enrolled in the Diabefly® program. During the 90 days program, three highly customized therapy sessions via video call for 45 minutes each were provided along with access to mobile application based digital logging, diabetes education and expert-led care. Gestalt, mindfulness-based therapies and motivational interviewing were used during the therapy sessions. Motivation and attitude towards changing health (MATCH) questionnaire pre and post the program was analyzed. t-test and ANOVA was used for statistical analysis.

Results: The overall motivation score improved significantly by 7.31% from the baseline score of 32.55 ± 3.94 (p = 0.001). The score for ableness increased from 11.45 ± 2.25 to 12.05 ± 1.97 (p < 0.001); worthwhileness increased from 8.93 ± 2.42 to 10.63 ± 2.89 (p = 0.001). The pre-motivation levels of males were higher than females (p = 0.01). The difference in pre and post motivation levels varied among different age groups with people in 15-35 years showing the lowest level of motivation (p = 0.019).

Conclusions: The study showed that overall motivation and ability to understand the worth of managing diabetes significantly improved after participation in the Diabefly® program. Thus, remotely executed psychotherapies can help in more comprehensive diabetes management, irrespective of their initial motivation level of individuals.

EP309 / #473

Topic: ***AS14-Human factor in the use of diabetes technology***

RESIDUAL B-CELL FUNCTION IN SUBJECTS WITH TYPE 2 DIABETES PROTECTS FROM NON-ADHERENCE TO INSULIN THERAPY VERSUS SUBJECTS WITH TYPE 1 DIABETES

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Background and Aims: Adherence to insulin therapy is known to impact on optimal glucose control in type 1 diabetes (T1D). However, the effect of intentionally or non-intentionally failing in treatment compliance in type 2 diabetes (T2D) is unknown. Here, we compare *in silico* the detrimental effects on glucose control of delaying or skipping insulin bolus in T2D versus T1D and the potential role of residual β-cell function in protecting subjects with T2D from hyper- and hypo-glycemia.

Methods: We performed two 6-month *in silico* trials, using Padova T2D and UVA/Padova T1D simulators, in 100 advanced-stage T2D and 100 T1D adults receiving 3 meal/day under basal/bolus insulin therapy. In one case, the pre-meal insulin bolus was optimally administered at each meal; in the other case, it was randomly delayed or skipped in 3 lunches during workingdays and 1 dinner during weekends. Standard glucose control metrics, based on continuous glucose monitoring, were calculated in the two occasions and their changes from optimal to non-optimal adherence to therapy were compared in T2D versus T1D.

Results: are reported in Table 1. Delaying/skipping pre-meal insulin bolus worsen glucose control in both T1D and T2D, but degradation is mitigated in T2D versus T1D.

Conclusions: Even in subjects with T2D, non-adherence to insulin therapy worsens postprandial glucose control but to a lower extent compared to subjects with T1D. This is likely due to the residual β-cell function, as we found that insulin secretion increased three-fold (statistical p-value <0.001) after meals with delayed/skipped insulin bolus versus those with optimal adherence to therapy.

Table 1: CGM outcome metrics assessed during 6-month 3-meal/day *in silico* trials

Metric change	T2D	T1D	p-value
Mean CGM (mg/dL)	-13.7 [-21.1, -4.4]	-8 [-14.9, 0.8]	0.001
SD CGM (mg/dL)	13.8 [7.5, 20.1]	18.4 [10, 25.7]	0.003
CV CGM (%)	8.3 [3.9, 16.5]	13.5 [3.7, 21.2]	0.160
% CGM 70-180 mg/dL	-1.2 [-18.3, 5.3]	-15.8 [-27.3, -2.4]	<0.001
% CGM <70 mg/dL	1.4 [0, 7.8]	7.3 [0.1, 16]	0.028
% CGM <54 mg/dL	0.3 [0, 3.2]	3 [0, 7.8]	0.012
% CGM >180 mg/dL	-3.9 [-7.7, 4.7]	4.2 [-2.3, 9.2]	<0.001
% CGM >250 mg/dL	0.2 [-0.4, 1.4]	2.8 [0.2, 6.6]	<0.001

Chances in CGM-based outcome metrics are reported as median [25th, 75th] percentile. Statistical comparisons between T2D and T1D were performed by Wilcoxon ranksum test (*p*-value<0.05); CGM: continuous glucose monitoring; SD: standard deviation; CV: coefficient of variation).

EP310 / #474

Topic: ***AS14-Human factor in the use of diabetes technology***

ANALYSIS OF CHANGES IN GLYCEMIC CONTROL AND DISTRESS AMONG PEOPLE WITH DIABETES AFTER 90 DAYS ON DIABEFLY® DIGITAL THERAPEUTICS PROGRAM

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Background and Aims: Diabetes Distress is a unique, often hidden, emotional burden and worries experienced by an individual when managing a chronic disease like diabetes. Higher diabetes distress is associated with poor glycemic control and compromised diabetes self-care. To break this vicious cycle, managing diabetes distress is extremely important, which may subsequently lead to improved glycemic control. The aim is to study the real world effectiveness of virtual psychotherapy on the distress levels and HbA1c of patients with Type 2 diabetes.

Methods: 43 individuals with Type 2 DM, across India were given three highly customized virtual therapy sessions via google meet with a psychologist (45 minutes each). Gestalt, mindfulness and cognitive behaviour therapies were used. These patients were also consulted by nutritionists and physiotherapists for adequate support. Initial and final assessment was done using Diabetes Distress Scale (DDS) & HbA1c levels. Paired sample t-test on SPSS 21 was used to analyse the data.

Results: Pre and post assessment scores on DDS & HbA1c levels were found to be statistically significant. Post intervention,

distress scores decreased by 22% from baseline 1.55 ± 0.90 to 1.18 ± 0.45 (p = 0.002); and HbA1c levels reduced by 21% from baseline 1.72 ± 0.45 to 1.30 ± 0.46 (p = 0.000).

Conclusions: After completion of the program a significant improvement in glycemic control and reduction in distress was observed. The study showed that the Diabefly® DTx program can help in better management of diabetes by providing comprehensive and expert driven care by specialists like psychologists, nutritionists and physiotherapists.

EP311 / #497

Topic: ***AS14-Human factor in the use of diabetes technology***

PSYCHOLOGICAL OUTCOMES OF CSII TREATMENT IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES: A LONGITUDINAL CASE-CONTROL STUDY

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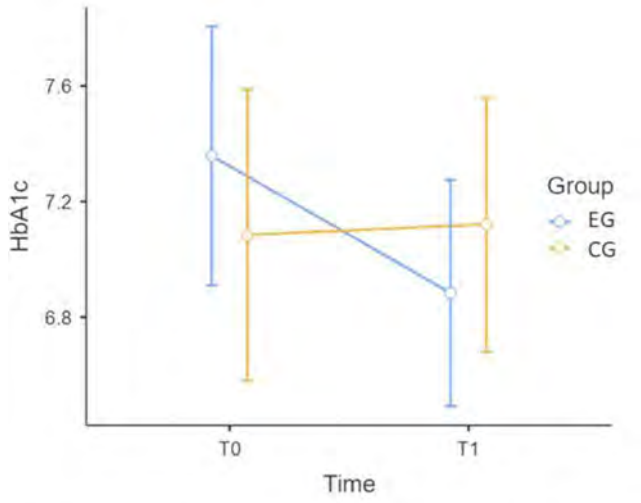
Background and Aims: Diabetes technologies positively affect glycemic control and diabetes distress. However, psychosocial evidence for automated insulin delivery systems is still limited. This study aims to explore the psychosocial impact of 6-months CSII with HCL treatment in young patients with T1D compared to peers with MDI treatment.

Methods: 24 children/adolescents with CSII (14 girls, 14.2 years ±2.68; 9-19), and 24 MDI controls (14 girls, 13 years ±2.67; 9-19) were involved. Illness acceptance, anxiety, depression, quality of life (QoL), intolerance of uncertainty were assessed at two time points: T0 (before CSII treatment) and T1 (6 months later). The following glucose metrics were registered: HbA1c, time in range (TIR, %), time in hypoglycemia (%), time in hyperglycemia (%).



Results: Repeated measure ANOVA showed a greater decrease in HbA1c in the experimental group (EG) compared to controls. Concerning psychological variables, the EG obtained higher QoL and lower anxiety scores than controls. Negative Spearman correlations emerged between anxiety and HbA1c at T0 in the EG (*rho* = -.44, *p* = .048).

Conclusions: New technologies for diabetes treatment have several medical benefits, but psychosocial outcomes must be also considered. Patients reported an improvement on glycemic control after 6-months CSII treatment. The EG presented lower anxiety and better QoL compared to controls: HCL could contribute to improve psychological health. At T0, higher anxiety was associated with lower HbA1c in the EG. This could be due to the use of anxiety-based strategies to manage diabetes; therefore, patients with high anxiety could benefit from HCL tools.

EP312 / #526

Topic: ***AS14-Human factor in the use of diabetes technology***

EASE OF USE STUDY - GLUCOMETER FIRST DEMO EFFECTIVENESS IN CENTRAL INDIAN POPULATION.

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Background and Aims: Glucometer remains the cornerstone of therapy in a substantial number of patients with type 2 diabetes mellitus (T2DM). Inadequate knowledge regarding glucometer use is likely to influence its acceptance and adherence, and outcome of therapy, underscoring the need to teach proper technique of using a glucometer to T2DM patients.

Methods: In 2020–2021 we conducted a survey of 438 respondents (male: 242, female: 196), novel glucometer user patients who were enrolled as outpatient in a Diabetes clinic during last years (2020–2021), to assess the ability to use glucometer after one demonstration by a Diabetes educator. anxiety score calculated by Generalised Anxiety Disorder Questionnaire (GAD-7)

Results: Out of 438 respondents, 26% could not use a glucometer after the first demonstration. The inability to use glucometer was more in rural patients 72%, in females 65% as compared to males 35%, was more in lower educational status and was more in patients with higher anxiety scores.

Conclusions: This study shows that there is a pressing need to develop strategies to teach patients a better way to self-monitor blood sugar by a glucometer. We can predict based on educational status and other parameters mentioned in the study to give more elaborate training to those groups in need. And there is a further need to study the efficacy and adaptability of various ways of teaching patients about the Glucometer

EP313 / #532

Topic: ***AS14-Human factor in the use of diabetes technology***

SLEEP IN CAREGIVERS OF VERY YOUNG CHILDREN WITH TYPE 1 DIABETES USING A SENSOR AUGMENTED PUMP OR CLOSED-LOOP INSULIN DELIVERY

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Background and Aims: Parents of children with type 1 diabetes (T1D) worry about their child's nighttime glucose levels and are often sleep deprived. Technology has changed management of T1D with the development of closed-loop (CL) systems promising to be transformative. This study compared sleep in caregivers of a subset of children in the KidsAP02 study using sensor-augmented pump (SAP) therapy or CL therapy.

Methods: The sample comprised 40 parents (classified as caregiver 1 or 2 based on contribution towards treatment management) of 21 very young children with T1D (mean age 4.7[SD = 1.7]). Assessments were made at a single post-randomisation time-point when children were completing either SAP arm (n = 11) or CL arm (n = 10) of the main study. Data were obtained using accelerometers and sleep diaries from parents.

Results: Overall, there was a mixed pattern of results. When comparisons were restricted to the primary caregiver (caregiver 1), actiwatch data showed that parents of the SAP group (as compared to the CL group) had: greater sleep onset latency (25.5 vs 16.7 mins); more wake-after-sleep-onset (WASO) (39.1 vs 28.2mins); and lower sleep efficiency (85.1% vs 88.1%). Sleep diaries data showed that SAP group (as compared to CL group) reported a higher sleep duration (8.2 vs 7.8h), but lower sleep quality (3.3 vs 3.6), more awakenings (3.2 vs 1.9) and more WASO (52.6 vs 28.6 min). None of the comparisons reached the $p < .05$ significance level due to small sample size.

Conclusions: Preliminary results from this study suggest that CL treatment could be associated with better sleep quality in the primary caregiver.

EP314 / #535

Topic: ***AS14-Human factor in the use of diabetes technology***

LIFESTYLE CHANGES FROM ONLINE INFORMATION AMONG PEOPLE WITH DIABETES – THE HUMAN FACTOR STILL COUNTS CROSS SECTIONAL STUDIES

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Background and Aims: Lifestyle changes may reduce morbidity and mortality in patients with diabetes. Little is known about how experienced human support may relate to lifestyle changes after seeking lifestyle information online. Our objectives in two cross sectional studies were to assess the associations between lifestyle changes among people with diabetes based on online information, and human support achieved by participating in online groups or discussing the information with a doctor.

Methods: We used self-reported survey data from 1,250 members of The Norwegian Diabetes Association (18-89 years), collected in 2018. The first study included 540 respondents diagnosed with type 2 diabetes (T2D), while the second study included 847 respondents with type 1 diabetes (T1D) or T2D. By logistic regressions we studied the associations between self-reported lifestyle changes and participating in online groups or discussing the internet information with a doctor.

Results: In the T2D study, 41.9% reported lifestyle changes based on internet information, whereas 46.9% in the T1D/T2D study did. The odds of positive lifestyle changes were more than doubled for those who had participated in online groups (T2D) (odds ratio [OR] 2.56, confidence interval [CI] 1.13-5.83) and likewise for those who had discussed information from the internet with a doctor (T1D andT2D) (OR 2.54, CI 1.90-3.40).

Conclusions: Lifestyle changes from internet information among people with diabetes are associated with online group participation and with discussing the information with a doctor. Online groups and doctors can play an important role in lifestyle changes additional to health-advice from the internet. The human factor still counts.

EP315 / #580

Topic: ***AS14-Human factor in the use of diabetes technology***

INCOME- AND INSURANCE STATUS-BASED DISPARITIES IN PATIENT-PROVIDER DISCUSSION OF DIABETES TECHNOLOGY AMONG PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Socioeconomic and insurance-based disparities in diabetes technology use have been widely reported among people with type 1 diabetes (T1D). Provider bias is a known source. This analysis assessed income- and insurance-based differences in T1D patient reports of provider-initiated discussions about continuous glucose monitoring (CGM) and insulin pump technology.

Methods: In June 2021, 2,283 people living with T1D in the United States completed an online questionnaire. Non-CGM users (n = 155) were asked whether their healthcare provider (HCP) has ever initiated a conversation about CGM, and non-pumpers (n = 519) were asked whether their HCP has ever initiated a conversation about pumping. Health and demographic information were collected.

Results: Non-CGM users with incomes <$50,000 (36%) were less likely to report a conversation about CGM than those with incomes of $50,000-$100,000 (58%) or >$100,000 (73%). Those with private insurance (63%) were more likely to report discussion of CGM than were those on Medicare only (38%). Non-pumpers with a household income of <$50,000/year or $50,000-$100,000/year were less likely to report a conversation about

pumping than those with incomes >$100,000/year (66% vs. 74% vs. 84%). Those on private insurance were more likely to report discussing a pump than those on any other insurance.

Conclusions: These results suggest that income- and insurance-based biases may impact HCPs' likelihood to initiate conversations about diabetes technology, which is concerning given that these technologies have proven effective regardless of income or insurance status.

EP316 / #589

Topic: ***AS14-Human factor in the use of diabetes technology***

CURRENT INSULIN INFUSION SET CRITERIA DO NOT REPRESENT REAL-LIFE SETTING AND MAY SKEW INFUSION SET FAILURE OUTCOMES IN EXTENDED-WEAR INFUSION SET STUDIES

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Background and Aims: In a recent clinical study, people living with diabetes (PLWD) found it difficult to correctly interpret/adhere to the state-of-the-art insulin infusion set failure criteria, often removing the infusion set later than proposed per-protocol. This work aims to challenge the currently accepted insulin infusion set failure criteria which are too stringent for home-use extended-wear infusion set studies and are more suitable for controlled inpatient settings within a research facility.

Methods: Insulin infusion set survival data from an extended-wear home-use study in PLWD were retrospectively analyzed applying the following criteria: (i) actual wear time (days) and (ii) hypothetical wear time according to the state-of-the-art criteria (protocol endpoint). Data from 13 participants were included in the analysis (6 female, age 36.7 ± 10.5 years, diabetes duration 22.5 ± 7.4 years, HbA1c 52.7 ± 8.4 mmol/mol). Participants wore a total of 66 infusion sets during 52 wear periods of up to 14 days.

Results: 46/66 (69.7%) infusion sets were kept in place between 0.2 and 11.9 days longer (median 3.2 days) and were not removed at time of per-protocol set failure. The remaining 20 infusion sets (30.3%) were removed per primary endpoint definition.

Conclusions: PLWD often have a good knowledge their glucose profiles and may not be easily concerned by rising glucose values, thus, will choose to leave an infusion set in place longer than predefined in the study protocol or recommended by manufacturers' instructions. We propose a new set of less stringent failure criteria intended to safely mimic real-world decision processes for future use in extended wear infusion set studies.

EP317 / #615

Topic: ***AS14-Human factor in the use of diabetes technology***

THE IMPACT OF SOCIOECONOMIC DEPRIVATION ON ACCESS TO DIABETES TECHNOLOGY IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: As technology rapidly advances, there are growing concerns surrounding the disparities in provisions and diabetes health-related outcomes in areas of greater deprivation. We sought to assess the relationship between area deprivation and socioeconomic status with access to diabetes technology and their outcomes in adults with type 1 diabetes (T1D).

Methods: Retrospective, observational analysis in adults with T1D attending three hospitals in the UK. Socioeconomic deprivation was assessed by English Indices of Deprivation 2019. HbA1c change was assessed between pre-initiation and 1-year post-initiation for each form of diabetes technology. Chi-squared tests and one-way ANOVAs were used to analyse data.

Results: 1,631 adults aged 43.9 ± 15.3 years and 758 (46.5%) females were included. Median deprivation decile was 5 (3-7). 391 (24.0%) used continuous subcutaneous insulin infusion (CSII), 312 (19.1%) used real-time continuous glucose monitoring (rtCGM) and 558 (34.2%) used intermittently scanned continuous glucose monitoring (isCGM). Technology use was highest in the least deprived quintile and lowest in the most deprived (67.4% vs 44.5% respectively; $p < 0.0001$). There was no association between deprivation and HbA1c-related outcomes of technology ($p > 0.05$). Structured education participation almost doubled from the most deprived to the least deprived groups (23.4% vs 42.8%; $p = 0.0002$). Adults with white ethnicity were more likely to use technology compared to black ethnicity (58.9% vs 40.0%; $p < 0.05$).

Conclusions: Adults living in more deprived socioeconomic areas had less technology use, with reduced participation in structured education. No overall differences in HbA1c related outcomes were observed, and glycaemia was positively affected in all groups.

EP318 / #627

Topic: ***AS14-Human factor in the use of diabetes technology***

EFFICACY OF TECHNOLOGY IN EVERYDAY LIFE MANAGEMENT OF TYPE 1 DIABETES IN CHILDREN AND ADOLESCENTS

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Background and Aims: The development of the most recent technologies for the management of T1D is expected to significantly improved metabolic control in everyday life.

Methods: We evaluated 248 subjects (2-20 yrs), T1D duration at least 1 year, duration of therapy ≥8 weeks. We divided subjects in 5 groups based on therapeutic strategies: 1) multiple daily injection (MDI)+self-monitoring blood glucose (17%); 2) MDI+continuous glucose monitoring (CGM) (42%); 3) Sensor Augmented Pump therapy (SAP) (17%%); 4) Predictive Low Glucose Suspension systems (PLGS) (15%); 5) Advanced Hybrid Close Loop systems (AHCL) (13%).

Results: Mean HbA1c was 7.53 ± 1.4. We found a significant reduction in mean HbA1c in the AHCL group (-0.9% compared to the both MDI groups, -0.7% and -0.56% compared to SAP and

PLGS groups respectively); 66.7% of subjects in AHCL reached the target of HbA1c ≤7%. AHCL group showed a statistically significant increase in Time in Range (TIR, 70-180 mg/dl) compared to MDI+CGM, SAP and PLGS (21%, 13% and 17% respectively) and a reduction of the Time Above Range (TAR) compared to MDI+CGM and PLGS (21% and 16% respectively), without increasing in Time Below Range (<70mg/dl). In a longitudinal analysis in a subgroup of 23 subjects who switched to AHCL systems from other types of pump treatment, HbA1c was improved by 0.4%, increasing TIR by 13% and reducing TAR by 13.5%. CHO counters reached better goals of metabolic control in all the subgroups.

Conclusions: In real life conditions, AHCL systems are significantly associated to improved glucose metabolic control compared to other therapeutic strategies.

EP319 / #631

Topic: ***AS14-Human factor in the use of diabetes technology***

ESTIMATED A1C IS HIGHLY CORRELATED WITH HOME KIT A1C IN A LARGE REMOTE DIABETES MONITORING PROGRAM

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Background and Aims: Growing evidence supports the use of home A1c testing and estimated A1c (eA1c) from self-monitoring blood glucose (SMBG) to close the gap in meeting A1c testing recommendations. This study investigated the correlation between A1c home kit (hA1c) values and eA1c in a large real-world population.

Methods: The cohort included all members with valid A1c home kit values for Fall 2020 and Spring 2021 and eA1c measured for both timepoints. Change in A1c values were calculated for members with home kit values and eA1c data from both timepoints. Pearson's R-squared was performed to analyze overall correlation between eA1c and hA1c.

Results: The cohort (N = 7,665) was 65 years old (SD 11), 51% female, mostly identified as White (68%), non-Hispanic (90%), with type 2 diabetes (95%), and an average self-reported baseline A1c of 7.13% (SD 1.34%) and Fall home kit A1c of 6.85% (SD 1.01%). Members had a mean change in hA1c of 0.13% (SD 0.70) and eA1c of 0.01% (0.64%). Figure 1 shows similar hA1c and eA1c changes by Fall 2020 A1c value. A strong, positive correlation was shown between eA1c and hA1c ($r^2 = 0.69$).

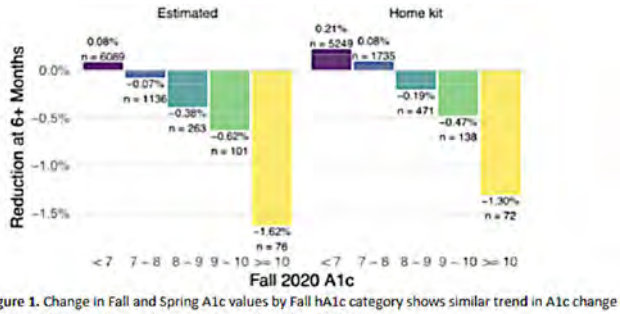

Figure 1. Change in Fall and Spring A1c values by Fall hA1c category shows similar trend in A1c change between the home kits and eA1c estimates based on SMBG data.

Conclusions: Though there is positive correlation between hA1c and eA1c, eA1c slightly under estimates increases at low hA1c values and overestimates reduction at high hA1c values. However, the ability to have more frequent eA1c estimates based on SMBG values is useful for assessing population trends.

EP320 / #643

Topic: ***AS14-Human factor in the use of diabetes technology***

TREATMENT SATISFACTION AND STRESS LEVEL: OUTCOMES AFTER ONE MONTH OF ADVANCED HYBRID CLOSED-LOOP (AHCL) THERAPY IN LATIN AMERICA

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Background and Aims: Burden of diabetes treatment has been previously associated to high levels of stress, low satisfaction and poor glycemic outcomes in people living with T1D. Novel therapies such as aHCL systems, could potentially reduce burden of treatment through insulin delivery automation. Aim: to evaluate treatment satisfaction, stress level and glycemic control in T1D patients during the first month of aHCL.

Methods: Two self-reported questionnaires were applied: DTSQ-s for treatment satisfaction and DDS for level of stress. Levels of stress were categorized as high (HS), moderate (MS) and low or absent (LAS). Metabolic control was assessed using time in range (TIR).

Results: Nine patients were included (4 women). Mean age 31.4 ± 12.8 years old. Mean weight 74.3 ± 14.5 kg. Mean BMI 24.9 ± 4.0kg/m^2. Duration of the disease 17.3 ± 7.6 years. Previous treatment HCL = 7 and PLGM = 2. Mean A1c before aHCL was 6.8 ± 0.6%. From baseline to 28 days after initiating therapy, TIR increased from 70,4 ± 11,4% to 77,2 ± 7,2% (p = 0,012), TBR54 decreased from 0,9 ± 0,8% to 0,6 ± 0,5% (p = 0,027) and TAR180-250 decreased from 20,9 ± 6,4% to 15,8 ± 4,8% (p = 0,011). Patient's stress levels were: HS = 22,2%, MS = 33,3% and LAS = 44,4%; whilst TIR as by stress level were HS = 73%, MS = 77% and LAS = 74%. Diabetes treatment satisfaction score was 32,75 ± 4,62. All patients perceive a low rate of hypo and hyperglycemias on aHCL. The majority of them reported high treatment satisfaction score (60,97%).

Conclusions: The majority of patients on aHCL reported a low or absent level of stress and a high treatment satisfaction. Despite of stress load, all patients achieved optimal glycemic control.

EP321 / #67

Topic: ***AS14-Human factor in the use of diabetes technology***

HYPO-CHEAT: A NOVEL BEHAVIOUR CHANGE TECHNOLOGY THAT REDUCES REAL-WORLD HYPOGLYCAEMIA.

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Background and Aims: Hypoglycaemia is a life-threatening risk for many patients and prevention is complex. Continuous Glucose Monitoring (CGM) and Machine Learning are increasingly used in prevention technologies but ignore weekly hypoglycaemia patterns and neglect the importance of changing behaviour. Therefore, these technologies have demonstrated no real-world reduction in hypoglycaemia. Children with congenital hyperinsulinism (CHI) have recurrent hypoglycaemia and thus we developed **HYPO-CHEAT** (**HY**poglycaemia-**P**revention-thr**O**ugh-**C**gm-**HE**atmap-**A**ssisted-**T**echnology).

Methods: HYPO-CHEAT undertakes novel, iterative analysis of CGM data and generates personalised heatmaps detailing high-risk periods throughout the week as well as targets for reflection designed to change patient behaviour and reduce hypoglycaemia (<3.5mmol/L). Ten patients with CHI used a blinded CGM for four weeks (baseline) and then unblinded for four weeks, at the end of which they used HYPO-CHEAT. CGM was subsequently re-blinded for four weeks.

Results: In the five patients with initial time below range (TBR) >1%, TBR improved from mean 7.1% to 4.5% when devices were unblinded. After using HYPO-CHEAT, families identified specific behaviours contributing to their hypoglycaemia ''hotspots''. Within targeted hotspots, families did 70% more fingerpricks than outside hotspots and reduced TBR by 67%, despite re-blinding. Total TBR remained 25% below baseline (5.4%). For those without initial hypoglycaemia and thus no hotspots, TBR increased from 0.2% at baseline to 3.2% when reblinded.

Conclusions: HYPO-CHEAT's personalised, hypoglycaemia heatmaps facilitated patient reflection and behaviour change to target fingerpricks and reduce total and targeted TBR even when CGM was reblinded. HYPO-CHEAT offers a novel and immediately available approach to prevent hypoglycaemia while minimising family burden, reducing CGM costs and empowering patients.

EP322 / #785

Topic: ***AS14-Human factor in the use of diabetes technology***

MANAGING STEROID RELATED HYPERGLYCEMIA WITH A HYBRID CLOSED LOOP SYSTEM

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Background and Aims: Hybrid Closed Loop (HCL) systems decrease the burden of diabetes through the ability to manage the basal rates and assist with adjustments after meals or during exercise. HCL systems have been shown to increase Time in Range (TIR), decrease Time Below Range (TBR), decrease variability and prevent hypoglycemia. Increasing use of these systems has demonstrated the need for an adjustment to the settings if there is a sudden increase in the insulin requirements, such as during steroid treatment.

Methods: Case report of patients using an insulin pump in HCL when treated with high dose steroids during admission for solid organ transplant.

Results: Patients are assessed upon admission to the hospital to determine if capable of self-managing the insulin pump. The Diabetes Consult team develops a plan to adjust the pump settings once high dose steroids are administered. Data is uploaded and reviewed daily. Patients are seen each day to discuss glucose trends and levels, and to plan adjustments to pump settings as the steroid dose is rapidly tapered down each day

Conclusions: Maintaining the pump in the HCL with the usual pump settings is inadequate to control glucose during steroid therapy, whether in the hospital as described in this case of in the outpatient setting where oral steroids, such as prednisone and dexamethasone, are frequently prescribed to our patients with diabetes. We recommend the following approach: Change settings such that you: 1) Increase daytime basals by 1.5-2X 2) Increase carb ratios by 30-50% 3) Increase correction factor by 2X

EP323 / #809

Topic: ***AS14-Human factor in the use of diabetes technology***

PSYCHOSOCIAL OUTCOMES IN YOUNG PEOPLE WITH TYPE 1 DIABETES AND THEIR PARENTS USING GLUCOSE SENSORS

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Background and Aims: It is crucial to understand psychosocial outcomes in children and adolescents with type 1 diabetes (T1D) and their families to provide optimal family-centered care. Hence, the aim of this study was to explore psychosocial outcomes in young people with T1D and their parents using currently available glucose monitoring.

Methods: Children and adolescents aged 2-18 years with T1D for <6 months and using currently available glucose sensors and their parents were recruited into a cross-sectional study to complete validated questionnaires pertaining to fear of hypoglycaemia (FOH) and quality of life (QoL) from February 2020 to January 2021. Demographics and diabetes specific parameters were obtained from medicals records.

Results: Seventy children and adolescents (male = 36, age 14.2 years(3.8), diabetes duration 7.1 (4.1) years, HbA1c of 7.5% (1.1), CSII users = 31) and their parents completed the questionnaires. Parents of children had higher mean (SD) FOH (worry subscore) than children, 17.8 (10.4) vs. 12.8 (9.0),$p = 0.01$, and lower diabetes specific QoL score 78.8 (12.2) vs 82.7 (10.3),$p = 0.02$. Multiple linear regression analysis revealed no association of parental FOH and diabetes-specific QoL score with HbA1c, age, mean glucose levels or time spent in hypoglycaemia. In flash glucose monitoring (FGM) users (n = 45), lower diabetes-specific QoL correlated with higher scanning frequency, $r^2 = 0.23$,$p = 0.004$.

Conclusions: Parents are more likely to experience higher levels of psychosocial burden related to their child's diabetes

management than children and adolescents with T1D. In FGM users, lower diabetes-specific QoL correlated with a higher scanning frequency, indicating the potential impact of glucose monitoring modality on psychosocial outcomes.

EP324 / #815

Topic: ***AS14-Human factor in the use of diabetes technology***

COMPARISON OF ATTITUDES OF PHYSICIANS, PARENTS AND PEOPLE WITH DIABETES TOWARDS DIGITALIZATION AND NEW TECHNOLOGIES IN DIABETES

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Background and Aims: Are there differences in the attitudes of physicians, parents and people with diabetes (PwD) towards digitalization and new technologies in diabetes and how do these change from 2019 - 2021?

Methods: In 2019 and 2021, PwD and diabetologists in Germany were asked via online surveys about their attitudes and assessment of digitalization and new technologies in diabetology. 2019: 324 diabetologists (43% female, average age 52.2 years) and 3.427 PwD (47.7% female, 56.6% type 1 diabetes (T1D), 25.5% type 2 diabetes (T2D), 8.1% parents of children with diabetes; Ø 49.2 ± 19.3 years). 2021: 305 diabetologists (48% female, average age 53.7 years) and 2.417 PwD (47.5% female, 57.8% type 1 diabetes (T1D), 20.7% type 2 diabetes (T2D), 19.0% parents of children with diabetes; Ø 47.7 years).

Results: Parents (T1D) (2019: 89.5% positive; 2021: 91.7%) PwD-TD1 (2019: 85.3%; 2021: 91.1%) have more positive attitudes towards digitalization than PwD-T2D (2019: 73.3%; 2021: 87.1%) or diabetologists (2019: 75.8%; 2021: 81.9%). Within 2 years, positive attitudes increased in all 4 groups. There was a great agreement between all 4 groups regarding the most important topics for the future of diabetology: AID systems were in first place in the ranking, followed by interoperability of systems, software for analysing glucose data and artificial intelligence.

Conclusions: PwD have very positive attitudes towards digitalization and new technologies in diabetes with only very small differences between TD1 and TD2. These are significantly higher than those of physicians. All groups have very high expectations for the further development of AID systems in particular.

EP325 / #820

Topic: ***AS14-Human factor in the use of diabetes technology***

GREEN DIABETES: PACKAGING WASTE AND SUSTAINABILITY

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Background and Aims: More and more people with diabetes (PwD) are paying attention to the waste associated with new technologies and want more sustainable concepts for waste prevention and a positive ecological footprint. In an online survey, we wanted to determine the extent of these wishes and ecological needs of PwD.

Methods: People with diabetes (PwD) in Germany were asked via online surveys about their attitudes and assessment of AID-Systems (2.417 PwD; 47.5% female, 57.8% type 1 diabetes (T1D), 20.7% type 2 diabetes (T2D), 19.0% parents of children with diabetes; Ø 47.7 years).

Results: Overall, there were only slight differences between the groups of PwD. For more than half of all respondents, the topic of packaging waste is important (54.5%), two out of three respondents say they would like to see more reusable utensils in diabetes therapy (67.1%). However, the amount of packaging waste in diabetes technologies does not seem to be a decision criterion for most PwD when selecting modern technologies – this is only significant for 15%.

Conclusions: As in other areas of life, environmental protection, the amount of packaging waste and disposal are playing an increasingly important role for PwD. The desire for recyclable materials is clearly visible. However, there is still a gap between the attitude and the actual behavior.

EP326 / #117

Topic: ***AS15-Trials in progress***

USE OF AN ALGORITHM TO DETERMINE TYPE 2 DIABETES BY AN ECHOCARDIOGRAPHY SIGNAL

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Background and Aims: According to the Diabetes Register, the number of type 2 diabetes (T2D) patients in the Russian Federation as of January 1, 2021 was 4.43 million. The results of a national epidemiological study demonstrated that the real prevalence of T2D among the population is two times higher. Therefore, T2D is diagnosed in the late disease stages when complications appear. This indicates the need to develop population surveys with the aim of early diagnosis and reducing the disease burden. The aim was testing a new screening algorithm for the early T2D detection.

Methods: A one-time survey of 173 patients (with type 1 diabetes (T1D) 55 (32%), T2D - 48 (28%), without diabetes - 70 (40%), the median age is 40 years [28–55], 74 men (43%), 99 women (57%)) was carried out: screening of T2D, using the express recording method with the help of a single-channel echocardiography "CARDIO-CHAIR". The records were analyzed by the previously developed T2D CardioQVARK algorithm. The likelihood of T2D, the reliability of the assessment was analyzed.

Results: 39 records with T2D were correctly diagnosed, 24 had false result, 7 - excluded, 2 - the algorithm showed a low assessment reliability for the probability of T2D. Method's sensitivity - 85%, specificity - 81%. The algorithm was insensitive to T1D since it was impossible to separate it from nondiabetic subjects.

Conclusions: The algorithm for detecting diabetes in this sample is able to diagnose T2D with a high degree of sensitivity and specificity, but it doesn't fit for the diagnosis of T1D.

EP327 / #166

Topic: ***AS15-Trials in progress***

LOW CARBOHYDRATE DIET VERSUS MEDITERRANEAN DIET IN ADOLESCENTS WITH TYPE 1 DIABETES: A RANDOMIZED CONTROL TRAIL

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Background and Aims: Improved glycemic control of type 1 diabetes, with low rates of adverse events was reported via an online community of children and adults who consume a of low carbohydrate diet (LCD). We aim to compare the effects of a low carbohydrate diet (LCD) with those of a Mediterranean diet (MD) on glycemic control, anthropometric measures and lipid profile in adolescents with type 1 diabetes.

Methods: Randomized control study of 12-week intervention participants using CGM (continuous glucose monitoring) were randomly assigned into 2 diet treatment arms, the LCD (n = 12) and the Mediterranean diet (n = 12). Baseline nutrition teaching session and individual meal plans were conducted for all participants and their parents. Measurements of weight, height, blood pressure, HbA1c, Time in range, number of hypoglycemia, lipid profile, were measured at baseline and 12 weeks.

Results: Twenty-four adolescents with T1DM completed the study. The average amounts of carbohydrates per day under LCD and MD were 59 ± 20 and 152 ± 55 (p value = *0.00) respectively. Time In Range (TIR) was 66 ± 16 % in the LCD and 55 ± 16% in the MD (p = *0.04). Participants in LCD and MD showed no difference in the percentage of time spent below 54 mg/dl, 1.6 ± 1.9% and2.4 ± 2.3% respectively. HbA1c levels decreased significantly in the LCD group from 8.3 ± 1.3 % to 7.2 ± 0.9 p = 0.006. Triglyceride decreased to a greater degree p = 0.005 after the LCD compared to the MD p = 0.39.

Conclusions: LCD significantly improved glycemic control (both HbA1c and TIR). In addition, there were no safety events. Finally, all adolescents with LCD completed the diet over 12 – week period.

EP328 / #197

Topic: ***AS15-Trials in progress***

PSYCHOMETRIC PROPERTIES OF HYPO-METRICS: A SMARTPHONE APPLICATION TO INVESTIGATE THE DAILY IMPACT OF HYPOGLYCAEMIA

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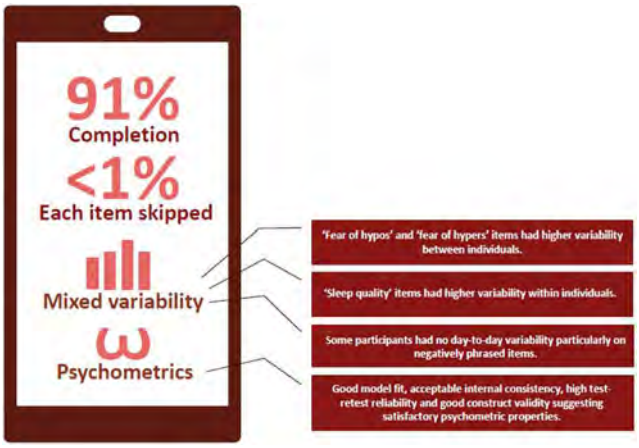
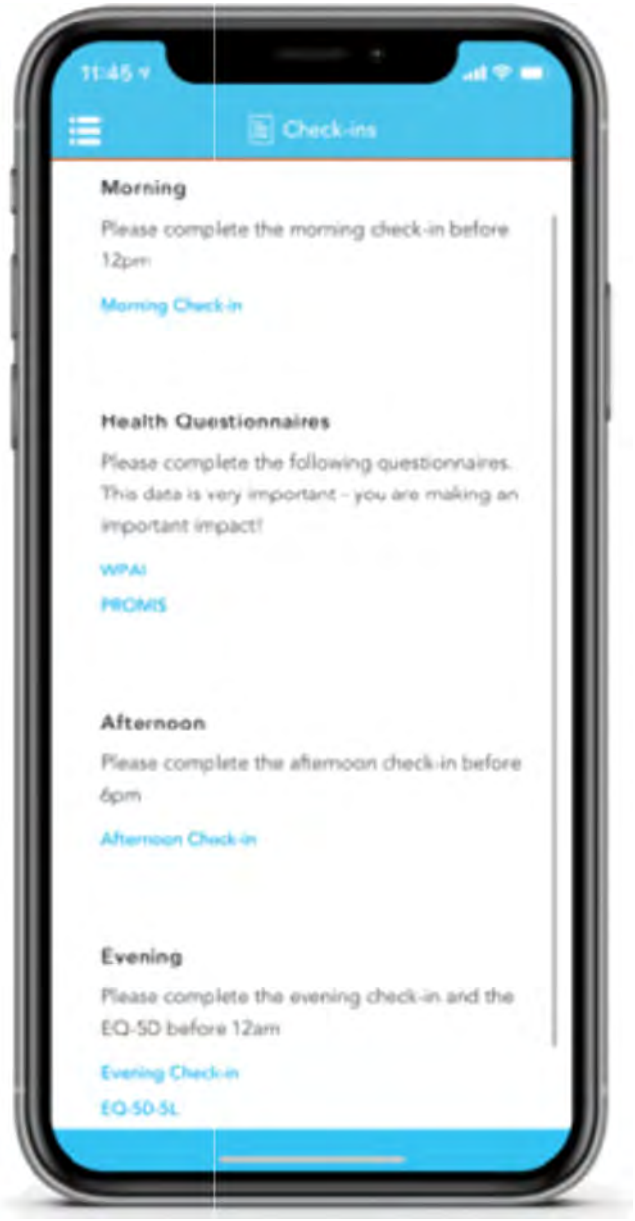
Background and Aims: With increasing recognition of the importance of person-reported outcomes measures (PROMs) in assessing the impact of hypoglycaemia in diabetes therapies, we aimed to assess the acceptability and psychometric properties of the Hypo-METRICS (Hypoglycaemia MEasurement, ThResholds and ImpaCtS) application (app): a novel, mobile-phone based app designed to capture the impact of symptomatic and asymptomatic hypoglycaemia on daily functioning in real time.

Methods: 100 adults with type 1 (T1DM) or insulin-treated type 2 diabetes (T2DM) completed a 70-day multinational prospective study. Three times daily, participants used the app to respond to brief questions (29 unique items) concerning their daily functioning, including: sleep quality, overall mood, negative affect, energy level, cognitive functioning, fear of hypo- and hyper-glycaemia, social functioning, and work and productivity. These data were examined in terms of completion rates, structural validity and internal consistency. Convergent and divergent validity were investigated via correlation with validated PROMs completed at start and end of study.

Results: App completion rates were high, with a mean (SD) of 191 (16) of 210 possible check-ins submitted per participant. Structural validity was confirmed with multi-level confirmatory factor analysis showing satisfactory model fit on the adjusted model. All scales had satisfactory internal consistency reliability (all $\omega \geq 0.5$). Satisfactory convergent and divergent validity was demonstrated, with all correlations supporting predefined hypotheses for most subscales.





Conclusions: The psychometric analyses demonstrated that, overall, the Hypo-METRICS app is an acceptable, valid and reliable new tool to assess the daily impact of hypoglycaemia among adults with T1DM and T2DM.

EP329 / #486

Topic: ***AS15-Trials in progress***

A NEW COMBINED DIABETES AND CGM EDUCATION PROGRAM FOR ADULTS WITH INSULIN-TREATED TYPE 2 DIABETES.

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Background and Aims: CGM education programs for T2D are sparsely described. We aim to describe and evaluate the

newly developed program for participants with insulin-treated T2D included in the on-going study ''Steno2tech''.

Methods: Steno2Tech is a 12-month study aiming to include 100 adults with T2D treated at Steno Diabetes Center Copenhagen. Participants are randomized 3:2 to use CGM or BGM during the study. All receive a diabetes re-education program and the CGM group receive additional training in using the device. The education program aims to ensure that the participants have the knowledge, support and confidence to work collaboratively with their HCPs to increase TIR and HbA1c. Questionnaires are used to evaluate satisfaction with the education program (5-Likert Scale) and prior educational experience.

Results: Based on international guidelines and user inputs a 3-hour session on diabetes management and CGM use was developed. The session included information on general T2D management as well as the influence of antidiabetics, different food items and exercise on glucose levels. For the CGM part, hands-on training on insertion and handling of the CGM device were given along with information on data interpretation. Each session had 3-8 participants. Baseline; age 61 years, men 63,2%, HbA1c 69 mmol/mol, diabetes duration 18 years (all medians). Overall participant-rated dividend with the program: 42,4% good, 57,6% very good. Previously, 62,9% had received diabetes education, among them 54,6% more than 6 years ago.

Conclusions: The content for a new CGM education program for T2D is presented, and satisfaction is rated high.

EP330 / #489

Topic: ***AS15-Trials in progress***

MYDIAMATE: IMPLEMENTING SELF-GUIDED WEB-BASED SUPPORT FOR MENTAL HEALTH IN TYPE 1 DIABETES.

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Background and Aims: MyDiaMate is a self-guided, web-based application for adults with type 1 diabetes (T1D), designed to assist in preserving/improving mental vitality. A pilot test confirmed its feasibility and usability. Since March 2021 the application is offered freely to Dutch speaking adults with T1D. Here we report on interim results regarding usage of MyDiaMate and user profiles.

Methods: Users can opt for participating in the user-profile study, providing self-reported socio-demographics, diabetes-distress (PAID-11), emotional wellbeing (WHO-5) and fatigue (CIS). User profiles, number of downloads, and usage were analyzed using log-data.

Results: N = 777 persons downloaded MyDiaMate (date November 2021), n = 281 participated in the study. Mean age was 43 years (SD = 14.8), 64.1% females, and 62.5% higher educated. The majority was not receiving psychological treatment (86.8%). Of the 281 participants, 162 (59%) persons reported low emotional wellbeing (WHO-5 ≤ 50), 194 (70%) elevated diabetes-distress (PAID-11 ≥ 18) and 138 (49.8%) were severely fatigued (CIS ≥35). 698 persons (96.9%) opened the start module 'Diabetes in Balance', of whom 25.6% completed the module. In-depth modules 'My Mood' and 'My Energy' were opened by 16.8% and 18.9% participants respectively, of whom 21.5% and 6.1% completed these modules. Median usage of all modules together was 2 hours (3 sec – 882 hours).

Conclusions: Preliminary results 9 months after launching the app show that participants in the user-profile study have relatively low well-being and high fatigue scores, indicating a need for psychosocial support. Log-data showed a wide variety of user behaviors, indicating a spectrum of individual support needs. Further data collection in ongoing.

EP331 / #599

Topic: ***AS15-Trials in progress***

IMPACT OF ENDURANCE TRAINING ON PHYSICAL PERFORMANCE IN PEOPLE WITH TYPE 1 DIABETES – AN ANALYSIS OF THE ULTRAFLEXI-1 STUDY

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Background and Aims: The ongoing ULTRAFLEXI-1 trial compares two basal insulins, Glargine U-300 and Degludec, when used around spontaneous exercise sessions in people with type 1 diabetes (T1D). This analysis presents the training adaptation of 24 endurance training sessions over 13 weeks in a subgroup of 13 participants.

Methods: We included 25 people with type 1 diabetes (mean age 41.4 ± 11.9 years, median diabetes duration 17 years) in the main study. Data of 13 participants was entered into this present analysis. Before and after 24 training sessions (60 minutes moderate intensity, ~65 % VO_{2max} cycling each session), that are announced spontaneously in the morning of the exercising day, maximum incremental cardio-pulmonary exercise (CPX) tests were performed. Data were analysed using a paired student t-test ($p < 0.05$).

Results: In this analysis, data of 13 people (7 female) with T1D (mean age of 43.6 ± 9.0 years, a body weight of 77.2 ± 17.2 kg, and an HbA_{1c} of 57 ± 7 mmol/mol) was included. The maximum performance increased from 190 ± 62 at baseline to 201 ± 70 ($p = 0.0482$) watt at study end. The relative maximum performance increased from 2.46 ± 0.57 to 2.62 ± 0.70 watt/kg) ($p = 0.04$). The first and second lactate turn points also significantly improved from baseline to study end (LTP_1 $p = 0.003$; LPT_2 $p = 0.0014$). While peak oxygen uptake did not change ($p = 0.1843$), VO_2 at LTP_1 und LTP_2 significantly increased ($p = 0.0064$ and $p = 0.0010$, respectively).

Conclusions: Maximum performance and performance at the first and second lactate turn points improved in people with type 1 diabetes, following a 13 weeks period of cycling exercise sessions.

EP332 / #645

Topic: ***AS15-Trials in progress***

THE ENDORSE FEASIBILITY PILOT TRIAL: ASSESSING THE IMPLEMENTATION OF SERIOUS GAMES STRATEGY AND ARTIFICIAL INTELLIGENCE- BASED TELEMEDICINE IN GLYCEMIC CONTROL IMPROVEMENT.

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Background and Aims: Following the trend of digital health applications, implemented especially during the COVID-19 pandemic, the Greek funded project, named ''ENDORSE'', is designed as an innovative integrated platform for supporting clinical decision making and telemedicine in children with Type 1 Diabetes Mellitus (T1DM), harnessing the power of explainable artificial intelligence along with gamification and mobile technologies.

Methods: ENDORSE platform utilizes various data sources such as glucose sensors, smart insulin pens, activity trackers, mobile apps, Electronic Health Records and serious games. A two-phase pilot trial is foreseen to evaluate its effectiveness. In the pre-pilot phase, 14 T1DM children and adolescents followed in the Diabetes Center (Table 1) were enrolled and preliminary data regarding patients' adherence, are presented.

Results: As shown in Table 2, most of the patients were able to regularly perform FGM scanning through mobile phones while the engagement to the ENDORSE serious game, aiming at training in self-disease management, along with the activity trackers is highly variable.

Conclusions: ENDORSE platform along with changes in daily diabetes care practices like CGM usage, is expected to improve diabetes management through facilitating training, monitoring and feedback to the patients and their caregivers. In order to further improve ENDORSE's adherence and acceptance, factors such as the level of digital literacy and internet access should be also taken into consideration. **Acknowledgements**: Supported within the framework of the ENDORSE project, which is funded by the NSRF (Grant agreement: T1EΔK-03695)

Table 1: Patients' Characteristics

	Number / Mean (Min, Max)
Sex	10: Females, 4: Males
Age (years)	11.05 (6.5, 15.9)
Diabetes Duration (years)	3.08 (1.4, 6.3)
HbA1c (%)	7.5 (6.1, 9.1)

Table 2: Patients' adherence to the ENDORSE clinical protocol

Adherence to activity trackers		Adherence to Serious Game (%days) Mean ± SD	Sensor usage (%days) Mean ± SD
Steps (%days) Mean ± SD	Quality of sleep (%days) Mean ± SD		
32.53 ± 32.01	16.09 ± 25.24	26.46 ± 28.09	76.33 ± 18.83

EP333 / #647

Topic: ***AS15-Trials in progress***

LONG-TERM OUTCOMES ON GLUCOSE CONTROL, SLEEP, AND HEALTH ECONOMY AFTER IMPLEMENTATION OF TANDEM CONTROL IQ IN A PEDIATRIC POPULATION

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Background and Aims: Advanced hybrid closed-loop systems are associated with beneficial effects in terms of glucose control and sleep. In this study, Tandem Control IQ was started in reasonably well-controlled children. The aim was to evaluate long-term glucose control after 6, 9, and 12 months, and to evaluate the impact on sleep, sick leaves, and health economics.

Methods: In an observational study, we evaluated the outcomes related to MDI, free-standing CSII and CGM, and Tandem Control IQ for 12 months. Outcomes were evaluated with regards to glucose control (Mean glucose, SD glucose, TIR, TBR, TAR, and TIT), attitudes to the use of Tandem Control IQ (INSPIRE), sleep (questionnaire), sick leaves in guardians, and health economics.

Results: Tandem Control IQ has been used in 35 children for 6 months, 25 children for 9 months, and 18 children for 12 months. Mean TIR±SD after 6 months: 75.9 ± 8.5%, 9 months: 76 ± 8.5 and 12 months 75.2 ± 8.3%. Improvements were noted already after 1 month and clear differences are noted when compared with MDI and freestanding CSII along with CGM. Ongoing analyzes are conducted regarding attitudes, sleep, and sick leaves in guardians.

Conclusions: The analyses that have been carried out so far demonstrate clear benefits of an AHCL system as Tandem Control IQ in terms of glucose control and ongoing analyzes are conducted to further clarify the effects in the remaining areas.

EP334 / #710

Topic: ***AS15-Trials in progress***

TRENDS OF GLUCOSE, LACTATE AND KETONES DURING ANAEROBIC AND AEROBIC EXERCISE IN SUBJECTS WITH TYPE 1 DIABETES: THE ACTION-1 STUDY

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Background and Aims: Exercise is part of type 1 diabetes (T1D) management based on its cardiovascular and metabolic benefits. However, despite the use of real-time continuous glucose monitoring (CGM) glycaemia during exercise remains difficult to control. We assessed trends in glucose, lactate and ketone profiles during anaerobic and aerobic exercise in people with T1D and explored whether patterns could be identified that could guide insulin dosing.

Methods: Twenty-one men with T1D (age 29 years [28-38], BMI 24.4 kg/m^2 [22.3-24.9], HbA1c 7.2% [6.7-7.8]) completed a symptom-limited maximal cardiopulmonary exercise test

(CPET) and a 60-minute aerobic exercise (AEX) at 60% VO2-peak on an ergometer bicycle. Subjects consumed a standardised Ensure® breakfast before exercise without administering an insulin bolus.

Results: During CPET, glucose levels increased, peaking at 331mg/dL [257-392] 1-3h after exercise and reaching a nadir 6h after exercise at 176mg/dL [118-217] and lactate levels peaked to 12.5mmol/L. During AEX, glucose levels also increased, peaking at 305mg/dL [245-336] 80 minutes after exercise and reaching a nadir 6h after exercise at 211mg/dL [116-222]. Lactate levels rose quickly to a maximum of 4.3mmol/L [2.7-6.7] after 10 minutes, indicating that some participants performed a mixed aerobic anaerobic test. Ketone levels were low in both tests (median ≤0.2mmol/L).

Conclusions: High intensity exercise resulted in hyperglycaemia coinciding with an increase in lactate levels. In the context of using only basal and no bolus insulin, no events of late hypoglycaemia or ketosis were recorded during or after the aerobic and the anaerobic test, indicating safety under current circumstances.

EP335 / #125

Topic: ***AS16-COVID-19 and Diabetes***

REMOTE AND IN CLINIC INITIATION OF ADVANCED HYBRID CLOSED LOOP SYSTEM MINIMED 780G IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: The aim of the study was to evaluate glycemic control between Remote Initiation and In Clinic Initiation of Advanced Hybrid Closed Loop (AHCL) System MiniMed 780G (Medtronic, Northridge, US) in patients with Type 1 Diabetes (T1D).

Methods: Children and adolescents (7 to 18 years old) with T1D were offered to initiate MiniMed 780G system either following the remote initiation program (Remote group) or the in-clinic initiation program (In Clinic group). Remote program was performed using Zoom Conferencing, while in clinic program was performed at the hospital. Both programs followed same structured education protocol of 4 days. HbA1c, Time in Range, AHCL system characteristics were analyzed three months after AHCL initiation.

Results: A total of 64 patients (age 13.1 ± 3.4 years) were included in the analysis: 28 patients in the Remote group and 36 patients in the In Clinic group. HbA1c in f the Remote group decreased from 8.3 ± 1.2% (66 ± 13.1 mmol/mol) at baseline to 6.7 ± 0.9% (50 ± 9.8 mmol/mol) at the end of the study (p = 0.002), compared to the In Clinic group for which HbA1c decreased from 8.2 ± 1.3% (66 ± 14.2 mmol/mol) to 6.2 ± 1.1% (48 ± 12.0 mmol/-mol), (p = 0.001), respectively). No significant difference of HbA1c levels, TIRs and SmartGuard use between groups was found at the end of the study. No DKA events and severe hypoglycemia in both groups was observed during the study.

Conclusions: Remote Initiation Program for AHCL system should be offered to people with T1D as alternative to In-Clinic Initiation Program. Both programs can improve glycemic control in a safe manner without severe hyoglycemia or hyperglycemia.

EP336 / #236

Topic: ***AS16-COVID-19 and Diabetes***

IMPACT OF FINANCES ON DIABETES CARE AND SUPPLY ACCESS DURING COVID-19 AMONG U.S. ADULTS LIVING WITH DIABETES

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Background and Aims: Diabetes is one of the most financially burdensome diseases in the U.S., and the COVID-19 pandemic has exacerbated financial stress among people with diabetes (PWD). This study investigated how finances have impacted diabetes care from June 2020 to June 2021.

Methods: In June 2021, 4,780 adults living with diabetes in the U.S. completed an online survey in which they reported the influence of finances on their diabetes care on a scale of 1 to 5 and whether they delayed medical care due to cost in the last year. Respondents who reported delaying their medical care due to cost (n = 759) were asked in which ways they delayed care.

Results: Finances have a significant influence on diabetes care for 24% of respondents. In the last year, 13% of PWD delayed care due to cost, and those in lower income brackets were more likely to delay care. Among those who delayed care, 48% of CGM users delayed ordering CGM supplies and 30% of CGM users delayed starting on a new diabetes device. Half of respondents using a pump delayed ordering pump supplies. Among those on MDI, 50% delayed an insulin refill compared to 38% of respondents using a pump.

Conclusions: At a time when high costs of care are intersecting with pandemic-related financial stress, PWD are postponing care and delaying orders of necessary supplies, which may lead to further health complications. COVID-19 has amplified the need for policy and industry to take action to ensure PWD can access the care and supplies they need to live.

EP337 / #267

Topic: ***AS16-COVID-19 and Diabetes***

THE IMPACT OF COVID-19 PANDEMIC ON DIABETES HEALTH PROFESSIONALS – THE AUSTRALIAN STORY

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Background and Aims: Australia implemented some of the toughest and longest COVID-19 lockdowns worldwide, causing significant disruption to diabetes care and delivery. Tertiary outpatient services stopped face-to-face appointments and many diabetes health professionals were seconded to COVID-specific tasks and/or adjusting to government/institutional restrictions. The aim of this study was to understand the impact on diabetes services and health professionals as a result of COVID-19.

Methods: A 10-question survey was distributed to Australian Diabetes Society (ADS) and National Association of Diabetes Centres (NADC) membership, at the beginning of April 2020 for 4 weeks and followed up in August 2020.

Results: Of 243 respondents, 40.9% were endocrinologists and 33.1% diabetes educators who predominantly worked in tertiary services (33.3%) or private practice (25.9%) and 67.4% located in metro and 21.1% in regional areas. 50.1% respondents reported increased workload, with the majority of this being diabetes-related (80.7%). The biggest challenge was telehealth set-up (63.0%) and reimbursement (37.9%) and fear of being infected/infecting family members (49.3%).

Conclusions: Australia tertiary diabetes centres and private practices found it challenging to establish and be appropriately reimbursed for remote delivery of services under existing funding models. Healthcare providers described a real fear of being infected/infecting family members. In response, ADS and NADC advocated and successfully received reimbursement for telehealth services, developed a Telehealth and Diabetes Position Statement and online resource tools for patient education. Further support included webinars on establishing and best practice in telehealth services provision and a focus on mental health and COVID-19 to support Australian diabetes health professionals during the pandemic.

EP338 / #281

Topic: *AS16-COVID-19 and Diabetes*

ANALYSIS OF THE EFFECT OF COVID-19 ON GESTATIONAL DIABETES IN PREGNANCY. OBSERVATIONAL STUDY IN A GYNECOLOGY SERVICE

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Background and Aims: Some bibliography suggest that COVID-19 disease can produce deleterious effects on gestation, for example: preeclampsia, gestational diabetes, preterm births, low birth weight. Aim: to determine if there is an increase in the incidence of gestational diabetes, preeclampsia or alterations in gestational time/birth weight, in those affected by COVID.

Methods: Retrospective study, in primary care, analyzing pregnant women assigned to a gynecology service. A representative sample was selected, discriminating those who suffered from COVID during their pregnancy.

Results: 135 pregnant women were analyzed. 36 affected by COVID (26.7%). 49 were close contacts, who did not develop COVID disease, and 50 women without a COVID environment. 13 pregnant women (9.6%) had gestational diabetes and 47 were referred to the HOR (high obstetric risk) service. Of the COVID-free women, a total of 25 suffered from postpartum COVID (18.5%). Comparing the group with/without COVID, statistically significant differences were observed in: gestational period (266.7 ± 51.2 d, vs 278.2 ± 11.9, $p = 0.04$) as well as in birth weight (3.16 ± 0.62 kg, vs 3.51 ± 0.42; $p = 0.03$). Not significant differences was appreciated in pregnant woman's previous weight or age. Gestational diabetes was not different in both groups (4 vs 9, $p = 0.45$) nor was preeclampsia (2 vs 2, $p = 0.226$). Instead, more COVID patients were referred to HOR (17 vs 37, $p < 0.005$).

Conclusions: Similar prevalences of gestational diabetes and preeclampsia were observed in this sample. Being the birthweight and gestational period significantly lower in COVID cases. Significant increase in referrals to HOR, can be attribuible to the indication to administer heparin as prophylaxis of thrombosis.

EP339 / #44

Topic: *AS16-COVID-19 and Diabetes*

LESSONS LEARNT FROM COVID-19 FOR HEALTH SYSTEMS: THE USE CASE OF DIABETES REMOTE MONITORING

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Background and Aims: The goal of increased telemedicine as part of diabetes care has been intensified and accelerated as a consequence of the COVID-19 pandemic. Made possible since the advent of cloud-connected technologies for diabetes management, such as continuous glucose monitoring systems, the development of telemedicine as part of the standard of care for people with diabetes still faces significant challenges in Europe.

Methods: A group of multidisciplinary experts from across Europe participated in an in-depth needs assessment and review of the benefits and challenges to wider access and implementation of telemedicine and telemonitoring in the post-pandemic future.

Results: Challenges include: 1) a fragmented approach to healthcare technology assessment and reimbursement; 2) lack of eHealth education and literacy, amongst healthcare professionals and patients; 3) lack of data integration with electronic health records; 4) patient consent, privacy and data protection. To meet these challenges, the following actions were identified: 1) investment in telemedicine and technology that allows remote monitoring; 2) bridge health inequities; 3) protect patient data and privacy; 4) incentivize broad adoption by patients, providers and health systems; 5) ensure a true measure of the value these technologies bring.

Conclusions: There is a strong consensus among experts on the challenges that must be overcome to secure access to telemonitoring and telemedicine for the diabetes community. There is a significant need for action across European health policymakers, to move forward in establishing digital competencies and developing sustainable solutions that support wider implementation of digital technologies and telemedicine in diabetes care.

EP340 / #492

Topic: ***AS16-COVID-19 and Diabetes***

EVALUATION OF GLYCAEMIC CONTROL IN PATIENTS WITH DIABETES MELLITUS HOSPITALIZED DUE TO COVID-ASSOCIATED PNEUMONIA

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Background and Aims: Glycaemic control during a COVID-19 pneumonia is affected by illness severity and required therapeutic measures (e.g. corticosteroids) in patients with diabetes. The aim is to compare glycaemic control and therapeutic changes during the inpatient stay in patients with HbA1c <7.0% compared to those with ≥7.0 on admission.

Methods: Clinical data of 59 patients with diabetes, who were hospitalized between October 15th-December 31th 2020 at our pulmonary department due to a COVID-19 illness, were retrospectively collected and stratified according to their metabolic control at admission (HbA1c<7.0% or ≥7.0%)

Results: Compared to patients with sufficient metabolic control (HbA1c<7.0%,n = 24), patients with HbA1c≥7.0% (n = 35) had longer duration of diabetes (p = 0.013), were more often male (74%vs.46%,p = 0.032) and were more frequently treated with metformin (74%vs.46%,p = 0.032) and DDP4-inhibitors (34%vs.8%, p = 0.029). The average glucose on admission (175vs.225mg/dl) worsened during inpatient stay in both groups. Patients with higher baseline HbA1c consistently showed higher glucose values during their stay (299vs.205mg/dl, p <0.001). Insulin requirement increased in both groups, whereby the maximum insulin dose per day over observation period was 13 IU in patients with baseline HbA1c<7.0% and 52 IU in patients with HbA1c≥7.0% (p < 0.001). In contrast, there was no difference in hospital mortality (17%vs.26%,p = 0.529). Using logistic regression, the patient's age was identified as a significant risk factor for hospital mortality (OR:1.07, 95%CI:1.01–1.14, p = 0.034).

Conclusions: Patients with diabetes, particularly those with HbA1c ≥7.0 on admission, and severe COVID-19 disease show a significant deterioration in their glycaemic control during their inpatient stay. Increasing age in patients with diabetes is associated with a higher risk of mortality.

EP341 / #557

Topic: ***AS16-COVID-19 and Diabetes***

SARS-COV-2 AND TYPE 1 DIABETES IN CHILDREN: IS THERE A DIFFERENCE IN INCIDENCE OR PATIENT CHARACTERISTICS DURING THE PANDEMIC? PRELIMINARY RESULTS

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Background and Aims: In 2020 the Sars-CoV-2 pandemic affected the whole world. Some centers reported changes in incidence of type 1 diabetes (T1D) in children and in the severity of the disease at presentation. In our center as well we had the impression that incidence and severity of illness at presentation of new onset T1D changed during the pandemic. The aim of this study is to provide data on incidence and severity of illness at presentation of new onset T1D in children in our center (covering the province of Antwerp (Belgium)).

Methods: In this observational, (large) single center study including children (<16 years) with newly diagnosed T1D, patient characteristics, anamnestic data and biochemical values were evaluated. Data from children with diagnosis between January 2015 and February 2020 (n = 203) where compared to children with diagnosis from March 2020 to February 2021 (n = 51).

Results: Non-parametric testing showed no significant difference in age, glycemia, HbA1c, C-peptides, ketone bodies, pH, bicarbonate and base-excess at diagnosis during the first year of the pandemic. Duration of complaints before presentation was not longer and the need for intensive care was not higher during the pandemic. The total daily insulin dose at discharge did not differ from to the five years prior to the pandemic.

Conclusions: We conclude that Sars-Cov-2 pandemic did not change presentation of new onset T1D in children in our center: there was no increase in incidence, no delay in presentation, no change in patient characteristics or severity of illness. Efforts should be made to obtain nationwide data.

EP342 / #593

Topic: ***AS16-COVID-19 and Diabetes***

EFFECT OF THE COVID-19 PANDEMIC ON METABOLIC CONTROL IN INSULIN PUMP USERS IN A DIABETES CENTER IN COLOMBIA.

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Background and Aims: The COVID-19 pandemic has led to changes in the management of insulin pump patients, requiring the use of telemedicine as a follow-up strategy. This study aimed to describe the metabolic control before and during the pandemic following the implementation of a teleconsultation program.

Methods: Observational study of a cohort of insulin pump users at the Diabetes Center, Fundación Santa Fe de Bogotá from January 2020 to July 2021. Changes in HbA1c, time in range, episodes of hypoglycemia in both, pre-pandemic (January to April 2020). and the pandemic (April to July 2021) period were evaluated.

Results: During the study period, 44 patients were included, 22 males (50%), with a mean age of 41 years and time of diabetes 20.9 years. Micro-infusion systems incluided paradigm754 (11%), veo640 (72%), and veo670 (15%). No significant changes in metabolic control or time in the range were observed in the patients under follow-up (Table 1). Table 1

	Pre-pandemic	Post-pandemic	T/Wilcoxon p-value
	Mean (SD)	Mean (SD)	
HBA1C	7.7 (0.8)	7.5 (1.3)	0.324
Time > 250 mg/dl	3.3 (3.9)	4.1 (5.5)	0.233
Time 181 A 250 mg/dl	18.9 (9.2)	18.7 (8.4)	0.853
Time 70-180 mg/dl	74.3 (11)	74.1 (11.1)	0.924
Time 70-55 mg/dl	2.59 (2.2)	2.36 (1.6)	0.462
Time < 54 mg/dl	0.65 (1)	0.65 (0.8)	0.904

Conclusions: The implementation of a telemedicine program for follow-up of patients on insulin pumps provided maintenance of metabolic control.

EP343 / #594

Topic: ***AS16-COVID-19 and Diabetes***

IMPACT OF COVID-19 LOCKDOWN ON GLYCEMIC CONTROL IN PATIENTS WITH TYPE 1 DIABETES. WHAT HAS HAPPENED 1 YEAR AFTER LOCKDOWN?

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Background and Aims: People with type 1 diabetes (PWT1D) using flash glucose monitoring (FGM) showed no deleterious effect or even an improvement on glycemic control during COVID-19 lockdown. The aim is to assess the impact on glycemic control after 8 weeks and one year after lockdown.

Methods: Observational retrospective study in PWT1D using FreeStyle Libre®. Glucometric data from the 2 weeks before lockdown start (PRE) were compared with data of the last 14 days after 8 weeks of consecutive lockdown (POST), and last 14 days one year after lockdown (1 YEAR POST).

Results: Data from 287 patients were analyzed (median age 45,5 ± 12,6 years, 50,2% male (n = 144), median diabetes duration 20,5 ± 12,1 years). Median lockdown time was 53,9 ± 4,4 days.

FGM Metric	PRE	POST	1 YEAR POST	P value (PRE vs POST)	P value (PRE vs 1 YEAR POST)
Mean glucose (mg/dl)	166.3± 7.9	157.1±27.9	160.2±25.1	<0.001	<0.001
Estimated HbA1c (%)	7.4±1.0	7.1±1.0	7.1±0,6	<0.001	<0.001
Time in range 70-180 mg/dl (%)	58,0±15,6	62.8±15,8	62.1±14.5	<0.001	<0.001
Time < 70 mg/dl (%)	4.9±4.0	5.6±4.4	4,4±4,0	0.007	0.029
Time < 54 mg/dl (%)	0.8±1.5	0.9±1.6	0.6±1.1	0.642	0,007
Time >180 mg/dl (%)	37.0±16.5	31.6±16.5	33.5±15,4	<0.001	<0.001
Time > 250 mg/dl (%)	12,9±10,9	9,9±9,9	10.0±9,1	<0.001	<0.001
Coefficient of variation (%)	38.4±6.7	37.9±6.7	37.0±5,8	0,123	<0.001
Sensor use (%)	94.9±9.6	94.2±6.3	94.4±6.6	0.179	0.362
Number of scans per day	11.1±6.5	11.5±8,0	11.7±6,7	0.097	0.044

Conclusions: PWT1D using FGM monitoring during COVID-19 pandemic in our clinic showed an improvement in glycemic metrics which was sustained 1 year after lockdown.

EP344 / #629

Topic: ***AS16-COVID-19 and Diabetes***

DEPRESSION AND ANXIETY AMONG PATIENTS WITH TYPE 2 DIABETES IN COVID 19 PANDEMIC

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Background and Aims: To determine the prevalence and factors associated with depression and anxiety among people with diabetes during the coronavirus disease 2019 (COVID-19) outbreak.

Methods: A cross-sectional questionnaire-based study was performed. We collect demographic data from 80 participants consulting in endocrine clinic . Depression and anxiety were assessed using the HAD Questionnaire .

Results: The prevalence of depression and anxiety symptoms were 60% and 52,5 %, , respectively in people with type 2 diabetes .A1C of ≥9 %, high educational level , obesity , anterior cardiovascular events and low income are associated to depression and/or anxiety (P < 0.05) in this study. Fear of acquiring the coronavirus infection and requiring hospitalization or death from covid 19 were the most stressful factors reported by patients (p = 0,01) . The lack of access to care is also reported by depressive and/ anxious patients (p = 0,03)

Conclusions: The high prevalence of depression and anxiety symptoms during the COVID-19 pandemic, encourage focus on health policies to mental health during the pandemic and re-establish health care access for patients with diabetes. New technologies such telemedecine could help te attend theese goals.

EP345 / #770

Topic: ***AS16-COVID-19 and Diabetes***

EVALUATION OF COMPLICATIONS AND OUTCOMES IN PATIENTS WITH DIABETES MELLITTUS AND COVID-19

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Background and Aims: Purpose of the study was to research the complication rate of acute complications and outcomes of hospitalized patients with COVID-19 and diabetes mellitus

Methods: . A retrospective analysis of the 1,500 medical histories of hospitalized patients with a confirmed diagnosis of COVID-19 at the infectious hospitals in Karaganda city, Republic of Kazakhstan. Among patients there were 86 (36.6%) men, 149 (63.4%) women, the median age was 63, (Q1 = 53, Q3 = 71). The complication rate of acute complications of COVID-19 and the outcomes of the disease was conducted. The comparison group consisted of patients without diabetes, n = 1265 patients.

Results: The following complications were more common in the presence of diabetes mellitus: acute respiratory distress

syndrome in 2.9 times ($p < 0.001$), acute respiratory failure in 1.8 times ($p < 0.001$), oxygen insufflation requirement in 1.9 times ($p < 0.001$). Artificial pulmonary ventilation and the requirement for treatment in the intensive care unit were higher in the group of patients with diabetes mellitus 3.7 and 2.4 times, respectively ($p < 0.001$). The lethal outcome was 2.1 times higher than in the group of patients without diabetes ($p < 0.001$). The main causes of the mortality were: acute cardiopulmonary failure – 28.2%, pulmonary embolism in 24%, multiple organ failure in 10.9%, infectious-toxic shock in 30.4%, other types of shock in 2.2 %, cerebral edema in 4.3%.

Conclusions: The course of Covid-19 on the background of diabetes mellitus is distinguished by a high rate of complications and mortality.

EP346 / #782

Topic: ***AS16-COVID-19 and Diabetes***

DIABETES AUTOANTIBODIES STATUS IN NEWLY DIAGNOSED CHILDREN AND YOUTH WITH TYPE 1 DIABETES MELLITUS DURING COVID-19 PANDEMIC AT SINGLE SETTING (2020-2021)

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Background and Aims: Four pancreatic islet cell autoantibodies (Abs) mostly associate with Type 1 diabetes (T1D) - glutamic acid decarboxylase antibodies (anti-GAD65), tyrosine phosphatase antibodies (IA 2-Ab), insulin autoantibody (anti-IAA) and zinc transporter 8 antibody. ***Aim:*** To evaluate the frequency of positive islet autoantibodies at T1D diabetes onset in youth at Varna's diabetes center during COVID-19 pandemic (2020-2021).

Methods: A total of 66 newly-diagnosed patients were tested for anti-GAD65, anti-IA2 and anti-IAA (2020-2021) by ELISA.

Results: The mean age of the participants was 9.0 ± 4.3 years (52% boys), 63.6% were prepubertal. At the onset of T1D, 83.3% were with at least one positive diabetes related autoantibody while 16.7 % were with negative Abs ($p < 0.0001$). At diagnosis, 6.1% of patients were with 3 positive Abs, 39.3% had 2 Abs and 37.9% had 1 positive Ab. Of all positive, 89.1% had anti-GAD65, followed by 60% anti-IA2, and 16.4% anti-IAA positive, resp. ($p < 0.01$). Of all participants, 81.8% had low level of C-peptide. Weak significant correlations were found between positivity for Abs, gender ($r = -0.325$, $p = 0.008$) and age ($r = 0.259$, $p = 0.036$); as well as between C-peptide levels and age ($r = 0.483$, $p < 0.001$), anti-GAD65 ($r = -0,210$, $p = 0.018$), and anti-IA2 ($r = -0.259$, $p = 0.036$). Four patients were positive for COVID-19 at diagnosis. All of them had low C-peptide levels and at least one positive Ab.

Conclusions: Most frequent diabetes associated antibody at our setting was anti-GAD65, followed by anti-IA2 and anti-IAA as reported worldwide. No Abs differences were found between those who were COVID-19 positive at diagnosis, compared to the rest, although the numbers were too small to conclude.

EP347 / #118

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

IDENTIFICATION OF VOCAL BIOMARKERS FOR SCREENING DIABETES AND MONITORING HEALTH OF PEOPLE WITH DIABETES: PRELIMINARY RESULTS FROM THE COLIVE VOICE STUDY

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Background and Aims: People with diabetes have distinct vocal signatures than the general population, however, few studies investigated how to use this specificity for screening purposes. Voice is a rich source of information that may be used to develop digital biomarkers for diagnosing diseases or tracking symptoms thanks to advances in artificial intelligence and signal processing. Our aim is to compare audio features of people with type 1 diabetes (T1D), type 2 diabetes (T2D), and people without diabetes.

Methods: Colive Voice (https://www.colivevoice.org/) is an international platform for the identification of vocal biomarkers for chronic diseases. Classification of the diabetes status and type was performed using linear discriminant analysis (LDA) based on audio features extracted from standardized recordings (here, three consecutive forced coughs) with the OpenSMILE library. A one-way ANOVA was used to analyze the distribution of the components obtained in the three groups.

Results: We included 31 participants (5 with T1D, 6 with T2D, and 20 without diabetes). The average age of the participants was 49 years old, and 70% were female. The LDA explained 100% of the variance and identified audio features that accurately distinguished the three categories ($p < 0.001$).

Conclusions: These findings suggest the feasibility of screening for T1D and T2D based solely on voice characteristics. More volunteers are needed in Colive Voice to confirm these findings, but also to develop vocal biomarkers for monitoring symptoms including diabetes distress, hypoglycemia, and fatigue, which might be integrated into medical devices such as closed-loop insulin systems.

EP348 / #138

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

DECISION SUPPORT SYSTEM IMPROVES GLUCOSE CONTROL DURING AND AFTER AEROBIC EXERCISE FOR USERS ON MULTIPLE DAILY INJECTION AND CLOSED-LOOP THERAPY, IN SILICO

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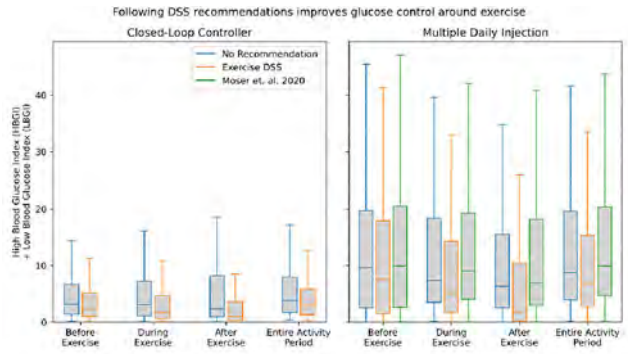
Background and Aims: People with type 1 diabetes (T1D) have difficulty managing glucose during and after exercise. A decision support system (DSS) may help.

Methods: Meal and exercise scenarios were extracted from a four-week, free-living clinical study of 33 adults with T1D from whom glucose, insulin, meal, and exercise data were collected (mean±sd: age 33 ± 13 years, BMI 26.3 ± 2.9 kg/m^2). Mean glucose changes during and after exercise were -8.7 mg/dL and -32.0 mg/dL, respectively. Digital twins from the 99-subject OHSU *in silico* simulator were matched to clinical study participants by insulin and weight to *replay* exercise scenarios from the clinical study under two interventions and a no-intervention arm under both multiple daily injection (MDI) and closed-loop therapy. One intervention was a DSS system providing recommendations during pre-exercise meals and at the start of exercise. The second intervention was to follow exercise consensus guideline (Moser et al., 2020). Recommendations included eating a snack before exercise, altering pre-exercise mealtime insulin, changing exercise duration/intensity/timing.

Results: MDI participants achieved better glucose control during and four hours post-exercise when following DSS recommendations vs. consensus guidelines vs. no intervention (during-exercise: 61.7% vs. 47.6% vs. 51.2% time-in-range (TIR), 0.7% vs. 1.1% vs. 2.5% time-in-hypoglycemia (TIH); post-exercise: 70.7% vs. 53.4% vs. 57.4% TIR, 0.3% vs. 1.7% vs. 4.3% TIH). Closed-loop participants improved glucose outcomes when following DSS recommendations vs. no intervention (during-exercise: 87.5% vs. 79.1% TIR, 0.6% vs. 2.4% TIH; post-exercise: 87.0% vs. 76.1% TIR, 0.5% vs. 1.4% TIH).

Conclusions: Exercise-specific DSS improves glucose control during and after exercise *in silico*.



EP349 / #140

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

REMOTE CONTINUOUS DATA MONITORING AND PERSONALIZED DATA-DRIVEN APPROACH FOR MANAGING DIABETES IN A VIRTUAL AND PHYSICAL SETTING

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Background and Aims: The GluCare care model encompasses two components, a physical component and a Remote Continuous Data Monitoring (RCDM) as a standard care for patients with diabetes. Continuous monitoring and analysis of numerous parameters, under the responsibility of the primary caregiver allow for data-driven actionable insights by the care team.This report describes the RCDM approach and the associated outcomes on preliminary clinical data and patient engagement from the patient's initial visit through their 3 month follow up.Primary outcomes were glycosylated hemoglobin and interstitial glucose time in range . Secondary outcomes included reduction in cardiovascular risk,BMI, lipids, liver transaminase, uric acid and C-reactive protein.We also describe the number of CGM readings, food logs and patient interactions with the team.

Methods: Retrospective and observational analyses were performed by linking data from the GluCare app and data from other devices. Blood tests were collected and analysed inside our facility. Statistical analysis was performed by Microsoft Excel and presented as a mean. Correlations between the analysed variables were assessed by Pearson's product - moment correlation ($r > 0.5$). A paired t-test was used to compare pre and post-intervention outcomes ($p < 0.05$).

Results: Initial data ($n = 22$) indicate that patient engagement via the GluCare model lead to significant improvement in HbA1c (-2.14% point, $p = 0.00013$) and other metabolic parameters such as LDL (-17.25%, $p = 0.0071$), body mass index (-4.55%, $p = 0.0003$), triglycerides (-18.52%, $p = 0.0165$) and uric acid (-20.4%,$p = 0.0052$).

Conclusions: These initial findings suggest that management of diabetes under the GluCare model of care has the potential to significantly improve diabetes outcomes.

EP350 / #192

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

RELIABILITY OF THE PROBABILITIES OF THE DIABETES RISK IN LOGISTIC REGRESSION AND GRADIENT BOOSTING DECISION TREE METHODS USING BIG HEALTH CHECKUP DATA

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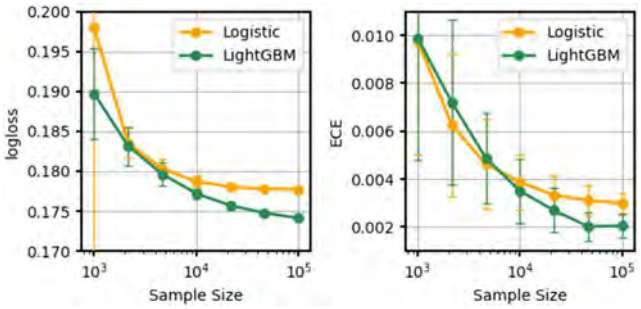
Background and Aims: While the accurate estimation of risk is indispensable for motivating individual lifestyle improvement, few risk prediction models for diabetes correctly evaluate their reliability, especially those made by machine learning. We aimed to develop a machine learning-based model predicting the probability of near future diabetes and to evaluate and compare its reliability to that of a regression model as accurately as possible.

Methods: We had access to Kokuho-database (KDB) in Osaka prefecture, Japan. To develop and evaluate models accurately, we focused on 16 predictors from health checkup data during 2012-2014 of 275,644 eligible participants. Diabetes was



defined as fasting plasma glucose of ≥126 mg/dL or HbA1c of ≥6.5%, and self-report. Models were developed using LightGBM and logistic regression. Their reliability was measured in expected calibration error (ECE), Negative log-likelihood(logloss), and reliability diagram. Also, we analyzed their reliability while changing the sample size for training.

Results: Model performance in biggest sample size ECE and log loss were respectively 0.005, 0.166 for logistic regression, 0.002, 0.162 for LightGBM. **Sample size analysis** LightGBM outperformed logistic regression in larger sample size, and continue to improve the reliability, while such improvement was limited to around 10,000 on logistic regression.

Conclusions: We developed probability prediction models for diabetes and evaluate their reliability. The reliability of LightGBM became better than that of logistic regression in larger sample sets and continued to improve as sample size increased, unlike logistic regression. **Acknowledgement** We acknowledge the fruitful collaborations of the Osaka University team and the use of big checkup data of Osaka prefecture.

EP351 / #200

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

PREDICTION OF NOCTURNAL HYPOGLYCAEMIA IN ADULTS WITH TYPE 1 DIABETES USING MACHINE LEARNING CLASSIFIERS

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Background and Aims: One of the biggest challenges for people with Type 1 Diabetes (T1D) using multiple daily injection (MDI) therapy is nocturnal hypoglycemia (NH). The majority of hypoglycemic episodes occur during sleep, at a time when hypoglycaemia awareness is attenuated. Recurrent nocturnal hypoglycaemia can lead to impaired awareness of hypoglycemia and is associated with the dead-in-bed syndrome. This work aims to provide bedtime decision support to people with T1D, to minimize the risk of NH.

Methods: We present the design and development of binary classifiers that can be used to predict NH (<3.9mmol/L). Using data collected from a 6-months study of adult participants with T1D under free-living conditions (n = 37, 15F, mean ± std TIR (%) = 63.1 ± 15.5), we extract daytime features from continuous glucose monitor (CGM) sensors, administered insulin, meal and physical activity information. We use these features to train and test two machine learning algorithms; Random Forests (RF) and Support Vector Machines (SVM).

Results: At population-level model, SVM outperforms RF algorithm with a ROC-AUC 73.79% (95% CI, 70.92%-76.67%). Additionally, for some participants, individual models can achieve higher ROC-AUC score up to 85%. We also show that the most important predictors come from the statistical and frequency domain extracted from CGM time series, whereas insulin, meals and physical activity do not contribute as much.

Conclusions: The proposed algorithm is a potential viable approach to inform people with T1D about their risk of NH before it occurs. Additional datasets will be used to prove the generalization power of the algorithm.

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Topic: ***AS17-Big data and artificial intelligence based decision support systems***

OPTIMIZING HEALTH COACHING FOR PATIENTS WITH TYPE 2 DIABETES USING MACHINE LEARNING: A PILOT STUDY

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Background and Aims: Diabetes health coaching is an emerging approach to facilitate self-management and has been shown to improve clinical and patient relevant outcomes. Recent advances in artificial intelligence may allow for further improvement for a more personalized, adaptive and cost-effective system for diabetes health coaching.

Methods: In this pilot study, we fit a two-stage Q-learning model on the 177 subjects from the intervention arm of a community-based randomized controlled trial conducted in Canada. From the Q-learning model, we constructed a dynamic treatment regime that can recommend an optimal coaching intervention at each decision point that is tailored to a subject's accumulated history and is expected to maximize the long-term health outcome of A1C reduction and quality of life improvement.

Results: Among the 177 subjects, our model mirrored the observed diabetes health coach's interventions in 17.51% of the subjects in stage 1 and in 14.12% of the subjects in stage 2. Where there was agreement in both stages, the average long-term health outcome (0.839, 95% CI: [0.460, 1.220]) is better than those for whom the optimal dynamic treatment regime agreed with the diabetes health coach in only one stage (0.791, 95% CI: [0.747, 0.836]) or differed in both stages (0.755, 95% CI: [0.728, 0.781]). Additionally, the average long-term health outcome expected by the Q-learning model is significantly better than that of the diabetes health coach's interventions (paired t-statistic = 10.040, $p < 0.001$).

Conclusions: Applying Q-learning to diabetes health coaching has the potential to automate coaching and yield substantial improvement in long-term health outcomes.

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Topic: ***AS17-Big data and artificial intelligence based decision support systems***

CHARACTERISTICS OF GLYCOMETABOLISM IN INDIVIDUALS WITHOUT DIABETES AND A MODEL TO ASSESS THEIR GLUCOMETABOLIC CATEGORY

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Background and Aims: To classify and characterize glucose metabolism in individuals without diabetes using oral glucose tolerance test (OGTT) results. Furthermore, to develop a model for predicting their glycometabolic category using lifestyle questionnaire.

Methods: OGTT was performed on 1,085 participants (aged 20-64 years) without diabetes; blood glucose and insulin levels were measured. Participants were classified into four categories based on 30-min and 120-min post-load plasma glucose and Matsuda index. Furthermore, participants completed a questionnaire consisting of following topics: exercise and sleep habits, diet, family history, constitution, and physical condition. Machine learning models (decision tree, support vector machine, logistic regression, random forest, and XGBoost) were developed for predicting glycometabolic category using questionnaire responses.

Results: Overall, 46%, 21%, 13%, and 20% of the participants were classified into category 1, 2, 3, and 4, respectively. Compared with category 1 (the best glucose metabolism group), the characteristics of the other categories were as follows: 2, low insulin sensitivity and high 120-min blood glucose levels; 3, low insulin-secreting capacity and rapid rise in blood glucose levels; 4, combination of categories 2 and 3. Random forest model provided the best performance. Its area under the receiver operating characteristic curve (AUC) for classifying [category 1, 2, 3, 4] and the others were [0.64, 0.64, 0.59, 0.67]. Moreover, development of this model required only 10 explanatory variables.

Conclusions: Individuals without diabetes were classified into four categories using OGTT results; 54% of the cohort showed relative defects in glucose metabolism. Additionally, this study developed a model that predicts the glycometabolic category using only ten questions.

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Topic: ***AS17-Big data and artificial intelligence based decision support systems***

PERSON-CENTERED TEMPORAL NETWORK MODELS AS A TOOL TO IDENTIFY INDIVIDUALIZED INTERVENTION TARGETS

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Background and Aims: Continuous glucose monitoring (CGM) paired with ecological momentary assessments (EMA) and ambulatory cognitive tests (ACT) provide unprecedented opportunities to examine dynamic relationships between BG, function, and well-being in daily life with type 1 diabetes (T1D). Traditional variable-centered statistical models, often geared toward predicting a single outcome, are poorly suited for capturing these relationships. We therefore present a person-centered model as an alternative to better understand the dynamic interconnections between BG, function, and well-being.

Methods: Participants completed 14 days of EMA and ACT at 3-hour intervals while wearing a blinded CGM. EMA measured stress, positive and negative affect (PA/NA), diabetes distress (DD), pain, fatigue, and self-reported function. ACT assessed processing speed and response inhibition. Group iterative multiple model estimation (GIMME) was used to estimate person-specific temporal networks. GIMME employs unified structural equation modeling to determine the best-fitting model for each individual's data, using a fully automated iterative parameter selection algorithm, making it potentially attractive for clinical applications.

Results: GIMME plots reveal a high degree of inter-individual variability in relationships between BG, function and well-being. For example, for Person A, higher BG level is associated with higher NA and lower PA. In contrast, for Person B, BG does not affect mood, but their perception of higher BG is associated with lower PA and higher DD.

Conclusions: GIMME plots are potentially useful for clinicians and people with T1D to gain insight into how BG, function, and well-being are interrelated on an individual basis. This may help identify targets for individualized interventions to promote optimal BG, function, and well-being.

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Topic: ***AS17-Big data and artificial intelligence based decision support systems***

EARLY MEAL DETECTION BASED ON DIFFERENT BODY SOUNDS

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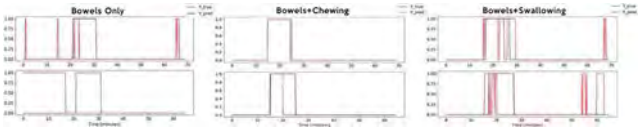
Background and Aims: Early meal detection (EMD) based on acoustic sounds has gained some attention in recent years because of its ability to detect the meal much earlier than the

current state-of-the-art continuous glucose monitoring system (CGM). While CGM based meal detection systems take about 40 minutes to detect the meal, bowel sounds can detect it after about 10 minutes. EMD can inform the patients about a missed meal bolus or can be used as a feed-forward input to an artificial pancreas so that it does not need to rely on patient intervention for meal bolusing.

Methods: In the present study, sounds from chewing, swallowing and bowel movements were recorded in non-diabetic subjects through a set of four microphones placed at the mastoid bone, the suprasternal notch and at each side of the stomach below the umbilicus. A machine learning model was trained for early meal detection based on these different sounds.

Results: The first part of the study was performed in a controlled environment where the subjects were quiet while eating. Figure shows the true and the predicted labels for the three cases. The detection time for bowels, chewing and swallowing are 60 sec, 10 sec, 40 sec, respectively. There are false positives in case of bowel sounds which are removed using chewing and swallowing sounds.

Conclusions: The chewing and swallowing sounds are more effective than using only bowel sounds for EMD. This work will be extended to more realistic environments where subjects will perform normal life activities like talking and different body movements.



EP356 / #372

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

PREDICTING TIME-IN-RANGE BASED ON PAST GLUCOSE RESPONSES FROM SIMILAR MEALS

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Background and Aims: Time-in-Range (TIR) is an important metric that allows for predicting complications in the future. The objective of this study was to evaluate the possibility to predict postprandial TIR of people using the SNAQ app. The predictions were based on previously recorded similar meals and their corresponding 3 hour postprandial glucose data.

Methods: Meal data from SNAQ users were collected, anonymized and analysed. The TIR predictions of a user's meals were based on TIR of similar meals recorded in the past by the same user. Similar meals are determined by matching components of the meals (i.e. potatoes, rice) and primarily considering the meals where the matching component had the largest portion of carbohydrates in those meals. The performance of this method is determined by comparing the TIR predictions with the ground truth TIR of each meal. A subset of 100 users were selected based on having at least recorded 10 meals and having imported more than 15,000 glucose data points. Values between 4 and 10 mmol/l were considered as in range.

Results: The calculated mean absolute error (MAE) was 23% and mean squared error (MSE) was 9% for TIR predictions based on past similar meals. (n = 578)

Conclusions: The presented findings suggest that predictions based off of past responses can be a viable solution in predicting TIR if further information is incorporated, such as insulin or activity data. Additionally, more meal data is required as large proportions of the data represents in-range scenarios, whereas outliers are more important to the users to be predicted correctly.

EP357 / #394

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

PREDICTING DIABETES AND ITS COMPLICATIONS FROM NAILFOLD CAPILLAROSCOPY IMAGES USING DEEP LEARNING: A PILOT STUDY

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Background and Aims: Patients with diabetes are at significant risk for complications. There is growing recognition that many of these may be linked to structural/functional abnormalities in the microcirculation of relevant organs. While research has established that capillary abnormalities in the eye can predict some of the complications of diabetes, it is not yet known whether other organ systems with visible microvasculature can provide similar (or even better) information. We carried out a pilot study to determine whether deep learning could predict diabetes and its complications from photographs of microvasculature in the nailbed.

Methods: We carried out an observational cross-sectional study of 120 participants aged 35-75 years, half with diabetes and half with cardiovascular disease. Nailfold capillary images were taken using a video capillaroscope. Images were analyzed using convolutional neural networks, with models developed to predict diabetes status, high HbA1c, albuminuria, retinopathy, hypertension, and cardiovascular disease.

Results: The models were best able to identify the presence of diabetes, with area under the receiver operating characteristics (AUC) of 0.84 (95% CI 0.76, 0.91). Performance was also good for predicting high HbA1c (AUC 0.77). The models could not effectively identify hypertension (AUC 0.51) and had only modest ability to identify people with a previous cardiovascular event (AUC 0.65), retinopathy (AUC 0.60) and albuminuria (AUC 0.65).

Conclusions: These pilot finding are limited by sample size, highly selected population, and absence of images from other organs such as the retina. Nevertheless, they demonstrate the potential of nailfold cappilaroscopy analyzed with deep learning to identify patients most likely to have diabtes-related complications.

EP358 / #449

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

RECURRENT GENERATIVE ADVERSARIAL NETWORKS FOR GLUCOSE TIME SERIES GENERATION

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Background and Aims: Glucose metabolism simulators have accelerated the development of closed-loop and decision support systems in type 1 diabetes (T1D) management. However, due to large inter- and intra-subject variability, it is challenging for existing simulators to generate realistic glucose time series using the clinical data of real-world T1D subjects. Recently, generative adversarial networks (GANs) have attracted increasing attention in time series generation. As a powerful data-driven generative model, GANs optimize the generator and discriminator networks through adversarial training, which offer the promise of glucose time series generation using personalized clinical data.

Methods: In this work, we propose a new GAN to generate personalized glucose time series for T1D individuals, which is based on recurrent neural networks. In addition to the generator and discriminator, we introduce embedding and recovery networks to convert input data into a latent space to learn the autoregressive dynamics of time series. The carbohydrate amount of food ingestion, meal insulin bolus, and self-monitoring blood glucose measurements are used as conditional features.

Results: We used the OhioT1DM dataset for evaluation purposes. Applying PCA for dimensionality reduction, we qualitatively observed that the distribution of synthetic glucose data is highly similar to that of real glucose data. When compared with a baseline method of TimeGAN, the proposed model significantly reduced the maximum mean discrepancy scores ($p < 0.05$).

Conclusions: The proposed recurrent GAN can generate realistic glucose time series, which has great potential to improve personalized data-driven algorithms for decision support in T1D management.

EP359 / #499

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

MULTIDIMENSIONAL CLUSTERING OF CGM-DATA HIGHLIGHTS THE IMPORTANCE OF HYPOGLYCEMIC EVENTS

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Background and Aims: Hypoglycemia is a major hurdle in diabetes management. By applying multidimensional data analysis of CGM-data hypoglycemic episodes and their importance for overall metabolic control can be explored.

Methods: CGM-data was collected from 175 pediatric type 1 diabetes patients, corresponding to 4706 weeks of data. Data was sorted based on weekly average occurrence of hypoglycemic episodes (<3.5 mmol/L), weighted against number of hyperglycemic episodes (>10.1 mmol/L) and plotted against markers of metabolic control. The parameters analyzed included time in range (TiR), mean glucose, glucose variability and the most likely underlying root cause for hypoglycemia interpreted by a custom-built machine learning (ML) algorithm (HypoCNN).

Results: For the majority of analysed weeks there were on average <2 hypoglycemic- and 2-3.5 hyperglycemic episodes. Mean TiR was greatest (73%) and mean glucose lowest (6.3 mmol/L) during the analysed weeks with >3 hypoglycemic- and <2 hyperglycemic episodes. Glucose variability was lowest during weeks with <2 hypoglycemic- and <2 hyperglycemic episodes and highest during weeks with >3 hypoglycemic- and >3.5 hyperglycemic episodes. Interestingly, for weeks with <2 hyperglycemic episodes, excessive basal insulin pressure was the most common underlying root cause for hypoglycemia regardless of frequency. However, in patients with >3.5 hyperglycemic episodes, overcompensation with insulin was the most common cause for hypoglycemia.

Conclusions: Basal insulin pressure is of key importance for achieving an optimal TiR, but the balance towards increasing the frequency of hypoglycemia is delicate. Multidimensional data analysis and ML hold the potential to identify adequate treatment modifications and hence greatly improve diabetes care.

EP360 / #514

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

DIABETES-RELATED ANTIBODY-TESTING IS A VALUABLE SCREENING TOOL FOR DIAGNOSING MONOGENIC DIABETES - A SURVEY FROM THE WORLDWIDE SWEET REGISTRY

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Background and Aims: To evaluate the access to genetic testing for monogenic diabetes in a large number of pediatric diabetes centres across the world and to determine the impact of systematic testing on treatment and clinical outcomes of children and youth with genetic forms of diabetes.

Methods: 79 centers from the SWEET registry caring for 53,207 children with diabetes participated in a survey on accessibility and current practices of diabetes related antibodies, c-peptide and genetic testing

Results: Of 79 participating centres, 73, 63 and 62 had access to c-peptide, antibody and genetic testing for monogenic diabetes, respectively. Proportion of type 1, type 2 and monogenic diabetes did not differ between centres with and without access.

Access to antibody testing was associated with higher proportion of patients being identified as monogenic form of diabetes (54% of in those with access versus 17% in centres without access to antibody testing (Wilcox test, $p=0.01$). A1C was significantly higher in individuals from centres without access to antibody testing: unadjusted regression (9.2 [9.2-9.3]% versus 8.2 [8.2-8.2]%, $p<0.0001$). Access to c-peptide or genetic testing was not related to diagnosis or A1C outcome.

Conclusions: Clinical suspicion and antibody testing have an impact in the diagnosis of the different types of diabetes while access to genetic testing for subtypes of diabetes does not. As A1C is higher in children and youth with a monogenic diagnosis from centers without access to genetic testing, improving A1c in those centres will need to not only provide support for diagnosis but also for individualized diabetes management.

EP361 / #560

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

QUICKEST MEAL DETECTION USING STATISTICAL MACHINE LEARNING

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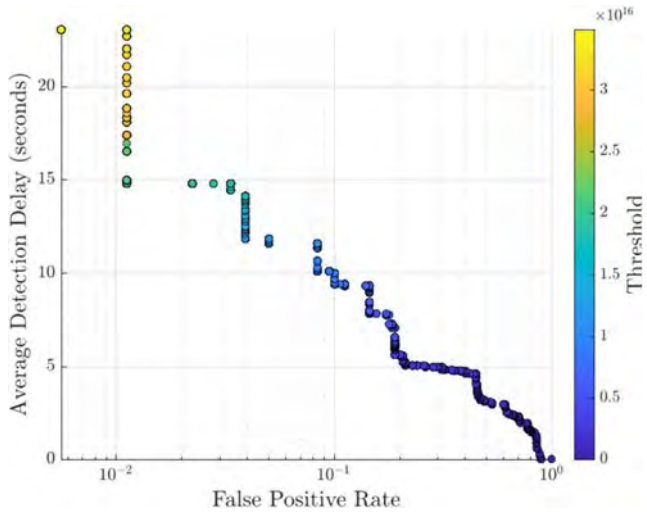
Background and Aims: Early meal detection (EMD) can improve the performance of the artificial pancreas, which facilitates insulin regulation. In the classical approach, this is done by continuous glucose monitoring (CGM) but it takes 30-40 minutes to detect the meal. In the recent literature, EMD is studied using bowel sounds and machine learning, which reduces the detection time to about 10 minutes. In this work, a statistical-based approach is proposed for quickest real-time meal detection.

Methods: The algorithm comprises three steps: i) sub-signals (features) are generated from the acquired signal; ii) each feature is assigned a value of log-likelihood of this belonging to a meal and a non-meal scenario, and the ratio of the two is computed, the log-likelihood ratios are then combined to give the original signal its value of log-likelihood ratio; iii) the latter result is processed with its past values via CUSUM method and a threshold test is performed for meal detection. The features are assumed Gaussian and uncorrelated and the maximum likelihood estimator is used to infer the features' parameters.



Results: The plot shows the performances: each point is obtained varying the algorithm's threshold according to the desired false positive rate. As the threshold increases, the detector becomes less sensitive causing fewer false alarms with a consequent increase of detection delay.

Conclusions: The results are obtained with three meals for the training and two for performance testing showing average detection delays of 15 seconds with few false positives. This combined with low complexity makes it suitable for real-time wireless applications.

EP362 / #624

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

DIABLOCKS: MULTIVARIATE PATTERN DETECTION FOR PATIENT-SPECIFIC IDENTIFICATION AND TARGETED ADJUSTMENT OF PROBLEM PATTERNS IN DIABETES CARE MANAGEMENT

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Background and Aims: Diabetes care requires careful analysis of interacting variables including insulin doses, meal timing, and exercise. However, accurately detecting repeatable patterns which cause undesirable glycemic outcomes (eg. hypoglycemia) remains a significant challenge. In this work, we present a novel methodology for identifying repeatable patterns and quantifying incidence and recurrence to guide adjustments in closed-loop system settings.

Methods: Time-matched continuous glucose monitoring (CGM), insulin pump, contextual movement patterns, and physical activity data were collected over 4 weeks from 17 individuals with type 1 diabetes. Individuals used their own insulin pumps with a breakdown of 42% Tandem, 29% Medtronic, 29% Insulet. Physical activity and contextual movement data was collected using a Polar M600 watch & MotioSens context-aware movement monitoring system. Each data source was clustered into clinically relevant bins which were used as bases in the DiaBlock format, transforming the multivariate time series data into a single timeseries of varying blocks. Recurrence Quantification Analysis and statistical methods are utilized to identify patterns leading to poor glycemic outcomes.

Results: On average, we identified four unique patterns per individual surrounding hypoglycemic events, with 74% eligible for clinical intervention. A mean of 30 (stdev 21) hypoglycemic events occurred per individual. Results are presented on the individual level as patterns vary greatly between individuals.

Conclusions: The DiaBlock method enables identification of problem patterns in diabetes control while accounting for interactions between variables. This method is demonstrated on a novel real-world data set and provides a basis for the follow-up study on efficacy of interventions selected to address detected problem patterns.

Figure 1: Sample individual report of overall glycemic outcomes, top identified patterns to be targeted for improved glycemic outcomes, associated potential recommendations, incidence, and percent recurrence within hypoglycemic events. Incidence is computed as percentage of time the pattern is associated with an adverse event (hypoglycemia). CF denotes correction factor.

Patient Report: Individual 206	
Number of Unique Lows (>30min apart)	52
CGM availability	76%
Percent time-in-range	72%
Percent Hypoglycemia	10%
Percent Hyperglycemia	18%

Top Patterns Resulting in Hypoglycemia	Possible Intervention	Incidence	Recurrence
Hypoglycemia within 60min of performing an activity, with any bolus insulin on board	Increase CF, avoid bolus insulin 2hr prior to activity	61%	15%
Hypoglycemia within 60min of performing an activity while basal rates are down-regulated, correction insulin on board, CGM in range or high and CGM trend is flat	Decrease insulin prior to activity, increase CF surrounding auto boluses	51%	6%
Hypoglycemia following a correction bolus	Increase CF	18%	29%
Hypoglycemia in the past 100min	Increase rescue carb intake	17%	17%
No CGM data for > 90min	None	7%	6%
No bolus insulin, CGM in-range and trending flat	None	1%	25%

EP363 / #644

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

ASSOCIATION OF THE REMISSION OF T2DM BY DIGITAL TWIN TECHNOLOGY WITH THE IMPROVEMENT IN THE GLYCEMIC METRICS

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Background and Aims: The Twin Precision Treatment (TPT) employs the Whole-Body Digital Twin platform with Artificial Intelligence and the Internet of Things. The intervention assesses multiple laboratory values and biometrics and uses connected devices and coaching to improve glucose control and induce T2D remission.

Methods: We matched for age, duration of diabetes, and HbA1c in an Indian and US cohort of subjects using TPT and compared change in Time In Range between 70-180mg/dL (TIR), Coefficient of Variation (CV), HbA1c and BMI between baseline and after 90 days of TPT.

Results: In India 86 and in US 62 subjects were evaluated. Mean age in both groups was $57+5.23$ years in India and $57.13+10.71$ in US; mean duration of diabetes was 13 ± 4.3 and 12 ± 9.9, in India and US, respectively. Mean HbA1c was 8.1 ± 1.6 at baseline and 6.5 ± 0.47 at 90 days in the India cohort, $p<0.0001$; and 8.1 ± 1.9 and 6.5 ± 0.86, in US, $p<0.0001$. Mean TIR in India changed from 65.2 ± 30.24 to 94.14 ± 10.51, $p<0.0001$. Mean TIR in US changed from 69.75 ± 27.68 to 93.11 ± 12.07, $p<0.0001$. Mean CV in India decreased from 23.97 ± 7.6 to 15.24 ± 5.19, $p<0.0001$. The mean CV in US changed from 18.5 ± 5.8 to 14.55 ± 4.5, $p<0.0001$. Mean BMI in India decreased from $26.35+3.52$ to $24.47+3.06$, $p<0.0001$ and from $33.18+8.64$ to $31.11+7.96$ in US, $p<0.0001$.

Conclusions: The early data employing the TPT intervention in the real-world setting in India and US improved glycemic variability and glycemic metrics. Long-term studies in larger cohorts are required to determine the effectiveness and durability of these early findings.

EP364 / #711

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

BLOOD GLUCOSE PREDICTION USING A TWO PHASE TSK FUZZY RULE BASED SYSTEM

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Background and Aims: People with diabetes should control their glucose levels to keep them at appropriate levels. The aim of this work is the proposal of a method for predicting blood glucose values by a fuzzy rule-based system.

Methods: In this work, we have used a two phase Takagi-Sugeno-Kang Fuzzy Rule Based System. The first phase is a learning process in which the membership functions and rules are optimized using a genetic algorithm. In the second phase (tuning), we use a genetic algorithm to perform the selection and optimization of the rules. The inputs are values measured by a continuous glucose monitoring system, as well as previous carbohydrate intake and insulin injections.

Results: The dataset is composed of real data from 10 patients with T1DM, Hospital Príncipe de Asturias in Madrid, Spain. For each patient we trained the models in two scenarios (What-If and Agnostic) and four predictive time horizons: 30, 60, 90 and 120 minutes. The results obtained show that the proposed method offers good accuracy in general terms, and are quite competitive with respect to the use of other AI techniques.

Conclusions: To the best of our knowledge, this is the first time that this type of approach has been applied in this field. One of the main advantages is that the obtained models are interpretable and would be easy to implement in mobile devices and wearables. Moreover, experimental results show that these predictive models are competitive when compared to other black box approaches such as those based on neural networks.

EP365 / #779

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

ELECTRONIC HEALTH RECORD WITH DECISION SUPPORT AS A TOOL TO IMPROVE QUALITY OF CARE FOR WOMEN WITH GESTATIONAL DIABETES.

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Background and Aims: The prevalence of gestational diabetes mellitus (GDM) in Russia is increasing and the true prevalence of GDM may be even higher because underreporting of GDM and lack of proper screening. Difficulties in documenting and reaching consensus on the prevalence of GDM exist for a number of reasons, including the use of various diagnostic criteria, past confusion about the specific criteria used to diagnose GDM, and the lack of knowledge about modern recommendations for screening and diagnosis. The aim of our study was to explore the quality of GDM care experienced by women in Russia in Fomin Women's Health Clinic in 16 cities in Russia and how it could be improved with the help of Electronic Health Record with decision support.

Methods: 106 Electronic Health Records of women with GDM before and after the start of the decision support (52 и 54 respectively) were analyzed and rated on a 100-point scale (diagnostics, nutrition, physical activity, self-control of glycemia recommendations were evaluated). The decision support system based on Guidelines of Russian Endocrinology Association, American Diabetes Association, National Institute for Health and Clinical Excellence and Royal College of Obstetricians and Gynaecologists.

Results: The average score before using decision support was 54, and after doctors started to use it the average score after 6 months of using became 86.

Conclusions: Electronic Health Record with decision support is great tool wich improves quality of care for women with gestational diabetes and refines the diagnosis and treatment of GDM in different cities in Russia.

EP366 / #799

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

CHRONIC KIDNEY RISK PREDICTION MODELING: CENTRALIZED LEARNING VS FEDERATED LEARNING

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Background and Aims: Risk prediction models for a variety of comorbidities in people with diabetes (PwDs) have been developed in Roche Diabetes Care using centralized datasets from US and UK populations. In this work, we present early results with Federated Learning using data distributed among many client servers.

Methods: A Federated Learning approach was used to perform model training while preserving data privacy. Each client trained a deep neural network on the data stored locally without the data leaving the site. A Federated Learning Neural Network-based logistic regression model was developed using the hub and spoke topology. Learning was synchronized between the clients, which were the spokes, and the central coordinator, which acted as the hub. A Federated Stochastic Gradient Descent (FedSGD) algorithm was implemented using multiple rounds of training. Both the hub and the spoke shared the same weights. In each round, the weights are updated on the hub and passed on to the spokes. Gradient calculation was performed on the spokes and sent back to the hub for averaging and updating the model weights.

Results: The Federated Learning logistic regression model was compared with a logistic regression model trained with the whole data aggregated on one server. Both models yielded similar model parameters and converged well with an AUC of 0.836 for the federated learning model and an AUC of 0.837 for the logistic regression model.

Conclusions: Preliminary assessment of Federated Learning with Centralized learning demonstrates feasibility of constructing disease prediction models of comparable performance using distributed data while preserving data privacy.

EP367 / #203

Topic: ***AS11-Advanced Medical Technologies to Be Used in Hospitals***

INVESTIGATION OF FOREIGN BODY RESPONSE AGAINST SUBCUTANEOUS DIABETES-REVERSING IMPLANTATION UTILIZING RAMAN MICROSPECTROSCOPY

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Background and Aims: The current treatment of type 1 diabetes still relies on daily insulin injection regimen, negatively affecting the quality of life for T1D patients. Therefore, islet transplantation within implantable devices has been regarded as a promising therapy to achieve insulin independence. Nevertheless, the foreign body response (FBR) induces the fibrotic capsule formation, which isolates the implant from surrounding tissues, impeding it from nutrients, oxygen and drug molecule diffusion. In this study, Raman microspectroscopy (RM), was utilized to investigate the characterization of the extracellular matrix (ECM) within the fibrotic capsule and discriminate healthy and diabetic groups, which can be applied to future medical device assessment.

Methods: Subcutaneous bioimplants were analyzed in regard to their potential to induce the FBR. ECM proteins were identified via RM and validated by immunofluorescence (IF) staining. Principal component analysis (PCA) was conducted to assess further molecular information.

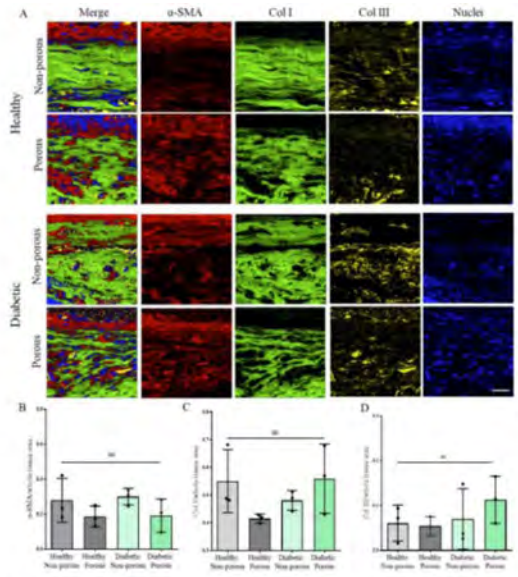

Figure 1: **Raman imaging and quantification showed no difference in the fibrotic capsules in diabetic and healthy animals and membrane porosity variations. (A)** True Component Analysis (TCA) of the spectral maps acquired of fibrotic tissue sites at porous and non-porous implant material in healthy and diabetic mice localized (red, α-SMA; green, Col I; yellow, col III; blue, Nuclei). **(B)** Quantification of αSMA based on the relative distribution of the whole area of the tissue reveals no significant differences between implant materials and animal models, respectively (p=0.3216). **(C)** Quantification of Col I based on the relative distribution of the whole area of the tissue reveals no significant differences between the groups (p=0.2230). **(D)** Quantification of Col III based on the relative distribution of the whole area of the tissue reveals no significant differences between the groups (p=0.4819). All the implant sites are on the top of the images. N=3/group, one-way ANOVA, mean ± SD; Scale bars = 20 μm.

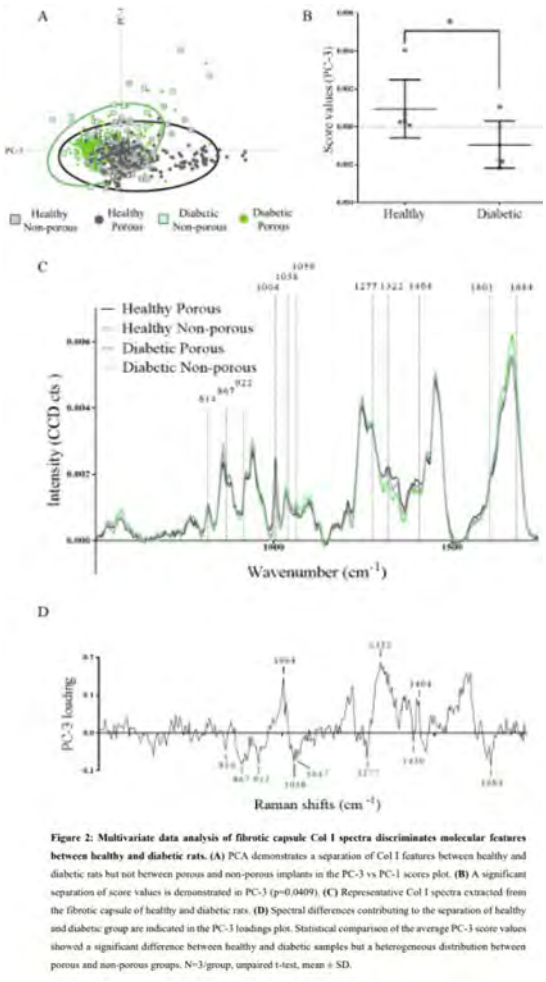

Figure 2: Multivariate data analysis of fibrotic capsule Col I spectra discriminates molecular features between healthy and diabetic rats. (A) PCA demonstrates a separation of Col I features between healthy and diabetic rats but not between porous and non-porous implants in the PC-3 vs PC-1 scores plot. **(B)** A significant separation of score values is demonstrated in PC-3 (p=0.0409). **(C)** Representative Col I spectra extracted from the fibrotic capsule of healthy and diabetic rats. **(D)** Spectral differences contributing to the separation of healthy and diabetic group are indicated in the PC-3 loadings plot. Statistical comparison of the average PC-3 score values showed a significant difference between healthy and diabetic samples but a heterogeneous distribution between porous and non-porous groups. N=3/group, unpaired t-test, mean ± SD.

Results: Fibrotic capsule structures could be identified. (Fig 1.) Raman imaging and TCA allowed the identification, localization and quantification of collagen I (Col I), collagen III as well as α-SMA. PCA of extracted Col I spectra indicated differences between diabetic and healthy groups, represented by shifts in Raman bands assigned to the presence of advanced glycation end-products. (Fig 2.)

Conclusions: RM provides a non-invasive approach to characterize the ECM of the fibrotic capsule. The alignment of collagens is comparable with immunofluorescence images as well as other approaches. PCA revealed differences in Col I between healthy and diabetic groups.

EP368 / #646

Topic: ***AS16-COVID-19 and Diabetes***

THE PROTECTIVE ROLE OF THE FGM SYSTEM IN IDENTIFYING TYPE 1 DIABETIC INDIVIDUALS AT RISK OF ACUTE DIABETES COMPLICATIONS DURING THE SARS COV2 PANDEMIC

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Background and Aims: The COVID emergency has led to a reduction in the volume of care dedicated to people with Type 1 DM. The use of telemedicine can represent a means of protection.

Methods: We investigated the role of FGM in 56 subjects with type 1 DM, AGP parameters were taken into consideration in the following periods: 1) October 2020 (start of the second wave in Italy), 2) May 2021 (reduction of hospitalizations due to SARS-Cov2 disease and opening of outpatient facilities) and 3) November 2021 (maintenance of dedicated COVID facilities and outpatient facilities). All subjects (ages 23.4 +/- 11.2) employed the CHO counting technique.

Results: The coefficient of variation and the Glucose Management Indicator increased significantly between period 1 and 2 (37.17 vs 42.30 P = 0.03 and 8.08 vs 9.1 P = 0.005 respectively). In the second period, all the subjects were called back to the center to be re-evaluated. The opposite trend was observed for CV and GMI from the second period to date (current CV and GMI 33.10 P = 0.0002 and 7.8 P = 0.0004). TIR, TAR, TBR were not significantly different between period 1 and 2 they were significantly different from the second period to date (TIR2 55.24 vs TIR 3 65.56 P = 0.001- TAR2 40.39 vs TAR3 27.59 P = 0.001).

Conclusions: Remote data control is a fundamental means of identifying those at risk of worsening glycemic control in an exponential manner and to re-propose structured training to guarantee the benefits obtained in the period prior to the pandemic.

EP369 / #616

Topic: ***AS01-Closed-loop System and Algorithm***

ACCEPTABILITY, SAFETY, AND EFFECTIVENESS OF HYBRID CLOSED-LOOP SYSTEMS IN PATIENTS LIVING WITH HIGHLY UNBALANCED TYPE 1 DIABETES

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Background and Aims: While closed-loop insulin delivery (CLID) systems demonstrated safety and effectiveness in patients with unbalanced type 1 diabetes (T1D), no studies have included patients with highly and chronically unbalanced diabetes.

Methods: We conducted a prospective, observational, and single-center study to evaluate the acceptability, safety, and efficacy of a CLID system in patients living with T1D (≥2 years) with a HbA1c>11% (97 mmol/mol) in the past 12 months and a mean HbA1c >10% (86mmol/mol) over the past three years. Efficacy was assed using continuous glucose monitoring parameters.

Results: Fifty-six patients met the criteria for inclusion in the study. The medical team excluded six patients for medical reasons. Twenty-nine patients presented an irregular follow-up (no response) or refused to try a CLID system. Finally, 21 patients (38%) accepted a CLID system: 62% of women, age [mean±SD(min-max)] 29 ± 9(19-49) years, duration of diabetes 16 ± 9(4-35) years, 76% already using an insulin pump, mean HbA1c in the last 3 months 11.8 ± 1.3(9.7-14.4), and mean 3-year HbA1c of 11.7 ± 0.8(10.6-13.6). In patients who started a CLID system to date (n = 18/21), the percentage of time-in-range (70-180 mg/dL) slightly increased from 32% ± 18(11-64) to 34% ± 20(0-72) with 75 ± 21%(25-100) of time spent under CLID system and a mean of 41 days (3-90) of use. 1 patient discontinued CL system after 19 days.

Conclusions: More than one third of a population with highly and chronically unbalanced T1D accepted to try a CLID system. We will report the persistence, safety, and efficacy of this treatment after 3 months.

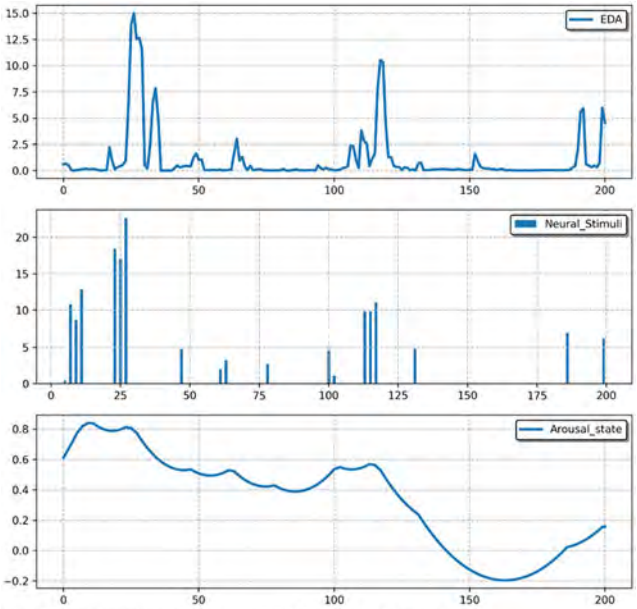

Fig 1. Representative patient from OHIOT1DM 2020 dataset.

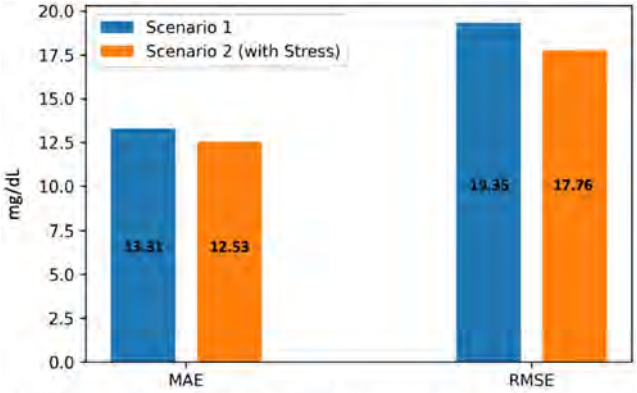

Fig 2. BG level prediction: *scenario 1*, using BG, Insulin and Carbohydrate intakes versus *scenario 2*, adding stress state into computations.

EP229A / ID:313

Topic: ***AS03-Artificial Pancreas***

DEMONSTRATING THE EFFECT OF DAILY STRESS ON BLOOD GLUCOSE LEVEL VARIATION IN TYPE 1 DIABETES

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Background and Aims: Episodes of stress activate the hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic nervous system, resulting in the release of stress and growth hormones, affecting glucose metabolism. Motivated by this, we investigate the effects of stress on blood glucose (BG) level prediction.

Methods: In a previous study we have shown that different types of stress, namely, emotional, cognitive, and physical, are detectable from electro dermal activity (EDA) signals [1]. In this work, we provide an estimation of stress-related state from the raw EDA and integrate it into a deep neural network (DNN)-based glucose predictive model, along with the CGM recorded BG level, meal, and insulin intakes. We apply our method to T1D patients' data recorded under free-living conditions [2].

Results: Via an ablation study, we show that including the estimated stress state improves the accuracy of forecasting future BG level in terms of mean absolute error (MAE), from 13.31 to 12.53 [mg/dL], and root mean square error (RMSE) from 19.35 to 17.76 [mg/dL], respectively.

Conclusions: Given these findings, we hypothesize that better glucose control in T1D patients can be obtained with behavioral interventions aimed at maintaining a healthy stress level. **References** M. Jaloli, D. Choudhary, and M. Cescon: Neurological status classification using convolutional neural network. *FAC-PapersOnLine*, *53*(5), 409-414. Marling, Cindy, and Razvan Bunescu. "The OhioT1DM dataset for blood glucose level prediction: Update 2020." In *CEUR workshop proceedings*, vol. 2675, p. 71.

ATTD 2022 Read by Title

R001 / #563

Topic: ***AS01-Closed-loop System and Algorithm***

USE OF ADVANCED HYBRID CLOSED-LOOP (AHCL) DURING PREGNANCY AND LABOR IN TYPE 1 DIABETIC WOMAN PREVIOUSLY TREATED WITH MULTIPLE DAILY INJECTIONS (MDI): A CASE REPORT.

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R002 / #732

Topic: ***AS01-Closed-loop System and Algorithm***

SUCCESFUL METABOLIC CONTROL IN A PREGNANT WOMAN WITH T1D USING DO-IT-YOURSELF ARTIFICIAL PANCREAS: A CASE REPORT.

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R003 / #586

Topic: ***AS02-New Insulin Analogues***

DIAGNOSIS OF TYPE 1 DIABETES WITH PREVIOUSLY UNKNOWN GITELMAN SYNDROME

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R004 / #493

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

PSYCHOMETRIC ASSESSMENT OF THE DECISIONAL CONFLICT SCALE IN SELF-MANAGEMENT OF TYPE 2 DIABETES PATIENTS

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R005 / #638

Topic: ***AS04-Clinical Decision Support Systems/Advisors***

ALIGNING DISPERSED INFORMATION IN ELECTRONIC HEALTH RECORDS AND EMPLOYING CLINICAL DECISION SUPPORT IS A STRATEGY TO OPTIMIZE DIABETES CARE IN THE HOSPITAL

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R006 / #462

Topic: ***AS05-Glucose Sensors***

MENTAL ILLNESS AND DIABETES: IMPROVING GLYCEMIC CONTROL WITH THE UTILIZATION OF THE OMNIPOD TUBELESS INFUSION SYSTEM

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R007 / #573

Topic: ***AS05-Glucose Sensors***

PERFORMANCE OF A NOVEL, MINIMALLY-INVASIVE WEARABLE CGM (K'WATCH SYSTEM) IN DIABETIC PATIENTS: A PROSPECTIVE CLINICAL TRIAL

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R008 / #103

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PROFESSIONAL AND POPULAR TERMINOLOGY IN OFFICIAL GUIDE FOR INSULIN PUMP: ORIGINAL ENGLISH VS. CROATIAN VERSION

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R009 / #178

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

CO-DESIGNING A DIGITAL HEALTH PLATFORM FOR DELIVERING A COMPLEX INTERVENTION TO PEOPLE WITH TYPE 1 DIABETES AND DISORDERED EATING

E. Konstantara[1], N. Zaremba[1], A. Harrison[1], J. Brown[2], D. Pillay[1], J. Waywell[3], G. Robert[4], D. Hopkins[2], J. Treasure[5], K. Ismail[5], M. Stadler[1]

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R010 / #259

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PEDIATRIC DIABETES HEALTHCARE PROVIDERS' PERSPECTIVES ON TRUSTSPHERE: AN INTEGRATED SECURE DIGITAL HEALTH PLATFORM

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R011 / #701

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

A FRIENDLY PATIENT INTERFACE FOR A 24/7 HELP AND TIPS PROVIDER FOR PERSONAL AND ORGANIZATIONAL HEALTH LITERACY IMPROVEMENT ON DIABETES MANAGEMENT

C. Barchielli[1], P. Zoppi[2], E. Salutini[2], M. Chiti[2], L. Mucchi[3], S. Jayousi[4]

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R012 / #708

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

VIRTUAL DIABETES CARE - TOMORROW DIABETES CARE

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R013 / #777

Topic: ***AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies***

PATIENTS' PERSPECTIVES ON USING VIDEO CONSULTATIONS FOR TYPE 1-DIABETES TREATED WITH INSULIN PUMPS IN THE OUTPATIENT CLINIC

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R014 / #797

Topic: ***AS07-Insulin Pumps***

"THE KENYAN EXPERIENCE USING AHCLS DURING THE COVID-19 PANDEMIC"

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R015 / #11

Topic: ***AS08-New Medications for Treatment of Diabetes***

ERYTHROPOIETIN FOR THE SUCCESSFUL MANAGEMENT OF POSTURAL HYPOTENSION SECONDARY TO DIABETIC AUTONOMIC NEUROPATHY: A CASE REPORT

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R016 / #215

Topic: ***AS08-New Medications for Treatment of Diabetes***

LIPID PEROXIDATION PRODUCTS CONTENT IN MEN WITH TYPE 1 DIABETES MELLITUS TREATED WITH A-LIPOIC ACID

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R017 / #551

Topic: ***AS10-Devices Focused on Diabetic Preventions***

ASSESSMENT OF DIABETOLOGY INTERNAL MEDICAL STUDENTS' COMMUNICATION AND INTERPERSONAL SKILLS BY SIMULATED PATIENTS

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R018 / #367

Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

LABEL-FREE METABOLIC DIAGNOSTICS FOR PANCREAS QUALITY ASSESSMENT

A. Kashina[1], P. Ermakova[1], I. Kornilova[1], A. Kashirina[1], D. Kuchin[2,3], N. Naraliev[2], E. Zagaynova[1,4], V. Zagainov[2]

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R019 / #390

Topic: ***AS12-New Technologies for Treating Obesity and Preventing Related Diabetes***

GRAIN-BASED DIETARY BACKGROUND IMPAIRED BLOOD FLOW RECOVERY IN HINDLIMB ISCHEMIA MODEL THROUGH ARTERIOGENESIS SUPPRESSION

I. Stafeev, M. Boldyreva, S. Michurina, E. Ratner, M. Menshikov, Y. Parfyonova

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R020 / #77

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

USING CHRONOBIOLOGY: THE EFFECT OF TIME RESTRICTED MEAL INTAKE ON ANTHROPOMETRIC AND BIOCHEMICAL PARAMETERS IN PATIENTS OF TYPE 2 DIABETES MELLITUS

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R021 / #378

Topic: ***AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals***

KANO MODEL IN HEALTH CARE: APPLICATION TO A GLUCOSE CONTROL DEVICE PROVIDED IN CANTABRIA (SPAIN)

L. Sanchez-Ruiz[1], D. Cantarero-Prieto[2], C. Montalban-Carrasco[3], C. Blazquez-Fernández[2], P. Lanza-León[2], J.I. Lera-Torres[4], I. González Rodríguez[4], F. Perez-Hernandez[5]

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R022 / #16

Topic: ***AS14-Human factor in the use of diabetes technology***

WEB-BASED SUPPORT FOR INDIVIDUALS WITH TYPE 2 DIABETES - A FEASIBILITY STUDY

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R023 / #324

Topic: ***AS14-Human factor in the use of diabetes technology***

CASE REPORT: HYPOGLYCEMIA IN A CHILD WITH T1D - THE STRANGE CASE OF DR. JAKYLL AND MR. HIDE.

D. Tinti, M. Trada, C. Valenti, S. Giorda, P. Matarazzo, L. De Sanctis

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R024 / #556

Topic: ***AS14-Human factor in the use of diabetes technology***

FEAR OF HYPOGLYCEMIA: OUTCOMES AFTER ONE MONTH OF ADVANCED HYBRID CLOSED-LOOP THERAPY IN LATIN AMERICA

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R025 / #450

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

AN OPENAI GYM ENVIRONMENT FOR REINFORCEMENT LEARNING ON GLUCOSE CONTROL IN TYPE 1 DIABETES

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R026 / #539

Topic: ***AS17-Big data and artificial intelligence based decision support systems***

IMPROVEMENT OF THE PREDICTIVE ABILITY OF NOCTURNAL HYPOGLYCEMIA MODELS BY USING SYNTHETIC DATA CREATED BY GENERATIVE ADVERSARIAL NETWORKS.

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