



TYPE 1 DIABETES CARE IN MEXICO: AN ANALYSIS OF THE RENACED-DT1 NATIONAL REGISTRY

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ABSTRACT

Background: Information regarding diagnosis, treatment, and follow-up of patients with type 1 diabetes (PWT1D) in Mexico is limited. We developed an on-line platform Registro Nacional de Pacientes con Diabetes Tipo 1 (RENACED-DT1). **Objective:** The objective of the study was to describe the characteristics and healthcare of PWT1D registered in RENACED-DT1. **Methods:** Analyses of 965 PWT1D from July 2014 to January 2018 in different endocrinology clinics around Mexico. **Results:** Sixty-one percent were female with median age of 21 years, age at diagnosis 11 years, and disease duration at inclusion 8.2 years. Treatment regimen was basal-bolus in 61% and insulin-pumps in 21% (mainly in the private sector); 33.3% with self-monitoring of blood-glucose (SMBG) ≥ 4 times/day. Mean HbA1c at last follow-up was $8.7 \pm 2.1\%$ (72 ± 23 mmol/mol), 18% had HbA1c $< 7\%$ (53 mmol/mol), and 35% $> 9\%$ (75 mmol/mol). SMBG ≥ 4 times/day was associated with HbA1c $< 7\%$. Time since diagnosis > 10 years, female sex, BMI ≥ 30 kg/m², SMBG < 4 times/day, and any hypoglycemia were associated with microvascular complications ($p < 0.05$). **Conclusions:** Percentage of patients achieving HbA1c $< 7\%$ is low; increased blood glucose monitoring is associated with better glycemic control. The achievement of optimal glycemic control must be increased to reduce the incidence of chronic complications and improve quality of life in PWT1D. (REV INVEST CLIN. [AHEAD OF PRINT])

Key words: Diabetes mellitus type 1. Registries. Mexico. Glycated hemoglobin A1c.

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INTRODUCTION

In Mexico, where type 2 diabetes (T2D) is highly prevalent, and its incidence and mortality are increasing¹⁻⁴, type 1 diabetes (T1D) is frequently overlooked and regarded as a low prevalence disease. Although the incidence and prevalence of T1D worldwide varies considerably, it is one of the most common chronic diseases in childhood⁵. It has been reported that patients living with T1D (PWT1D) receive suboptimal treatment for several years, increasing their possibility of developing chronic complications⁶. This situation leads to seeking care with private endocrinologists, increasing the out-of-pocket medical costs⁷. Until 2012, the only data available regarding T1D in Mexico reported in the DIAMOND Study, came from a small urban area in the State of Veracruz⁸. This report described a mean incidence rate of 1.15 (CI 0.75-1.9) per 100,000 individuals/year. Even though these results were not representative of the whole Mexican population, they positioned our country as one with the lowest incidence rate of T1D. Later, a study performed at the Mexican Social Security Institute (Instituto Mexicano del Seguro Social, IMSS) reported that the incidence of T1D among subjects younger than 19 years increased from 3.4 to 6.2/100,000 between 2000 and 2010⁹. In fact, the data from Mexico included in the 2017 International Diabetes Federation (IDF) Atlas¹⁰, comes from this single study⁹. Data obtained from the 2017 morbidity yearbook from the Dirección General de Epidemiología reported an incidence rate of new cases of 5.45/100,000, showing a marked increase in the incidence rate from 1993 to 2017¹¹. However, the precise prevalence of T1D in Mexico is still unknown and there is virtually no information regarding characteristics at diagnosis, treatment, and follow-up.

To provide information on PWT1D, several large-scale population- and clinical center-based T1D registries have been generated. These registries include the DPV Scientific Initiative in Germany and Austria¹², the EURODIAB study in Europe¹³, the DIABetes MONDiale (DIAMOND)¹⁴ and the SWEET¹⁵ world-wide studies, the T1D Exchange Clinic Registry¹⁶, and the SEARCH for Diabetes Youth Study from the United States of America^{17,18}. All these registries, as well as the IDF^{10,19}, have documented an increase in the incidence and prevalence of T1D in the past 20 years. Nevertheless, none of these registries include

Latin-American populations. The few studies available in Mexico only address the situation of PWT1D in childhood and adolescence^{8,20}, but not the long-term outcomes during adulthood⁶. To address this and to generate evidence about the characteristics of PWT1D in our country, the RENACED-DT1 (*Registro Nacional de Pacientes con Diabetes Tipo 1*, National Type 1 Diabetes Patient Registry) was developed. This registry focuses on obtaining health indicators to generate evidence on T1D prevalence, treatment practices, acute and chronic complications, and long-term follow-up²¹. We aim to describe the characteristics at diagnosis and at the last follow-up of patients recorded in this nation-wide registry, and to evaluate factors associated with adequate glyce-mic control (Glycated hemoglobin A1c, HbA1c <7%) and the presence of microvascular complications.

METHODS

Study population

The RENACED-DT1 is an initiative currently supported and endorsed by the Mexican Nutrition and Endocrinology Society (*Sociedad Mexicana de Nutrición y Endocrinología, SMNE*). The first version of the online database was created in 2014, based on the 1989 modified St. Vincent Declaration²². The registry gathers clinical and biochemical information from both private and public centers all over Mexico. All PWT1Ds are eligible to be included in the registry. Clinical diagnosis of T1D by a medical care provider, fulfillment of the ADA diagnostic criteria for diabetes with insulin requirement at diagnosis and thereafter was considered to establish T1D diagnosis. All adult participants signed a written informed consent and confidentiality agreement, which were also signed by the parents or guardians of participant children. In addition, all children provided assent to be included in the registry. The protocol was approved by the medical ethics committee of the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán. This study followed the principles of the declaration of Helsinki.

Data collection

Data were collected and registered by the attending endocrinologist or an assistant, at each office visit, as an adjunct to the medical record. HbA1c concentration

and other laboratory test results were also registered at each visit. Hypoglycemia was defined as glucose concentration < 70 mg/dL and severe hypoglycemia as an event with alteration of mental and/or physical functioning requiring assistance from another person for recovery. The presence of microvascular complications was determined by the attending physician (neuropathy), an ophthalmologist (retinopathy), and laboratory analysis (nephropathy) according to the 2017 American Diabetes Association Standards of Care²³. All data were downloaded, de-identified, manually cleaned, and analyzed by a statistician/epidemiologist. All investigators had full access in the database.

Statistical analysis

For continuous variables, central tendency measures were calculated (means for variables with parametric distribution and median for variables with non-parametric distribution). For categorical measures, percentages and proportions were estimated. Differences between quantitative variables were analyzed with Student's *t*-test. Pearson's Chi-square for qualitative variables was performed. Logistic regression models were performed to explore factors associated with glycemic control and the presence of any chronic complications. The diagnosis and selection for our logistic regression model were conducted by assessing the lowest Bayesian information criterion (BIC) along with the highest R^2 . Statistical analyses were conducted using STATA version 11. Missing data were excluded from the statistical analyses. $p < 0.05$ was considered as statistically significant.

RESULTS

Population characteristics

We present the data of patients included between July 2014 and January 2018. Of the 1,035 individuals who have been enrolled during the study period, 64 declined participation and another six were excluded for incomplete data. We extracted and analyzed information of 965 adults and children living with T1D. Data were collected from 29 endocrinology centers distributed among 26 of the 32 Mexican States. Patients registered from Jalisco represented 24.4% of the cases, followed by Mexico City with 20%, Mexico

State with 10%, and Nuevo León with 8.7% of the cases (Supplementary Figure S1). We observed that 564 (58%) were enrolled from private practices, whereas 401 (42%) were registered at public institutions; 222 (23%) at the Mexican Social Security Institute (IMSS), and 175 (18%) at clinics belonging to the Ministry of Health (SSA). The median age was 21 years (range 1–81 years). The median age at diagnosis was 11 years (IQR 7–15). We recorded that 85% ($n = 772$) of the patients were diagnosed before the age of 20 years, whereas 15% ($n = 129$) after the age of 20.

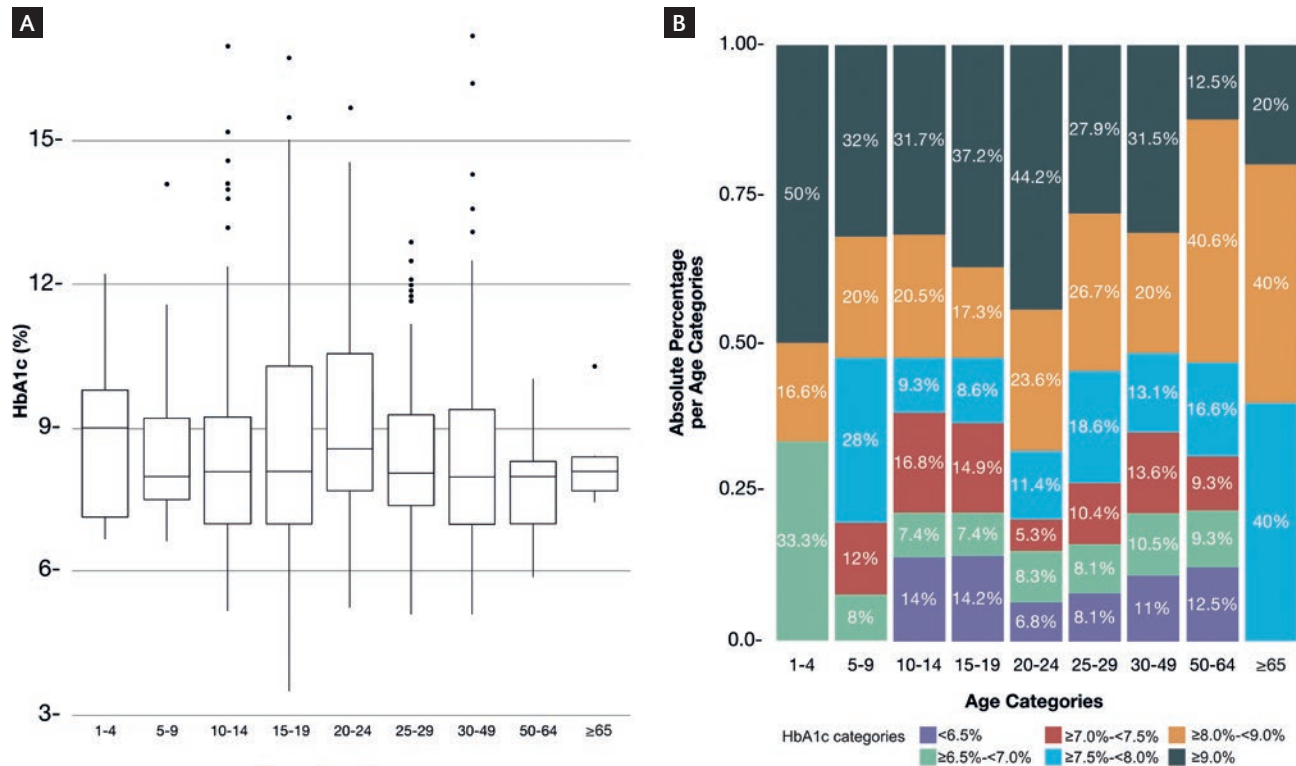
We observed a female predominance (61%) of registered patients (Supplementary Table S1). Among patients with available diagnosis date ($n = 901$), median diabetes duration was 8.2 years at enrollment, with 78 patients living with diabetes for 20–30 years and 38 for more than 30 years; 81% ($n = 946$) of these patients were diagnosed after the year 2000. Fifty-four percent of the patients were hospitalized at diagnosis ($n = 282/520$ with available information); of those, 72% ($n = 204/282$) presented diabetic ketoacidosis (DKA) and 17% ($n = 47/282$) required admission to the intensive care unit. A family history of T1D was reported by 13% of the patients, present in a first-degree family member in only 2%. A family history of T2D was reported by 58% of the participants, and a first-degree family member with T2D was reported by 11%.

Biochemical and anthropometric characteristics

Mean HbA1c registered at enrollment was $8.9 \pm 2.2\%$ (74 ± 24 mmol/mol), 16.3% of the patients having an HbA1c concentration below 7% (53 mmol/mol), and 40.8% above 9.0% (75 mmol/mol). In the last follow-up, the mean HbA1c was $8.7 \pm 2.1\%$ (72 ± 23 mmol/mol), with 18% of the participants having an HbA1c below 7.0% (53 mmol/mol) and 35% above 9.0% (75 mmol/mol) (Supplementary Table S1). Figure 1 shows HbA1c at the last follow-up according to age categories.

Height and weight information were recorded in 469 patients, of whom 42.4% had overweight or obesity ($\geq 85^{\text{th}}$ percentile for ages 2–< 20, and ≥ 25 kg/m² for ages ≥ 20) and 8.1% had obesity ($\geq 95^{\text{th}}$ percentile for ages 2–< 20 and ≥ 30 kg/m² for ages ≥ 20).

Figure 1. Box-plot of HbA1c levels in the RENACED-DT1 database stratified by age categories (A). Proportion of HbA1c categories according to age categories in the RENACED-DT1 (B).



At the last follow-up visit, 44.3% had overweight or obesity and 8.9%, obesity.

Treatment and glucose monitoring

Among patients with treatment information available ($n = 750$), 61% were on basal-bolus therapy by injection with insulin analogs, 21% were insulin pump users and 9% were using real-time continuous glucose monitoring (CGM) (Supplementary Table S1). These two latter were more common in patients with private medical care. Self-monitoring of blood-glucose (SMBG) ≥ 4 times/day was performed in 33.3% of patients.

Associated factors related to adequate glycemic control

At the last follow-up ($n = 545$), mean HbA1c levels on insulin pump users ($n = 144$) were $7.9 \pm 1.4\%$ (62 ± 15.3 mmol/mol), whereas in those treated by basal-bolus injections ($n = 401$) the mean HbA1c

was 8.8 ± 2.2 (73 ± 23 mmol/mol) ($p < 0.01$). Figure 2 shows the percentage of patients on basal-bolus injections or insulin pump with HbA1c $< 7\%$ (< 53 mmol/mol), 7–8.9% (53 mmol/mol–75 mmol/mol) and $n 9\%$ (75 mmol/mol).

The bivariate analysis showed an association with lower HbA1c levels and private health-care setting, insulin pump use, CGM use and SMBG ≥ 4 times/day. After adjusting for sex, education, age and time since diagnosis (≥ 10 years), only SMBG ≥ 4 times/day remained associated with better glycemic control: adjusted odds ratio (AOR), 2.62 (95% confidence interval [CI], 1.13–6.04) (Table 1).

Chronic complications and related factors

Of the 901 individuals with a registered diagnosis date, we recorded 12.0% ($n = 108$) of patients with any chronic complication; 6.3% ($n = 57$) reported diabetic neuropathy, followed by diabetic retinopathy in 5.4%

Figure 2. Percentage of patients with HbA1c <7% (<53 mmol/mol), 7 to <9% (53 mmol/mol-75 mmol/mol) and ≥ 9% (75 mmol/mol) according to the treatment regimen: basal-bolus regimen (blue), insulin pump therapy (orange), in RENACED-DT1 National Registry.

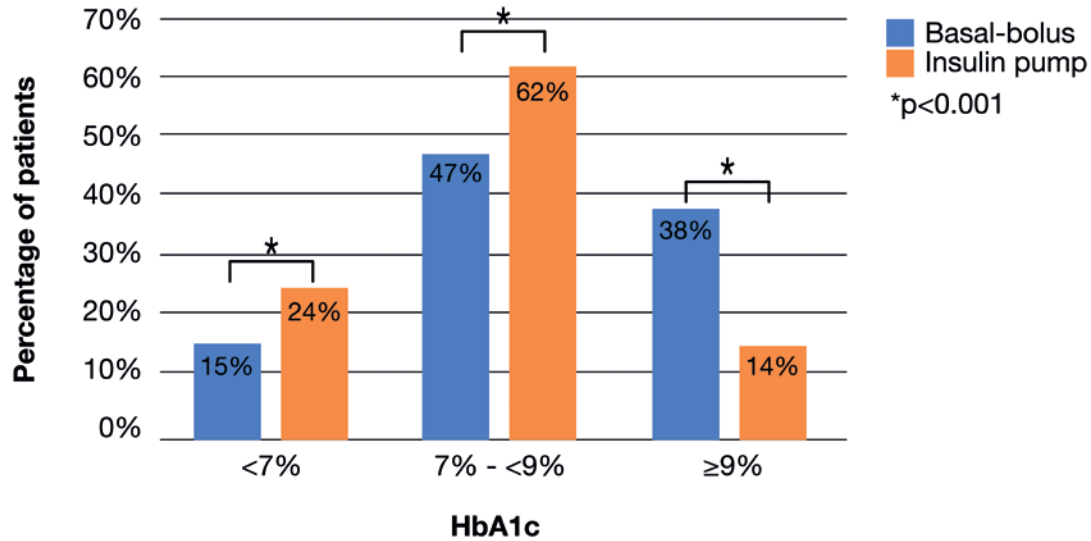


Table 1. Multivariate logistic regression analysis for adequate glycemic control (HbA1c <7%)

	Beta	SE	OR (95% CI)	p
SMBG ≥ 4 times/day	0.96	0.43	2.62 (1.13-6.04)	0.024
Insulin pump use	0.53	0.54	1.69 (0.59-4.88)	0.328
CGM use	0.67	0.64	1.95 (0.56-6.81)	0.293
Time since diagnosis (≥ 10 years)	-0.17	0.40	0.85 (0.39-1.84)	0.675
Private health-care setting	-0.25	0.47	0.78 (0.31-1.98)	0.607
Female	0.23	0.41	1.26 (0.57-2.82)	0.569
Completed High School	0.25	0.41	1.28 (0.57-2.88)	0.550

SMBG: self-monitoring of blood glucose; CGM: continuous glucose monitoring; BIC:228.49; R² = 0.0564.

(n = 49) in and diabetic nephropathy in 4.6% (n = 41) in our population of study (Table 2). As expected, with increased diabetes duration, the proportion of patients with chronic complications increased, with up to 45% (n = 17/38) in those with >30 years of diabetes duration (Table 2). In our logistic regression models, we found that time since diagnosis (> 10 years), female sex, obesity status, SMBG < 4 times/day, and the presence of hypoglycemia were associated factors to any chronic complication. After adjusting for HbA1c,

private health-care setting, insulin pump use and CGM use, the association of the previously mentioned variables persisted (Table 3).

DISCUSSION

RENACED-DT1 is the first longitudinal online registry for T1D in Mexico, from different states of the

Table 2. Presence of chronic diabetes complications (nephropathy, neuropathy and retinopathy) according to type 1 diabetes duration, in RENACED-DT1 National Registry

Diabetes duration at enrollment	Patients with available information	Chronic complications n (%)	Retinopathy n (%)	Neuropathy n (%)	Nephropathy n (%)
Overall	901	108 (12)	49 (5.4)	57 (6.3)	41 (4.6)
0 < 10 years	534	28 (5)	8 (1)	17 (3)	8 (1)
10 < 20 years	251	42 (17)	19 (8)	23 (9)	20 (8)
20 < 30 years	78	21 (27)	12 (15)	8 (10)	6 (8)
≥ 30 years	38	17 (45)	10 (26)	9 (24)	7 (18)

p < 0.0001.

country, and includes data from children and adults who are being followed at both public and private health-care settings. Enrollment of patients in the RENACED-DT1 registry is ongoing and open to all physicians in the country. In the 1st 3.5 years since its inception, a little over 1000 patients have been registered in RENACED-DT1. This figure illustrates the difficulty of gathering patient data for T1D in Mexico and the relevance of this initiative.

Our results are similar to those of the T1D Exchange Clinic Registry and SEARCH for Diabetes Youth Study, in which most of the participants do not reach the HbA1c targets recommended by the American Diabetes Association²⁴. Furthermore, in concordance with other registries²⁵⁻²⁷ we found a high prevalence of patients with overweight (35.4%) and obesity (8.9%). The SEARCH for Diabetes in Youth Study found an obesity rate of 12.6% in PWT1D²⁵, and the T1D Exchange Study found an obesity rate of 13.1% in adolescents²⁶. The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research (DCCT-EDIC) found that obesity prevalence, in the intensive treatment arm, increased from 1% at baseline in the DCCT Study to 31% at 12-year follow-up of the EDIC Study²⁷. Mexico has one of the highest prevalence of metabolic diseases worldwide, including mixed dyslipidemia, hypoalbuminemia, hypertriglyceridemia, and obesity²⁸. The evolution of PWT1D in Mexico, who may have other metabolic diseases, deserves a closer surveillance.

In the bivariate analysis of our registry, as in other registries around the world, more frequent SMBG, insulin pump therapy and the use of CGM devices are associated with an improved metabolic control²⁹⁻³¹. However, after adjustment for covariables, only SMBG ≥ 4 times/day remained an associated factor for good glycemic control as measured by HbA1c < 7%. Future studies will address whether the use of technology is associated with adequate metabolic control in our population. In several countries, especially in Europe, this knowledge has led to changes in clinical practices, which have improved metabolic control with decreased incidence of severe hypoglycemia, throughout the years³²⁻³⁴.

In Mexico, little is known about T1D, especially about the long-term follow-up and complications of people living with the disease^{6,35}. As expected, in our cohort, longer diabetes duration was associated with an increased presence of chronic complications. In addition, female sex, lower SMBG, hypoglycemia, and obesity were also associated variables. It is possible that hypoglycemia is associated with chronic diabetes complications, as it is associated with higher glycemic variability. The prospective and longer follow-up of the patients in our registry will aid to confirm the current findings.

We found a female predominance (61%) in our registered patients, in contrast to what occurs in other registries that report no gender difference. This finding needs to be tracked further as the number of

Table 3. Multivariate logistic regression analysis for T1D associated chronic complications

	Beta	SE	OR (95% CI)	p
SMBG <4 times/day	0.992	0.472	2.69 (1.11-7.18)	0.036
CGM use	0.689	1.088	1.99 (0.19-16.98)	0.526
Time since diagnosis (≥10 years)	1.029	0.3102	2.78 (1.53-5.21)	0.020
Private health-care setting	-0.057	0.509	0.94 (0.33-2.51)	0.909
Female	0.874	0.385	2.39 (1.15-5.26)	0.023
Obesity (BMI ≥30 kg/m ²)	1.05	0.461	2.87 (1.13-7.04)	0.022
Insulin pump use	-0.535	0.616	0.58 (0.16-1.86)	0.384
HbA1c	0.063	0.081	1.05 (0.89-1.23)	0.438
Hypoglycemia Event	0.719	0.312	2.09 (1.13-3.92)	0.021

SMBG: self-monitoring of blood glucose; CGM: continuous glucose monitoring; BIC: 255.2216; R² = 0.8364463.

patients registered increases to ascertain whether or not Mexican PWT1Ds are more frequently female, or if this is linked to a selection bias, related to women being more willing to participate.

In our country, government coverage for PWT1D is limited, leading to considerable out-of-pocket expenses. PWT1D require careful medical care^{36,37}. It would be desirable to have universal access to therapy (insulin analogues and glucose monitoring) and up-dated diabetes education for all PWT1D during their lifetime, to minimize complications and increase quality of life.

Some limitations of our work should be acknowledged. This is not a population-based study, which limits the extrapolation of the data to all PWT1D in Mexico. If we consider the prevalence of 26,578 cases reported by the IDF in 2019³⁸, and the 25,695 cases notified in the period between 2010 and 2018 by the Mexican Ministry of Health³⁹, our sample population is a small proportion (approximately 6%) of the diagnosed cases with T1D in Mexico. Our results are similar in gender and age distribution to those reported by the Mexican Ministry of Health in 2019⁴⁰.

In this analysis, there is limited representation of the public sector and there are missing data, as it occurs in all registries.

This work represents a description of the data obtained from the online T1D registry in Mexico RENACED-DT1. Increased SMBG is associated with better metabolic control and lower presence of diabetes complications. The percentage of patients achieving HbA1c < 7% must be expanded to reduce the incidence of chronic complications and improve the quality of life of those living with the disease.

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SUPPLEMENTARY DATA

The complete members list of the RENACED-DT1 Research Group is available as supplementary material. Supplementary data are available at Revista de Investigación Clínica online (www.clinicalandtranslational-investigation.com). These data are provided by the corresponding author and published online for the benefit of the reader. The contents of supplementary data are the sole responsibility of the authors.

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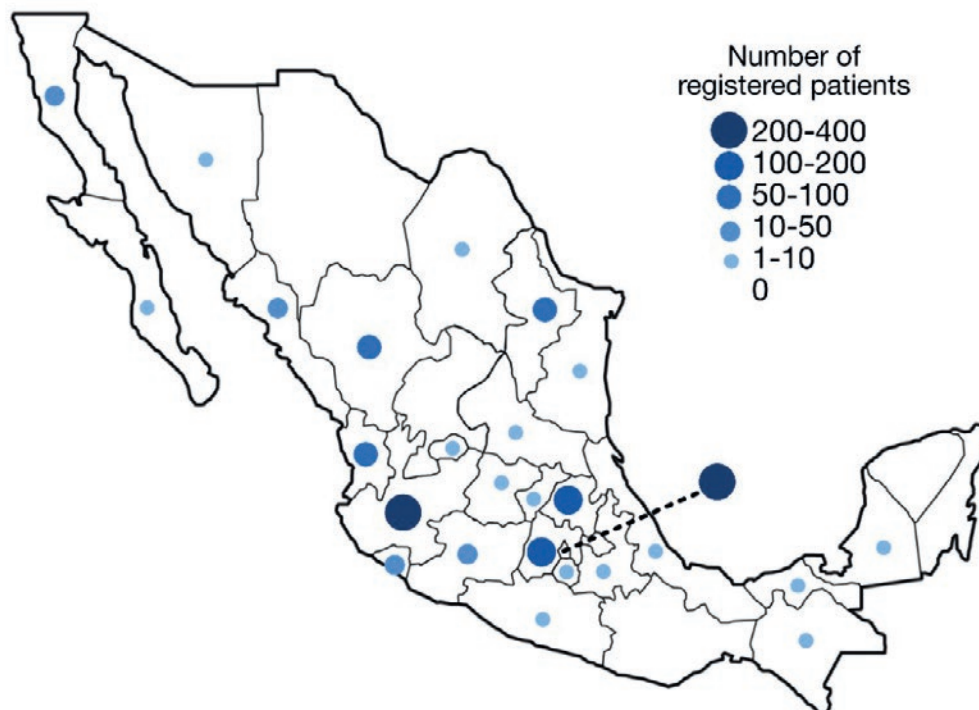
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TYPE 1 DIABETES CARE IN MEXICO: AN ANALYSIS OF THE RENACED-DT1 NATIONAL REGISTRY

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Supplementary Figure S1. Number of patients registered by state throughout Mexico in RENACED-DT1 National Registry by January 2018.



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Supplementary Table S1. Participant characteristics according to age at the last follow-up, in RENACED-DT1 National Registry

Age group	Total	0-4	5-9	10-14	15-19	20-24	25-29	30-49	50-64	≥65
n	965	10	42	168	206	164	106	227	34	8
Female (%)	61	40	52	59	59	60	55	65	76	75
Less than a high school diploma (%)	58	100	100	100	89	33	28	28	26	33
Health-care setting										
SS (%)	27	0	3	7	27	45	45	33	0	0
IMSS (%)	27	10	7	17	19	27	28	46	48	100
Private (%)	33	70	63	53	35	16	20	21	52	0
Other (%)	13	20	27	22	20	13	7	1	0	0
Treatment										
Pump use (%)	21	0	28	22	12	19	24	23	38	33
Basal Bolus (%)	61	0	59	67	65	62	60	59	53	50
CGMc use (%)	9	0	24	19	4	9	6	9	11	0
Acute complications										
Severe hypoglycemia in the previous year (%)	4	0	0	2	3	4	4	7	6	0
DKA after diagnosis (%)	12	0	0	18	13	13	8	11	10	0
HbA1c levels										
HbA1c % (mmol/mol), at enrollment	8.9 ± 2.2 (74.0 ± 24.0)	8.8 ± 1.8 (73.0 ± 19.7)	9.1 ± 1.9 (76.0 ± 20.8)	9.0 ± 2.5 (75.0 ± 27.3)	9.1 ± 2.7 (76.0 ± 29.5)	9.3 ± 2.2 (78.0 ± 24.0)	8.5 ± 1.7 (69.0 ± 18.6)	8.7 ± 2.1 (72.0 ± 23.0)	8.0 ± 1.5 (64.0 ± 16.4)	8.2 ± 1.2 (66.0 ± 13.1)
HbA1c % (mmol/mol), during the last year (n = 391)	8.7 ± 2.1 (72.0 ± 23.0)	8.3 ± 2.3 (67.0 ± 25.1)	9.0 ± 2.5 (75.0 ± 27.3)	8.7 ± 2.3 (72.0 ± 25.1)	8.9 ± 2.3 (74.0 ± 25.1)	9.4 ± 2.3 (79.0 ± 25.1)	8.3 ± 1.6 (67.0 ± 17.5)	8.5 ± 2.0 (69.0 ± 21.9)	7.9 ± 1.1 (63.0 ± 12.0)	8.3 ± 0.2 (67.0 ± 2.2)
Distribution of HbA1c values registered at the last follow-up										
< 6.5% (< 48 mmol/mL)	11	0	0	13	8	7	12	16	11	0
6.5 to < 7.0% (48 to < 53 mmol/mL)	7	50	13	7	7	3	8	6	16	0
7.0 to < 7.5% (53 to < 58 mmol/mol)	12	0	25	16	17	10	8	10	0	0
7.5 to < 8.0% (58 to 64 mmol/mol)	12	0	13	7	11	12	20	11	21	0
8.0 to < 9.0% (64-75 mmol/mol)	23	0	0	22	23	22	22	21	42	100
≥9.0% (≥75 mmol/mol)	35	50	50	35	35	45	29	35	11	0

Data expressed as mean ± standard deviation or percentages, as appropriate. SS: Secretaría de Salud (Ministry of Health); IMSS: Instituto Mexicano del Seguro Social (Mexican Social Security Institute); CGM: continuous glucose monitor, DKA: diabetic ketoacidosis.

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