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Predictors of traffic events due to hypoglycemia in adults with type 1 diabetes: A Brazilian prospective cohort study

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ABSTRACT

Background: Individuals with type 1 diabetes (T1D) are exposed to an elevated risk of automobile accidents especially because of hypoglycemia that impairs physiological and defense responses.
Objectives: To assess local risk factors for traffic events in T1D adult Brazilian patients.
Methods: This is a prospective study and 12-month follow-up to assess predictors for traffic events on a cohort of drivers with T1D (n = 168) in Brazil. The inclusion criteria for participants were Brazilian nationality, age ≥ 18 years-old, diagnosis of T1D for more than one year, driving license B, C or D categories (four-wheel vehicles), driving three-times per week or more, and checking blood glucose twice-daily or more. The primary outcome was hypoglycemia driving mishaps assessed by a seven-query questionnaire about the past 30 days. Secondary outcomes included driving mishaps not related to hypoglycemia. Statistical analysis was performed through Poisson regression models with robust variance estimarion, in which the measure of association is the relative risk.
Results: A total of 109 participants completed the 12-month follow-up. Most of them were men (66%) and 37 ± 11 years-old, and had a mean HbA1c of 8.2% (66 mmol/mol). In the follow up, the incidence of traffic events was high (70.6%); however, only a minority was attributed to hypoglycemia as the cause of the reported event (19.3%). The best predictors for new traffic events due to hypoglycemia were those related to driving characteristics. The best of them was a history of episodes of hypoglycemia while driving [RR 3.40 (1.22–9.43); $p < 0.05$].
Conclusions: We found that previous episodes of hypoglycemia while driving significantly increase the risk of new traffic events and are the best predictor for it. This highlights the need to assess the risks of traffic accidents especially in people who have had experienced episodes of hypoglycemia while driving.

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1. Introduction

Traffic accidents are one of the top ten global causes of death being at the seventh position in the last ranking [1]. Brazil is the fifth country in global ranking of number of traffic injury [2] and some groups of people are exposed to higher risks than others. People with type 1 diabetes mellitus (T1D) have a higher incidence of road injury than type 2 diabetes or those without diabetes [3]. The frequency of traffic crashes, driving violations, and the need for driving assistance varies from 15 to 22% in T1D in retrospective studies [3].

Individuals with T1D have an elevated risk of automobile accidents especially because of hypoglycemia that impairs physiological and protection responses [4]. Neuroglycopenic symptoms may include confusion, cognitive deterioration, seizures, and loss of consciousness [5]. A hypoglycemic episode can lead to cognitive impairment for up to 75 min [6], which may seriously compromise important daily activities including driving.

In the Diabetes Control and Complications Trial, the most common major accident related to hypoglycemia was car accidents. During follow-up, hypoglycemia was emphasized as the main cause of car accidents in 64.2% of the cases [7]. Another prospective analysis accompanied T1D American drivers for 12 months and found that driving mishaps were related to hypoglycemia at least once in more than a half of the sample, with 32% of them having two or more events and 5% having six or more driving mishaps [8].

Behavior changes related to hypoglycemia and driving are an important factor for traffic complications. Individuals with T1D with more traffic events reported choosing lower cut-of-points of blood glucose to decide not to drive and also reported checking their blood glucose before driving less frequently [3]. Peripheral neuropathy, visual impairment, and cerebrovascular accidents leading to cognitive impairment may also affect driving performance in these subjects [9]. Despite this, hypoglycemia remains the main factor related to traffic accidents in T1D population [10].

Risk factors for car accidents in diabetes may have different impacts in different populations because diabetes care, availability of technology to treat diabetes, and traffic rules vary among countries and different socio-cultural contexts [9]. For example, comparing unfavorable traffic events in patients with T1D in Europe and North America is not adequate because European drivers in general have fewer traffic events [10].

In this context, knowing the local risk factors for car accidents in T1D is important for an adequate approach to preventing traffic accidents in this population. Considering that hypoglycemia is the main risk factor for car accidents in T1D subjects, this study searched for clinical and driving predictors of traffic events due to hypoglycemia in a Brazilian population of subjects with T1D.

Our hypothesis is that clinical characteristics of diabetes, such as longer duration of the disease, poor glucose control, presence of hypoglycemia unawareness and diabetic neuropathy could be associated with traffic crashes and that *Risk Assessment of Diabetic Drivers*, a tool already used in other countries, could be useful for screening T1D Brazilian drivers for these events.

2. Methods

2.1. Study design

This was a cohort study with one-year follow-up. Data were collected prospectively through mensal calls to participants.

2.2. Setting

We studied 168 drivers with T1D from two tertiary care public institutions and from the state health department in Southern Brazil. Participants were recruited from March 2018 to April 2019 and were followed for 12 months since inclusion in the study. Data collection was performed in two steps: We first performed a cross-sectional evaluation of clinical data and possible predictors based on a previous published questionnaire for T1D drivers [11] and then evaluated subjects monthly with telephone calls searching for possible driving mishaps.

2.3. Participants and sample size

Inclusion criteria for participants were the following: Brazilian nationality, age $\geq$ 18 years-old, diagnosis of T1D for more than one year, Brazilian driving license B, C, or D categories (four-wheel vehicles), driving three times per week or more, and checking blood glucose twice-daily or more. Participants with cognitive deficit or any communication barrier that would impair follow-up were excluded. They were invited to participate in person at the institutions where they received medical care or by phone call through a contact list of patients with T1D receiving insulin from the state health department.

The study was conducted in two steps, and thus sample size and follow-up was different for each. We first conducted a cross-cultural adaptation of the *RADD* instrument - *Risk Assessment of Diabetic Drivers* (supplemental Fig. 1) - a tool used in the United States for screening drivers with T1D at higher risk for driving mishaps [11]. We performed a five steps protocol (translation of the instrument, synthesis, back translation, expert committee review and pretesting in a sample) as recommended by guidelines on the topic [12]. At the end of this process, 35 subjects were recruited for the test–retest step. These subjects answered the questionnaire two times, applied by different interviewers, within 15-day interval. The conclusion was to characterize the process as reliable or not.

The second step included 133 participants. In the first meeting, subjects answered two questionnaires. The main questionnaire consisted of questions about social-cultural information, diabetes status, and driving (supplemental Fig. 2). The second questionnaire had 11 questions that consisted of the *RADD* adapted to Brazilian Portuguese (supplemental Fig. 3). The clinical characteristics and answers

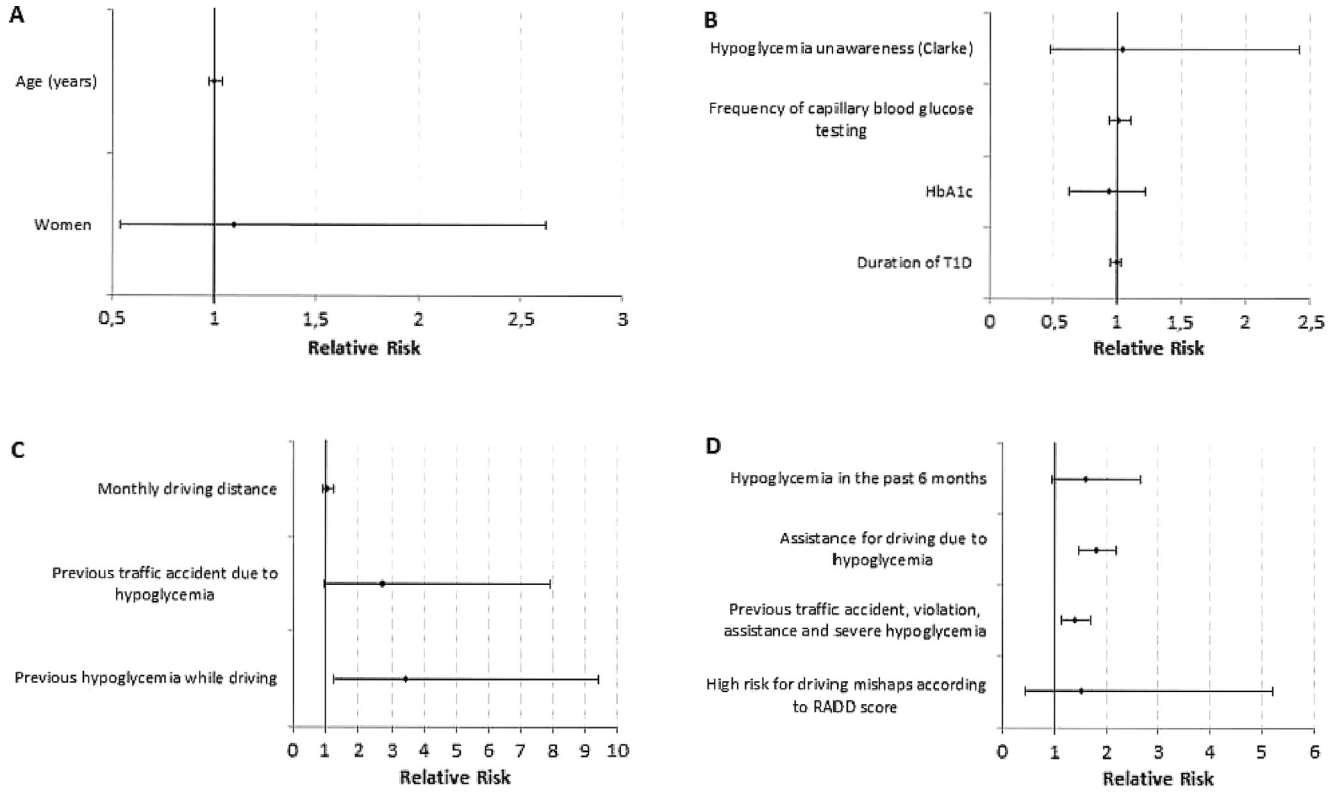

Fig. 1 – Association between social-demographic characteristics (A), diabetes condition characteristics (B), driving characteristics (C), RADD score (D) and the primary outcome (traffic events due to hypoglycemia). Relative risks (Poisson regression models with robust variance) and their 95% confidence intervals are presented. HbA1c, glycated hemoglobin; T1D, type 1 diabetes; RADD, Risk Assessment of Diabetic Drivers.

to the questionnaires were evaluated to find predictors for future driving mishaps. During this 12-month period, participants were followed by phone calls monthly. At each phone meeting, they were questioned about driving mishaps in the past month through a specific questionnaire (supplemental Fig. 4).

2.4. *Variables and data source*

The primary outcome was hypoglycemia driving mishaps as assessed by a seven-query questionnaire about the past 30 days (supplemental Fig. 4): presence of severe hypoglycemia episodes, loss of car control, collisions, police barrier assessment, automatic driving (that means arriving somewhere not knowing how you got there), unintentionally stopping driving, and the need for assistance for someone else for driving. Each positive answer for any of these questions was considered a driving mishap. In the case of any affirmative answer, the questions were followed by questioning whether hypoglycemia was the cause. Positive cases were considered a hypoglycemia driving mishap. The secondary outcome was driving mishaps not related to hypoglycemia as assessed through the same questionnaires when the answer for hypoglycemia as a causal factor was negative.

Predictors for these outcomes considered the following characteristics of the population: social-demographics, characteristics related to the diabetes condition, and characteristics related to driving. Social-demographic features evaluated were age, sex, skin color, marital status, education, occupation, and monthly income. Factors related to the diabetes condition were duration of diabetes, age at diagnosis, type and dose of insulin in use, metabolic control [assessed by glycated hemoglobin (HbA1c) and frequency of self-monitoring blood glucose], presence of vascular complications (retinopathy, nephropathy, neuropathy, cardiovascular disease; all assessed through medical records), treatment adherence assessed by the Self-Care Inventory-Revised (SCI-R) questionnaire (Brazilian validated version, good adherence > 48 points) and Diabetes Self-Management Profile (DSMP) questionnaire (Brazilian validated version, good adherence > 41 points) [13] and awareness of hypoglycemia (assessed by the Clarke questionnaire, Brazilian validated version) [14]. Features related to driving were the driver's license duration and category, time and distance driven per month, previous traffic accidents and traffic violations, previous episodes of hypoglycemia while driving, previous traffic accident due to hypoglycemia, the score obtained on the adapted driving questionnaire (RADD) and each of the questions of RADD evaluated separately.

2.5. *Statistical analysis*

Analyses were performed using IBM-SPSS (IBM Corp. IBM SPSS Statistics for Windows, version 20, Armonk, NY, USA).

Continuous variables were presented as mean values and standard deviation (SD); 95% intervals were presented when appropriate. Categorical variables were presented as frequencies and percentages. Non-parametric variables were presented as median and interquartile range (25 and 75 percentiles). To identify the association of clinical and driving variables with primary and secondary outcomes, Poisson regression models with robust variance estimation were used, in which the measure of association is the relative risk [15].

2.6. *Ethical aspects*

The study was designed according to the Guidelines and Standards Research Regulations Involving Humans Beings and National Health Council in accordance with resolution 466/12. The study was also approved by the local ethics research committee of both institutions from where patients were recruited, protocol numbers 2017–0595 and 18121. This document follows the STROBE Statement's checklist of items that should be included in reports of cohort studies [16].

3. Results

A total of 917 subjects were recruited from March 2018 to April 2019; 705 subjects were invited to participate because 212 of them could not be reached by phone. Of the 705 subjects, 168 fulfilled the inclusion criteria and signed the informed consent. Thirty-five subjects completed the first step of the study and the other 133 started the follow-up. (supplemental Fig. 5)

3.1. *Cross-cultural adaptation study*

Thirty-five participants completed the cross-cultural adaptation step. Most of them were men (77.1%), 43 ± 12 years-old, 19 (12.5–26.5) years of T1D diagnosis, and 15 (8–23) years of licensing driving. Glycemic control was less than desired with mean HbA1c 8.2% (66 mmol/mol). The most frequent diabetes complication was retinopathy (62.9%), and the majority of them reported previous episodes of hypoglycemia while driving (62.9%), although only 5.7% experienced traffic accidents due to hypoglycemia.

These subjects took part in the test–retest phase of cross-cultural adaptation answering the Brazilian version of *RADD* questionnaire two times. The questionnaire was applied by two different interviewers within 15 days. The intraclass range coefficient of 0.774 demonstrated that the results were reliable. The process of validation showed an Cronbach's alpha of moderate internal consistence (α = 0.483) with no good improvements upon removing some questions. The better result was reached including only questions number 7, 8, 10 and 11: Cronbach's alpha was 0.677, which is less than expected based on the literature.

3.2. *Cohort study*

Of the 133 participants included, 109 (82%) completed the 12-month follow-up. Fifteen participants (11.3%) were lost, four (3%) withdrew from participation, four (3%) stop driving for problems not related to diabetes, and one (0.7%) had sudden death during the follow-up. We present the data from the 109 participants who completed the follow-up.

Demographic, diabetes, and driving features are shown in Table 1 for participants. Most of them were men (66%); 37 ± 11 years-old. There were two professional drivers, and the majority did not have good control of their diabetes, 7.3% of them had an HbA1c < 7.0% (53 mmol/mol), and the majority of participants monitor their blood glucose less frequently than recommended (56.9% of participants measured three times/day or less), checking glucose before driving only 37% of times; 33% of them have poor adherence to treatment according SCI-R and DSMP scores and had a low prevalence of neuropathy (6.4%).

The primary outcome (traffic events due to hypoglycemia) was reported by few participants. Twenty-one participants (19.3%) reported some driving mishaps due to hypoglycemia. The median (IQR) of mishaps was 1.0 (0.0–5.5); 15 participants (13.8%) presented only one event during the follow-up and 6 participants (5.5%) presented two or more events. The driving mishap most reported due to hypoglycemia was automatic driving with a mean (SD) of 0.17 ± 0.67 times ranging for 0 to 5 times per person during the period of follow-up.

Baseline characteristics of the cohort were analyzed according to the primary outcome in search of predictors for it (Table 2). The groups were similar and did not differ from each other neither in relation to demographic characteristics (Fig. 1A) nor in relation to diabetes characteristics (Fig. 1B). The best predictors for new traffic events due to hypoglycemia were those related to driving characteristics (Fig. 1C and 1D). The best of them was history of episodes of hypoglycemia while driving. Participants that reported previous hypoglycemia in this context had an increase of 240% in the risk of driving mishaps due to hypoglycemia during the follow-up [RR 3.40 (1.22 – 9.43); p < 0.05] (Fig. 1C) and previous traffic accident due to hypoglycemia showed a tendency for new events [RR 2.73 (0.94–7.90); p = 0.063, Fig. 1C].

Characteristics such as duration of driver's license, hours and distance travelled per month and driver's license category were not good predictors of future hypoglycemia driving mishaps. The RADD score was also not a good predictor of future driving mishaps due to hypoglycemia in our sample [RR 5.28 (0.44–63.03); p = 0.188]. However, when looking at the issues not like a score and analyzing them separately, we found that the first three questions, when asked together, were associated to traffic events due to hypoglycemia (previous traffic accident, previous traffic violation and needing help from someone else for driving, all of them due to hypoglycemia). In this case, positive answers represented a 78% higher risk for new driving mishaps due to hypoglycemia [RR 1.78 (1.46–2.17); p < 0.05]. The best predictor for the primary outcome was that represented by question three (needing help from someone else with driving due to hypoglycemia) [RR 1.79 (1.46–2.18); p < 0.05]. Finally, the frequency of hypoglycemia in the past six months (question 7) also represented a tendency for being a good predictor [RR 1.59 (0.36–2.65) p 0.07].

The secondary outcome (presenting driving mishaps during follow-up independently of the presence of hypoglycemia) was reported by 70.6% of the sample and is presented in Table 3. The main causes of traffic accidents were obtained

through answers to a questionnaire (Supplemental Fig. 4), and they were fatigue and somnolence. However, drivers did not always check their glucose before driving to be sure of the absence of association with hypoglycemia. Being a professional driver and having a previous history of traffic accidents due to hypoglycemia were good predictors. Professional drivers had a 42% higher risk for driving mishaps [RR 1.42 (1.26–1.62) $p < 0.05$], which was the same risk represented by having a history of previous traffic accident due to hypoglycemia [RR 1.42 (1.25–1.61) $p < 0.05$]. Another good predictor was the distance traveled: those who moved for longer distances had 3% more traffic events during follow-up [RR 1.03 (1.01–1.06) $p < 0.05$]. Good adherence to diabetes treatment measured by the SCI-R questionnaire, despite the small effect, represented a protective factor for new traffic events [RR 0.97 (0.96–0.99) $p < 0.05$].

Supplementary analysis of the secondary outcome showed that the mishap most reported was having episodes of severe hypoglycemia in the last month. This occurred a mean (SD) of 1.56 ± 2.98 times ranging from 0 to 17 times but was not necessarily related to driving (only 13.3% of times were while driving). The second most common driving mishap was being assessed by the police barrier and had a mean (SD) of 1.32 ± 2.31 times ranging from 0 to 17. Participants judged that none of the police approaches were related to hypoglycemia episodes.

4. Discussion

This study provided the cross-cultural adaptation of *RADD* score to Brazilian Portuguese, and was the first to assess clinical predictors for traffic events among Brazilian T1D drivers. In the follow up, the incidence of traffic events was high (70.6%); however, only a minority was attributed to hypoglycemia as the cause of the reported event (19.3%). Interestingly, characteristics related to driving were the best predictors for new traffic events. We found that the report of previous episodes of hypoglycemia while driving increases the risk of new traffic events due to hypoglycemia in 3.4-fold. On the other hand, we did not find any association between diabetic neuropathy, diabetic retinopathy or demographic characteristics with traffic events. In the same way, the diagnosis of hypoglycemia unawareness was not a good predictor for traffic events.

Traffic events due to hypoglycemia are usually associated with some driving characteristics [17–19] as well as with some diabetes characteristics [11,20]. Previous episodes of hypoglycemia while driving increase the risk of a vehicle collision in insulin-treated diabetes patients around three-fold [21], and this risk increases exponentially with additional reported episodes [8]. Diabetic neuropathy is also classically associated with worse driving performance [11,20]. In driver-simulators, subjects with diabetic neuropathy had longer brake response time (0.757 *vs.* 0.679 s; $p < 0.001$) and had abnormally delayed reactions (57.5 *vs.* 35.5%; $p < 0.001$) when compared to patients without diabetic neuropathy [20]. Cox et al. also found that peripheral diabetic neuropathy is an important risk factor for driving mishaps in RADD score [11], which was the feature with the greatest weight in the logistic regression of this score.

The literature also suggests that demographic characteristics like age and gender do not lead to a higher risk of traffic events [3,8,10] and, despite visual decrements due to diabetic retinopathy are a potential risk factor in reducing driving performance [22,23], it did not show, until this moment, a significant risk association. Control studies show that driving events were independent of the presence of retinopathy and independent of its severity [19]. It was expected that hypoglycemia unawareness could increase the risk for new traffic events, once symptoms of hypoglycemia are an important protective mechanism for safety in T1D [5] and because patients who are unaware of their hypoglycemia perform their self-treatment less frequently while driving [18,24]. However, other studies also failed to prove significant statistical differences between patients with a diagnosis of hypoglycemia unawareness or not regarding the risk of traffic events [8,11].

Possible mechanisms related to these events are findings from other studies, which showed that people with a history of hypoglycemia driving mishaps have abnormal counter-regulatory responses to hypoglycemia [19] and greater cognitive impairments during moderate hypoglycemia [25]. In the same way, diabetic neuropathy affects distal lower limbs and can cause lesions in sensory and motor systems, reducing sensibility, increasing risk of amputation and causing lower extremities weakness [26]. Thus, diabetic neuropathy is classically associated with worse driving performance. On the other hand, the absence of association between diabetic retinopathy and traffic events is probably explained because people more severely impacted by retinopathy, the ones who are almost blind, spontaneously do not drive any more, or do not have a driver's license renewal [27]. Likewise, the ones who are treated with pan-photocoagulation keep good performance in the visual acuity exam as requested for safe driving; thus, being considered able to drive [28,29].

The absence of association of Brazilian adapted RADD score and traffic accidents in this study is probably associated with some sample characteristics. First of all, Brazilians drive shorter distances than Americans (341 versus 994 miles/-month) [11], making them less exposed to driving mishaps and making it more difficult to detect differences in the analysis, in addition to producing lower scores in the RADD. Another important issue is that one of the main questions of RADD is about diabetic neuropathy, which is unknown for a significant number of patients evaluated and a negative response also leads to lower scores.

The limitations of our study might have led to some unexpected results. First, we adaptated the plan of analysis, since the questionnaire did not reach validity in this sample of T1D Brazilian drivers. Thus, we proceeded with the study while evaluating the performance of a cross-cultural tool in the Brazilian population and searched for these and other variables that could be associated with driving mishaps due to hypoglycemia. Because sample size was not calculated for this specific purpose, data should be interpreted with caution. The low frequency with which participants usually perform SMBG may also have interfered with our results (more than half of them measured 3 times/day or less). Self-monitoring of blood glucose is useful for guiding diabetes treatment and management while avoiding hypoglycemia and

hyperglycemia [30]. Patients on intensive-insulin regimens (most patients with T1D) should check their glucose 6–10 times daily. We found that 77 participants (70%) in our sample reported some unexpected driving events during the 12-month follow-up, but only 21 of them (27%) reported that it happened due to a hypoglycemic event. Only 37% of the subjects reported that they checked their blood glucose before or during driving. Thus, many events reported during follow-up did not have a corresponding blood glucose check before driving. This prevents any association with hypoglycemia and possibly underestimates the incidence of events in the sample. Furthermore, the unexpected absence of risk association between traffic accidents and diabetic neuropathy in our study may be the result of its prevalence in our sample, which was low (6.4%), probably due to another limitation, the method used for evaluating neuropathy: asking participants if they have this diagnosis and reviewing their medical records. In Brazil, an important part of the population is unaware of their health problems, especially those related to diabetes [31]. Moreover, foot exams and searching for neuropathy is not always assessed or registered in Brazilian medical records [32].

Finally, recognizing risk factors associated with unfavorable traffic events in T1D drivers is important because we must search for strategies that improve this scenario. Whereas previous episodes of hypoglycemia while driving or previous traffic events demonstrated to be the best predictors for future events, asking patients about their traffic history is essential for us, as health professionals, to promote a better guidance to this population. The next step is education, talking with patients about hypoglycemia and driving, coaching them about the importance of frequent measurement of blood glucose before driving and about checking it while driving longer distances.

5. Conclusion

People with T1D are exposed to a greater risk of traffic events due to the consequences of hypoglycemia during driving. Previous episodes of hypoglycemia while driving significantly increase the risk of new traffic events and are the best predictor for it. Other important predictors are the positive history of previous traffic accidents, previous traffic violations and needing help from someone else for driving, all due to hypoglycemia. Therefore, asking patients who have previously experienced episodes of hypoglycemia while driving and mishaps associated with it are key subjects for advising and preventing future events.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A

See Tables 1–3.

Table 1 – Baseline characteristics of participants.

Table 1. Baseline characteristics of cohort participants

Variable	Total (N = 109)
Demographic features	
Men	72 (66%)
Age (years)	37.3 ± 11
White	97 (89%)
Education	
Primary and secondary school	48 (44.1%)
College education	61 (55.9%)
Diabetes features	
Duration of diabetes (years)	19 (12.5–26.5)
Age ate diagnosis (years)	18 (10–24)
Type of basal insulin in use	
NPH	31 (28.7%)
Long duration analogue	77 (71.3%)
Type of bolus insulin in use	
Regular	7 (6.4%)
Ultra-rapid acting analogue	102 (93.6%)
Total daily insulin dose (U/Kg)	0.68 (0.58–0.88)
Basal/Bolus ratio	1.6 (1.05–2.08)
HbA1c (%)	8.2 ± 1.5
Frequency of SMBG (times/day)	3 (3–4)
Nephropathy	19 (17.5%)
Neuropathy	7 (6.4%)
Retinopathy	36 (33%)
Cardiovascular disease	1 (0.9%)
SCI-R (points)	50.9 ± 6.1
DSMP (points)	45.9 ± 9.5
Clarke Scale	
Hypoglycemia awareness	75 (68.8%)
Hypoglycemia unawereness	34 (31.2%)
Driving features	
Duration of driver's license (years)	15 (8–23)
Category of driving license	
Only 4 wheel vehicles	58 (53.2%)
Others	51 (46.8%)
Time spent driving for month (hours)	30 (15–60)
Monthly driving distance (1000 Km)	0.550 (0.190–1.200)
Previous traffic accident	49 (45%)
Previous traffic violation	79 (72.5%)
Previous episodes of hypoglycemia while driving	61 (56%)
Previous traffic accident due to hypoglycemia	5 (4.5%)
RADD score	0.099 (0.066–0.149)
Risk for driving mishaps according to the RADD score	
Low	95 (87.2%)
Intermediate	7 (6.4%)
High	7 (6.4%)

Categorical variables are presented as frequencies and percentages; Continuous variables are presented as mean and standard deviation (mean ± SD); Non-parametric variables are presented as median and interquartile range (25 and 75 percentiles); NPH, Neutral Protamine Hagedorn; HbA1c, glycated hemoglobin; SMBG, Self-Monitoring of Blood Glucose; SCI-R, Self-Care Inventory-Revised questionnaire; DSMP, Diabetes Self-Management Profile questionnaire; RADD, Risk Assessment of Diabetic Drivers.

Table 2 – Predictors for driving mishaps due to hypoglycemia.

Table 2. Demographic, clinical, driving and RADD features of cohort participants according to the presence of driving mishaps due to hypoglycemia during follow-up

Variable	Did not have driving mishaps due to hypoglycemia (N = 88)	Have driving mishaps due to hypoglycemia (N = 21)	Relative Risk (RR) and 95% confidence interval
Demographic features			
Gender			
Women	29 (33)	8 (38)	1.19 (0.54–2.62)
Age (years)	37.1 ± 11.2	38.4 ± 10.6	1.00 (0.97–1.04)
Clinical diabetes features			
Duration of diabetes (years)	18 (13.0–25.7)	19 (8.0–28.5)	0.99 (0.95–1.03)
Type of basal insuline in use			
None (insulin pump)	0	1 (4.8)	
NPH	29 (33)	2 (9.5)	
Long acting analogue	59 (67)	18 (85.7)	3.62 (0.89–14.69)
Type of bolus insulin in use			
Regular	6 (6.8)	1 (4.8)	
Ultra-rapid acting analogue	82 (93.2)	20 (95.2)	1.37 (0.21–8.78)
HbA1c (%)	8.3 ± 1.5	7.9 ± 1.5	0.87 (0.62–1.22)
Frequency of SMBG (times/day)	3 (3–4)	4 (3–5)	1.01 (0.93–1.10)
Neuropathy	7 (8)	0	
Retinopathy	30 (34)	6 (28.6)	0.81 (0.34–1.91)
SCI-R (points)	50.7 ± 6.1	51.2 ± 6.4	1.01 (0.94–1.08)
DSMP (points)	45.5 ± 9	47.4 ± 11.5	1.01 (0.97–1.06)
Clarke Scale			
Hypoglycemia unawareness	27 (30.7)	7 (33.3)	1.07 (0.47–2.41)
Driving features			
Duration of driver's license (years)	14.5 (8.0–22.7)	15.0 (9.5–24.5)	1.01 (0.97–1.04)
Hours driving per month	30 (15–60)	45 (15–70)	1.00 (0.99–1.00)
Monthly driving distance (1000 Km)	0.500 (0.210–1.200)	0.600 (0.147–1.300)	1.05 (0.90–1.22)
Previous traffic accident	42 (47.7)	7 (33.3)	0.62 (0.27–1.42)
Previous traffic violation	65 (73.9)	14 (66.6)	0.73 (0.32–1.63)
Previous episodes of hypoglycemia while driving	**44 (50)**	**17 (81)**	**3.40 (1.22–9.43)**
Previous traffic accident due to hypoglycemia	3 (3.4)	2 (9.5)	2.73 (0.94–7.90)
RADD features			
RADD score	0.086 (0.066–0.141)	0.113 (0.077–0.170)	5.28 (0.44–63.03)
Risk for driving mishaps according to RADD score			
High	5 (5.7)	2 (9.5)	1.50 (0.43–5.22)
Previous traffic accident, violation, assistance and severe hypoglycemia (Questions 1–4)	0.63 ± 1.09	1.52 ± 1.77	**1.38 (1.12–1.70)**
Assistance for driving due to hypoglycemia (Question 3)	0.05 ± 0.25	0.62 ± 1.11	**1.79 (1.46–2.18)**
Hypoglycemia in the past 6 months (Question 7)	1.84 ± 0.62	2.10 ± 0.70	1.59 (0.96–2.65)

Categorical variables are presented as frequencies and percentages; Continuous variables are presented as mean and standard deviation (mean ± SD); Non-parametric variables are presented as median and interquartile range (25 and 75 percentiles). NPH, Neutral Protamine Hagedorn; HbA1c, glycated hemoglobin; SMBG, Self-Monitoring of Blood Glucose; SCI-R, Self-Care Inventory-Revised questionnaire; DSMP, Diabetes Self-Management Profile questionnaire; RADD, Risk Assessment of Diabetic Drivers.

Table 3 – Predictor for driving mishaps independently of hypoglycemia.

Table 3. Demographic, clinical, driving characteristics of cohort participants according to the presence of driving mishaps during follow-up, independently of hypoglycemia

Variable	Did not have driving mishaps (N = 32)	Have driving mishaps (N = 77)	Relative Risk (RR) ans 95% confidence interval
Demographic features			
Gender			
Women	11 (3.4)	26 (33.8)	0.99 (0.76–1.28)
Age (years)	38.2 ± 11.1	37 ± 11	0.99 (0.98–1.00)
Occupation			
Driver	0	2 (2.6)	
Not related to driving	32 (100)	75 (97.4)	**0.70 (0.61–0.79)**
Diabetes features			
Duration of diabetes (years)	17.5 (13.0–25.0)	19.0 (11.0–28.0)	1.00 (0.98–1.01)
Type of basal insuline in use			
None (insulin pump)		1 (1.3)	
NPH	11 (34.3)	20 (26)	
Long acting analogue	21 (65.7)	56 (72.7)	1.12 (0.84–1.51)
Type of bolus insulin in use			
Regular	3 (9.4)	4 (5.2)	
Ultra-rapid acting analogue	29 (90.6)	73 (9.5)	1.25 (0.65–2.40)
HbA1c (%)	8 ± 1.3	8.2 ± 1.6	1.02 (0.95–1.09)
Frequency of SMBG (times/day)	3.0 (3.0–4.7)	3.0 (3.0–4.0)	0.96 (0.91–1.02)
Neuropathy	1 (3.1)	6 (7.8)	1.23 (0.88–1.71)
Retinopathy	9 (28.1)	27 (35)	1.09 (0.85–1.39)
SCI-R (points)	**52.7 ± 5.6**	**50.2 ± 6,2**	**0.97 (0.96–0.99)**
DSMP (points)	44.8 ± 8.9	46.3 ± 9.8	1.00 (0.99–1.01)
Clarke Scale			
Hypoglycemia unawareness	8 (25)	26 (33.8)	1.09 (0.86–1.39)
Driving features			
Duration of driver's license (years)	14.5 (9.0–23.7)	15.0 (8.0–22.5)	0.99 (0.98–1.01)
Hours driving per month	20 (12–60)	30 (15–60)	1.00 (0.99–1.00)
Monthly driving distance (1000 Km)	0.600 (0.176–1.095)	0.500 (0.220–1.500)	**1.03 (1.01–1.06)**
Previous traffic accident	13 (40.6)	36 (46.8)	1.09 (0.86–1.39)
Previous traffic violation	24 (75)	55 (71.4)	0.91 (0.71–1.18)
Previous episodes of hypoglycemia while driving	16 (50)	45 (58.4	1.12 (0.87–1.44)
Previous traffic accident due to hypoglycemia	**1 (3.1)**	**4 (5.2)**	**1.42 (1.25–1.61)**
RADD score	0.083 (0.062–0.120)	0.103 (0.066–0.150)	1.67 (0.70–3.98)
Risk for driving mishaps according to RADD score			
High	2 (6.3)	5 (6.5)	1.04 (0.64–1.70)

Categorical variables are presented as frequencies and percentages; Continuous variables are presented as mean and standard deviation (mean ± SD); Non-parametric variables are presented as median and interquartile range (25 and 75 percentiles); NPH, Neutral Protamine Hagedorn; HbA1c, glycated hemoglobin; SMBG, Self-Monitoring of Blood Glucose; SCI-R, Self-Care Inventory-Revised questionnaire; DSMP, Diabetes Self-Management Profile questionnaire; RADD, Risk Assessment of Diabetic Drivers.

Appendix B. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2021.108954.

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