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# Hypoglycemia While Driving in Insulin-Treated Patients: Incidence and Risk Factors

AQ1 *Laura Lohan, PharmD,\*† Florian Clément, PharmD,\* Claire Duflos, MD, PhD,‡ Maxime Villiet, PharmD,\* Audrey Castet-Nicolas, PharmD, PhD,\*§ Catherine Boegner, MD,|| Antoine Avignon, MD, PhD,†|| Ariane Sultan, MD, PhD,†|| and Cyril Breuker, PharmD, PhD\*†*

**Objectives:** This study aimed to investigate a potential daily-life concern for patients with diabetes hypoglycemia while driving by (1) estimating their incidence in insulin-treated drivers, (2) determining factors associated with their occurrence, and (3) analyzing patients' behavior regarding prevention of hypoglycemia.

**Methods:** We conducted an observational study from November 2013 to May 2018 in the endocrinology-diabetology-nutrition department of our university hospital. All patients treated for diabetes older than 18 years admitted in the department were eligible. A specific questionnaire assessing attitudes, knowledge, and consequences of hypoglycemia was provided. In this study, only insulin-treated patients who regularly drive were analyzed.

**Results:** On the 233 insulin-treated drivers included, 45 (19%) self-reported at least 1 hypoglycemia while driving in the preceding year. Two factors were significantly associated with their occurrence: type 1 diabetes (odds ratio [OR] = 3.19; 95% confidence interval [CI] = 1.55–6.57) and experiences of asymptomatic hypoglycemia (OR = 2.20; 95% CI = 1.05–4.63). Awareness of the treatment hypoglycemia risk because of information provided by a medical specialist was also but nonsignificantly associated with hypoglycemia while driving (OR = 2.61; 95% CI = 0.86–7.92). Forty-one patients (18%) combined those 3 variables, 20 (49%) of them self-reported hypoglycemia while driving. Thirty-four percent of the patients never carried carbohydrates for hypoglycemia correction. Seventy-six percent do not monitor blood glucose level before driving.

**Conclusions:** Our questionnaire allowed us to highlight that 19% of our cohort of insulin-treated drivers declared experiencing hypoglycemia while driving. Risk factors identified and prevention data collected should help us better target patient education.

**Key Words:** diabetes care, hypoglycemia, driving, healthcare professional, therapeutic education

Glucose-lowering therapy can provoke hypoglycemia, notably in patients treated with sulfonylureas and/or insulin. The acute and long-term effects can be serious and include confusion, loss of consciousness, seizures, cognitive impairment, mood change, and even death.<sup>1,2</sup> Hypoglycemia also has social and psychological implications and thus may alter the quality of life.<sup>2</sup> One

of the common activities that is negatively affected by hypoglycemia is driving. This phenomenon has been mainly studied in type 1 diabetes patients. Safe driving is dependent on many functions that can be impaired by hypoglycemia,<sup>3–5</sup> and impaired driving performance and safety have been observed during hypoglycemic states in driving simulator studies.<sup>6,7</sup> Moreover, driving itself seems to be associated with significant metabolic demand that could lead to a drop in the glucose level.<sup>8</sup> This observation was partly confirmed in a real-life study using a continuous glucose monitoring system.<sup>9</sup> In addition, microvascular (notably retinopathy or neuropathy) and macrovascular complications of diabetes can interfere with driving.<sup>10,11</sup>

Therefore, there is a debate about whether diabetes is a relevant factor in determining driver ability.<sup>12</sup> However, the consequences in terms of road traffic accidents are still controversial, and 2 meta-analyses concluded that drivers with diabetes present only a slightly increased safety risk, often nonsignificant.<sup>13,14</sup> To properly consider, assess, and reduce this potential risk, the American Diabetes Association published a position statement on diabetes and driving that highlights the importance of individual risk assessment.<sup>12</sup> Indeed, attention must be focused on diabetic patients presenting a higher risk. As hypoglycemia while driving has been pointed out as a risk factor of motor vehicle collisions in diabetic patients,<sup>15</sup> identifying the risk factors would help individualize the assessment of patients for safe driving.

Therefore, the objective of this present study was to (1) estimate the incidence of hypoglycemia while driving in insulin-treated drivers, (2) determine the factors associated with hypoglycemia while driving, and (3) analyze patients' behavior regarding the prevention of hypoglycemia.

## METHODS

### Study Design and Participants

From November 2013 to May 2018, we conducted an observational study in the Nutrition-Diabetes Unit of the University Hospital of Montpellier, France. All patients older than 18 years treated for type 1 or 2 diabetes were eligible. Within 24 hours of admission to the unit, most were for uncontrolled glycemia or complications of diabetes. The questionnaire was adapted from the study by Seaquist et al<sup>1</sup> and contained specific questions to identify insulin-treated drivers and their experiences of hypoglycemia while driving in the past year (blood glucose [BG] level = <70 mg/dL). It assesses several hypoglycemia-related aspects, such as frequency, knowledge, perception, management, or repercussions of hypoglycemia at the time of admission, except for experiment of hypoglycemia while driving (in the past year) and severe hypoglycemia (in the past year). All patients who accepted to complete the form were prospectively included. Our study followed the World Medical Association's Declaration of Helsinki and received approval from the Commission Nationale de l'Informatique et des Libertés (CNIL, N° Q-2016-0903).

From the \*Clinical Pharmacy Department, CHU Montpellier, University Montpellier; †PhyMedExp, Univ Montpellier, CNRS, INSERM; ‡Clinical Research and Epidemiology Unit, CHU Montpellier, University Montpellier; §IRCM – INSERM U1194, University Montpellier; and ||Endocrinology-Diabetology-Nutrition Department, CHU Montpellier, University Montpellier, Montpellier, France.

Correspondence: Cyril Breuker, PharmD, PhD, Clinical Pharmacy Department, Hôpital Lapeyronie, 371 avenue du doyen Gaston Giraud 34295 Montpellier, France (e-mail: c-breuker@chu-montpellier.fr).

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A.S. and C.B. contributed equally to this work.

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## Data Collection

In addition to the self-reported data provided by the questionnaire, demographic, clinical, therapeutic, and biological data were prospectively collected from the medical records: age, sex, type and duration of diabetes, body mass index, HbA1c, and antidiabetic treatment. All data were anonymized and then incorporated into an Excel database.

## Statistical Analysis

Statistical analysis was performed only on the insulin-treated driving population (Fig. 1). Patient characteristics and questionnaire responses were expressed as frequency and proportion for categorical variables and mean  $\pm$  standard deviation for continuous variables. For comparative purposes, results are presented for all insulin-treated drivers and then for those who had experienced hypoglycemia while driving (HD group) or not (NHD group).

Comparisons were made with Student *t* test or the Mann-Whitney *U* test for continuous variables, and with  $\chi^2$  or Fisher exact test for categorical variables, depending on the distribution of variables and conditions for applying the tests.

Multivariable logistic regression analysis was performed to identify the factors that might increase the risk of becoming hypoglycemic while driving. The variables included were those with a raw *P* value of less than 0.20 after multiple imputation of missing data. Then, a parsimonious model was selected using backward selection of variables, with a *P* value to stay set at 0.10.

Statistical analyses were performed at the conventional 2-tailed  $\alpha$  level of 0.05 using SAS Version 9.4 (SAS Institute, Cary, NC).

## RESULTS

### Study Population

Four hundred seventy-four subjects were included in our whole cohort (63.5% men, mean age =  $68.5 \pm 14.8$  y). Three hundred

seventy-four (79%) were treated with insulin, and 233 (62%) of these were regular drivers. Therefore, the study population consisted in 233 drivers with insulin-treated diabetes (Fig. 1).

### Patient Characteristics

Baseline demographic and clinical characteristics are presented in Table 1. The mean age was  $57.8 \pm 13.9$  years and 30% were female, with mainly type 2 diabetes (67.8%). The mean diabetes duration was 17.8 years and the mean HbA1c was 8.8%. Forty-five patients (19%) reported experiencing at least 1 episode of hypoglycemia while driving. As shown in Table 1, the patients who experienced hypoglycemia while driving were younger (50.2 years versus 59.6 y) and had lower body mass index (BMI, 27.1 versus 29.7 kg/m<sup>2</sup>) than patients who did not. Type 1 diabetes was predominant in the HD group (60%), as the incidence of hypoglycemia while driving was 36% versus 11.4% in type 2 diabetes. Characteristics of patient according to diabetes type are presented in Supplementary Table 1, <http://links.lww.com/JPS/A337>.

### History, Perception, and Prevention of Hypoglycemia

Self-reported data on history, perception of hypoglycemia, and prevention are summarized in Table 2. One hundred patients (54.4%) reported having currently at least 1 episode of hypoglycemia per week. Episodes were more frequently reported in the HD group than the NHD group (78.4% versus 48.3%). The frequency of hypoglycemia was also very different between type 1 and type 2 diabetic patients. Whereas 61.6% of the type 2 diabetic patients reported no hypoglycemia on a weekly basis, only 11.9% of the type 1 patients reported so. Conversely, 27.1% of the type 1 diabetic drivers reported at least 4 episodes per week, whereas only 0.8% of the type 2 diabetic drivers reported this.

Severe hypoglycemia in the preceding year was reported by 22.6% of the participants. The incidence was higher in the HD group (38.6%) than in the NHD group (18.7%). Regarding

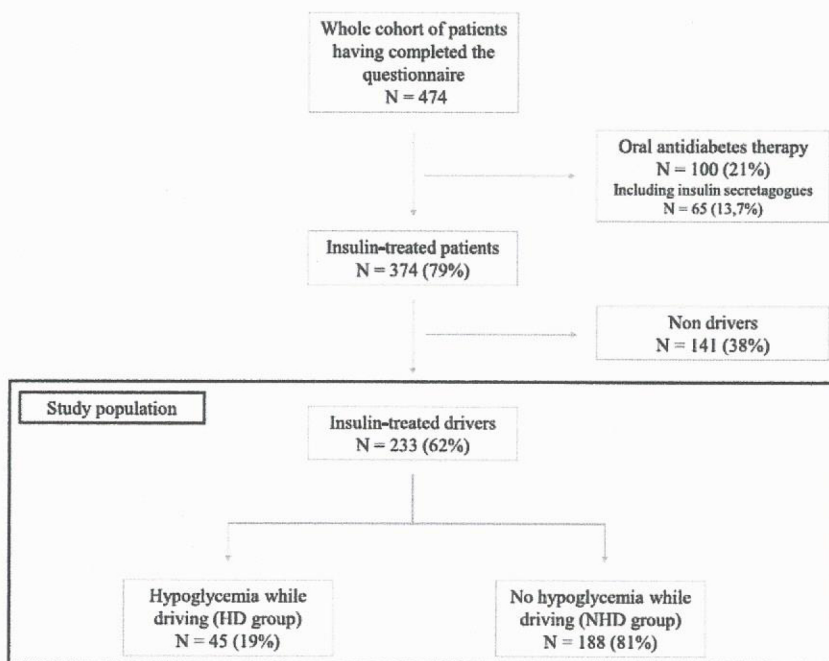


FIGURE 1. Flowchart of the study population.

**TABLE 1. Characteristics of Patients**

	Insulin-Treated Drivers (n = 233)	NHD Group (n = 188)	HD Group (n = 45)	P
Demographic variables				
Age, y (n = 233)	57.8 (13.9)	59.6 (12.6)	50.2 (16.3)	<0.0001
Sex, female (n = 233)	70 (30.0%)	53 (28.2%)	17 (37.8%)	0.21
BMI, kg/m <sup>2</sup> (n = 233)	29.0 (5.9)	29.5 (5.9)	26.9 (5.9)	0.01
Clinical variables				
Type of diabetes, type 2 (n = 233)	158 (67.8%)	140 (74.5%)	18 (40.0%)	<0.0001
Diabetes duration, y (n = 233)	17.8 (10.5)	17.8 (10.8)	17.8 (9.8)	0.94
HbA1c, % (n = 220)	8.8 (1.9)	8.9 (2.0)	8.7 (1.8)	0.49

Data are presented as mean (standard deviation) or n (%).

asymptomatic hypoglycemia, 109 participants (47.2%) were concerned, 50 of whom were type 1 diabetes patients (45.9%). There was an association between asymptomatic hypoglycemia and hypoglycemia, as asymptomatic hypoglycemia occurred in 31.3% of the patients who reported no weekly hypoglycemia, 60.2% of those reporting 1 to 3 weekly hypoglycemia episodes, 80% of those reporting 4 to 6 weekly episodes, and 100% of those reporting more than 6 weekly episodes. Almost 70% of the HD group experienced asymptomatic hypoglycemia versus 41.9% in the NHD group. In the HD group, 68.9% of these patients reported that their asymptomatic hypoglycemia occurred more than once a week and 31% reported daily experiences.

The risk of hypoglycemia was a real concern for the participants, as almost half of them (49.5%) admitted being worried about it every day. This proportion was even higher in the patients

with a history of hypoglycemia while driving (68.2%). For 42.9% of them, this concern led to activity restrictions.

Although 90% of the participants knew the risk of hypoglycemia associated with their treatment, only a small proportion took appropriate measures in cases of physical activity or skipped meals, respectively, 54.3% and 45.5%. No significant difference was observed between the HD and NHD groups on these points, with only a trend for greater adjustment of diabetes management in cases of physical activity in the HD group. One hundred subjects (44.2%) reported always carrying carbohydrates with them, more in the HD group (62.2%) than the NHD group (39.8%). Last, regarding BG monitoring, although 77.7% indicated always or frequently testing it before sugar intake, only 23.9% did so before driving. Furthermore, 58.1% never monitored BG before driving: 31% in the HD group and 64.8% in the NHD group.

**TABLE 2. Patient Self-Reporting About History, Perception, and Prevention of Hypoglycemia**

	Insulin-Treated Drivers (n = 233)	NHD Group (n = 188)	HD Group (n = 45)	P
Episodes of hypoglycemia per week at the time of admission (n = 184)				
None	84 (45.7%)	76 (51.7%)	8 (21.6%)	0.0008
1-3	83 (45.1%)	62 (42.2%)	21 (56.8%)	
4-6	15 (8.2%)	8 (5.4%)	7 (18.9%)	
>6	2 (1.1%)	1 (0.7%)	1 (2.7%)	
Episodes of severe hypoglycemia in the past year (n = 226)				
No	175 (77.4%)	148 (81.3%)	27 (61.4%)	0.005
Yes	51 (22.6%)	34 (18.7%)	17 (38.6%)	
Episodes of asymptomatic hypoglycemia (n = 231)				
No	122 (52.8%)	108 (58.1%)	14 (31.1%)	0.001
Yes	109 (47.2%)	78 (41.9%)	31 (68.9%)	
Daily concern about the risk of hypoglycemia (n = 220)				
No	111 (50.5%)	97 (55.1%)	14 (31.8%)	0.006
Yes	109 (49.5%)	79 (44.9%)	30 (68.2%)	
Modification of diabetes management				
In cases of physical activity (n = 231)				
No	101 (45.7%)	87 (48.9%)	14 (32.6%)	0.054
Yes	120 (54.3%)	91 (51.1%)	29 (67.4%)	
In cases of skipped or inadequate meal (n = 167)				
No or rarely	91 (54.5%)	76 (55.5%)	15 (50.0%)	0.59
Always or frequently	76 (45.5%)	61 (44.5%)	15 (50.0%)	

Data are presented as n (%).

MD, missing data.

**TABLE 3.** Patient Self-Reporting on Information About the Risk of Hypoglycemia Provided by Healthcare Providers

	Insulin-Treated Drivers (n = 233)	NHD Group (n = 188)	HD Group (n = 45)	P
Medical specialist (n = 196)				0.004
No	58 (29.6%)	54 (34.2%)	4 (10.5%)	
Yes	138 (70.4%)	104 (65.8%)	34 (89.5%)	
General practitioner (n = 198)		0.34		
No	83 (41.9%)	64 (40.3%)	19 (48.7%)	
Yes	115 (58.1%)	95 (59.7%)	20 (51.3%)	
Nurse (n = 122)		0.12		
No	84 (68.9%)	70 (72.2%)	14 (56.0%)	
Yes	38 (31.1%)	27 (27.8%)	11 (44.0%)	
Pharmacist (n = 174)				0.52
No	137 (78.7%)	107 (79.9%)	30 (75.0%)	
Yes	37 (21.3%)	27 (20.1%)	10 (25.0%)	

Data are presented as n (%).  
MD, missing data.

### The Role of Healthcare Providers in Raising Awareness About Hypoglycemia Risk

Patients were also asked which healthcare providers had made them aware of the risk of hypoglycemia (Table 3). Endocrinologists, general practitioners, nurses, and pharmacists gave information in, respectively, 70.4%, 58.1%, 31.1%, and 21.3% of the cases. Participants who experienced hypoglycemia while driving had been more often informed by endocrinologists (89.5% versus 65.8%) and nurses (44.0% versus 27.8%).

### Multivariate Analyses

Ten items emerged as potential variables to be added in the model. One of them was considered to have too much missing data: information about the risk of hypoglycemia provided by a nurse (111 [47%] missing data items). The 9 remaining variables were kept for further analysis. These variables were as follows: age (<65 y versus ≥65 y), BMI, diabetes type, hypoglycemia episodes per week (never versus sometimes) or severe hypoglycemia in the past year, experience of hypoglycemia without symptoms, daily concern about the risk of hypoglycemia, adaptation of diabetes treatment during physical activity, and hypoglycemia information provided by a medical specialist.

In the multivariate model, the 2 variables significantly associated with hypoglycemia risk while driving were type 1 diabetes and asymptomatic hypoglycemia. Information about the hypoglycemia risk provided by medical specialists was weakly associated with hypoglycemia risk while driving (Table 4).

### Population at High Risk for Hypoglycemia While Driving

Forty-one patients (17.6%) combined the 3 variables presented in Table 4 (HR group). The incidence of declared hypoglycemia while driving was 48.8% in this high-risk population.

Daily worry about hypoglycemia risk was reported by 73.2% of these patients, and 85% prevented hypoglycemia by taking measures before physical activities, 68.8% before skipping meals, and 68.3% always carried carbohydrates for hypoglycemia correction. Before driving, 41.7% monitored BG frequently or always and 33% never.

### DISCUSSION

This observational study assessed the incidence and risk factors of hypoglycemia while driving in regular drivers who were insulin treated. We found that 19% of our patients had experienced hypoglycemia while driving and were able to identify 2 risk factors significantly associated with its occurrence: type 1 diabetes and experiences of asymptomatic hypoglycemia. Another variable emerged as worthwhile to consider: awareness of the hypoglycemia risk due to treatment because of information provided by a medical specialist. We also investigated management and prevention of hypoglycemia in the insulin-treated drivers with a focus on the high-risk population. Results showed that some aspects need to be improved, particularly the recommendations on BG monitoring before driving.

We found that a nonnegligible proportion of insulin-treated drivers reported an episode of hypoglycemia behind the wheel

**TABLE 4.** Risk Factors of Hypoglycemia While Driving in Drivers With Insulin-Treated Diabetes

	Univariate Logistic Regressions		Multivariate Logistic Regression	
	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P
Type of diabetes (type 1 versus type 2)	4.37 (2.21–8.64)	<0.0001	3.19 (1.55–6.57)	0.002
Experience of hypoglycemia without symptoms (yes versus no)	3.07 (1.53–6.14)	0.0012	2.20 (1.05–4.63)	0.037
Hypoglycemia information from medical specialist (yes versus no)	4.41 (1.49–13.10)	0.041	2.61 (0.86–7.92)	0.091

CI, confidence interval; OR, odds ratio.

in the past year and it may even have been underestimated if self-reported hypoglycemic events were omitted because of fears of losing one's driver's license, as already described.<sup>16</sup> The rates reported in the literature vary widely from 13.4 to 66% in questionnaire-based survey including both type 1 and type 2 diabetic patients.<sup>15,17-19</sup> This broad range reflects firstly differences in populations in mean age,<sup>17,19</sup> proportion of,<sup>15,19</sup> proportion of patient with type 1 diabetes,<sup>15,18</sup> and sample size.<sup>15,18</sup> Secondly, temporality of reported hypoglycemia while driving is not always specified, and when restricted to episodes in the previous year, the incidence decreased.<sup>17-19</sup> The study to which we can best compare ourselves is that of Graveling et al<sup>17</sup> who found comparable results with ours (13.4%).

Regarding the factors associated with hypoglycemia while driving, we highlight that participants with a type 1 diabetes were at very high risk of hypoglycemia while driving. This was already demonstrated in others studies.<sup>17,18,20,21</sup> The incidence was 36% in our study, in the range of the published data<sup>17,21-24</sup> except for a New Zealander survey presenting a higher proportion (82%).<sup>18</sup> This higher risk in type 1 diabetic patients may be related to their more frequent experience of hypoglycemia, independently of driving,<sup>17,25-27</sup> and to their tendency to impaired hypoglycemia perception,<sup>2,28</sup> as we found. Indeed, we described that the experience of asymptomatic hypoglycemia was the second risk factor of hypoglycemia while driving. Unawareness of hypoglycemia is indeed considered an important risk for drivers with diabetes,<sup>11</sup> however, discussed for car collision.<sup>1</sup> A possible reason for these discordant results might be that the definition and assessment of an impaired awareness of hypoglycemia are not consensual.<sup>16</sup> This phenomenon seems to be associated with repeated exposure to hypoglycemia, partly by modifying the counter-regulation response to a BG decrease.<sup>1,2,29</sup> This implies that the impaired awareness of hypoglycemia might be associated with the notion of recurrent hypoglycemia, which was observed in our study. In addition, it should be noted that the last report from the ADA - Endocrine Society workgroup on hypoglycemia and diabetes pointed out that patients with a history of recurrent hypoglycemia or impaired awareness of hypoglycemia were in special need of education to prevent hypoglycemia.<sup>1</sup>

Patient education should include counseling about hypoglycemia and safe driving, which is not always the case, as 50% to 75% of survey participants stated never having discussed this issue with their healthcare providers.<sup>15,21</sup> However, we found that hypoglycemia education by endocrinologists was more frequent for the participants experiencing hypoglycemia. On the other hand, some data suggest that not all healthcare professionals are aware of current statutory requirements and recommendations to provide to their patients.<sup>30-32</sup> This is a key point that needs to be addressed to improve patient knowledge and application of hypoglycemia prevention measures and safe-driving practices.

Most patients with diabetes seem to rely on the symptoms that they feel to detect hypoglycemia,<sup>17,30</sup> whereas symptom perception is not a reliable estimation of BG levels.<sup>10</sup> The decision to drive has to be based on an objective measurement of the BG level. However, monitoring of the BG level before driving is not systematic, as 40% to 75% of participants reported that they never test it in this situation or do so only if they feel hypoglycemic,<sup>15,17,18,30</sup> which is in accordance with our results. Our study was conducted whereas interstitial blood measurement was not really widespread. It would be interesting to evaluate how this technology may change attitudes.<sup>33</sup> Furthermore, less than half of the participants reported always carrying appropriate snacks for hypoglycemia correction, versus a wide range of 30.3% to 87.6% in the literature.<sup>15,17,18,24,30</sup> This message should nevertheless be reinforced as it is a recommendation usually made with regard to road safety and diabetes.<sup>11,12</sup>

Good practices for hypoglycemia prevention and safe driving are inconsistently followed by diabetic drivers. Although this observation is disconcerting, it is encouraging to note that the practices of high-risk patients are more appropriate. Indeed, far fewer participants reported never measuring BG before driving in the HD group compared with the NHD group and in the HR group compared with all insulin-treated drivers. This observation also applied to the proportion of patients who reported always carrying a source of carbohydrates with them. The better attitudes of at-risk patients have been mentioned in the literature by Graveling et al,<sup>17</sup> who showed that diabetic drivers presenting impaired awareness of hypoglycemia reported no monitoring of their BG level less frequently than other patients. This observation can be partly explained by the greater concerns and worries about the consequences of hypoglycemia that at-risk patients may feel in their daily life.

Some limitations of our study should be noted. This was a monocentric study that enrolled a modest number of participants, although this number was sufficient to detect significant differences. In addition, the transversal design did not enable us to analyze the temporality of data. We focused on declarative data using a questionnaire, which implies inherent limitations like missing values and question interpretation issues. Moreover, we must acknowledge some of the limitations of the questionnaire itself, as it did not collect data on why some patients do not drive, on patients driving behavior, how long have they been driving, or on motor vehicle incidents. Further study with greater detail on the timing and content of the educational information provided by healthcare professionals about hypoglycemia risk would also undoubtedly reveal interesting data. Last, our study recruited hospitalized patients with insulin treatment. This suggests that these patients may have had more complicated diabetes or greater difficulty in managing their diabetes. Therefore, we cannot extrapolate our results to all diabetic patients.

## CONCLUSIONS

With a questionnaire that can be used by a variety of professionals in a wide range of institutions, we found that 19% of our sample of insulin-treated drivers declared experiencing hypoglycemia while driving and identified 2 risk factors of this occurrence: type 1 diabetes and asymptomatic hypoglycemia. It is important to be aware that not all subjects with diabetes do present the same risk regarding driving, which is supported by our results. This tool can help individually assess diabetic patients to detect more efficiently those who are most at risk and better target patient education, in our case notably by reinforcing messages about monitoring the BG level.

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