The Decision Not to Drive During Hypoglycemia in Patients With Type 1 and Type 2 Diabetes According to Hypoglycemia Awareness

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OBJECTIVE — In recent years, there has been an ongoing discussion on the relationship between diabetes and driving. As driving performance will inevitably decline at lower levels of glycemia, patients' decisions concerning driving or taking corrective action when hypoglycemia occurs immediately before or during driving seems paramount.

RESEARCH DESIGN AND METHODS — Twenty-four type 1 diabetic patients with normal awareness of hypoglycemia (T1Norm group), 21 type 1 diabetic patients with impaired awareness of hypoglycemia (T1Imp group), and 20 type 2 diabetic patients with normal awareness of hypoglycemia (T2 group) were studied. They were asked whether they felt hypoglycemic and whether they would currently drive during experimental euglycemia (5.0 mmol/l) and hypoglycemia (2.7 mmol/l).

RESULTS — In the T1Norm group, 1 patient (4.2%) decided to drive during hypoglycemia. In the T1Imp group, 9 patients (42.9%) said they would drive in the hypoglycemic condition. In the T2 group, 5 patients (25%) would drive. This was more frequently the case for patients on oral hypoglycemic agents ($\chi^2 = 4.44$; $P = 0.04$). No effect of sex ($\chi^2 = 0.78$; $P = 0.38$) or age ($\chi^2 = 0.22$; $P = 0.64$) was noted.

CONCLUSIONS — Patients with type 1 diabetes and impaired awareness of hypoglycemia frequently decided to drive while hypoglycemic, whereas patients with type 1 diabetes and normal awareness of hypoglycemia appeared to make safe decisions concerning hypoglycemia and driving. Strikingly, patients with type 2 diabetes and normal hypoglycemia awareness frequently made potentially dangerous decisions as well, particularly when using oral hypoglycemic agents. Therefore, early, clear, and consistent education is imperative.

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In recent years, there has been an ongoing discussion on the relationship between diabetes and driving, since (severe) hypoglycemia may impair driving performance and thus traffic violations and accidents may occur (1). Indeed, Cox and colleagues (2,3) have shown disrupted driving performance even at glycemic levels of 4.0–3.4 mmol/l. As driving performance will inevitably decline at low levels of glycemia, patients' decisions concerning driving or taking corrective action when hypoglycemia occurs immediately before or during driving seem paramount. The decision to drive may be complicated by the fact that hypoglycemia induces cognitive dysfunction; therefore, decision making may be impaired (4–6).

In previous studies in type 1 diabetic patients under experimental hypoglycemic conditions, only 22% of patients in a driving simulator pulled over or undertook corrective action while driving at 2.2 mmol/l (3). During hypoglycemia (2.8 mmol/l), 22–38% of the patients judged that they could drive safely (7). This perception was more frequent among older patients and female subjects. However, in another study (8), corrective action was only associated with normal awareness of hypoglycemia and not with age, sex, duration of disease, or other disease-related factors. In their natural environment, using hand-held computers, ~40% of patients with type 1 diabetes said they would drive when they estimated their own blood glucose at 3.9–3.3 mmol/l or even at <2.2 mmol/l. With an actual blood glucose <2.2 mmol/l, 38–47% decided to drive (9). No distinction was made according to awareness of hypoglycemia. In the only study involving type 2 diabetic patients, 89% of insulin-using (type 1 and type 2 diabetic) patients answered to a survey that they would stop when experiencing hypoglycemia during driving. However, 60% reported never testing blood glucose before driving or only when experiencing symptoms of hypoglycemia. Twenty-five percent indicated that they considered blood glucose values <4.0 mmol/l safe for driving (10). In the current study, we aimed to assess the decision to drive during moderate hypoglycemia (2.7 mmol/l) in controlled experimental conditions, objectively verifying hypoglycemia awareness in type 1 and type 2 diabetic patients.

RESEARCH DESIGN AND METHODS

— All subjects were adults between the ages of 20 and 65 years who participated in a larger study on the effect of hypoglycemia on driving performance in a state-of-the-art driving simulator. Patients were recruited from the outpatient clinic of the University Medical Center Utrecht, Utrecht, the Netherlands. Eligibility criteria included at least 2 years of

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A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

diabetes, absence of cardiovascular disease or neuropathy, visual acuity >16/20 in both eyes, possession of a driver's license for at least 2 years, and at least 8,000 km driven in the past year. No subject could use medication that would influence hypoglycemia counterregulation or the ability to drive. The study was approved by the institutional review board of the University Medical Center Utrecht, and all subjects gave written informed consent.

Patients were withdrawn from long- and intermediate-acting insulin for 24 h before the study and were managed with short-acting insulin. They completed a validated questionnaire on hypoglycemia awareness (11). Subjects arrived at the TNO Human Factors Research Institute at 8:00 P.M. on the evening before the study. Two antecubital veins were cannulated. No caffeinated beverages were consumed after arrival. Subjects were given a bedtime snack at 11:00 P.M. and remained fasting from bedtime until the end of the study. Nocturnal near-normoglycemia was maintained using a variable, low-dose insulin infusion (12). In the morning, a hyperinsulinemic glucose clamp was started. Via one cannula, insulin (human actrapid in a 4% solution of the subject's own plasma in 0.9% saline; Novo Nordisk, Gentofte, Denmark) was infused at 2.0 mU · kg^{-1} · min^{-1} (IVAC P2000; IVAC, San Diego, CA) and dextrose 20% (IVAC 560; IVAC) at a variable rate. Via the other cannula, arterialized venous blood samples were obtained every 5 min, using a heating sleeve to warm the arm to 55°C. The cannula was kept patent with 0.9% saline. Plasma glucose was measured using a glucose oxidase method (YSI 2300 STAT; Yellow Springs Instruments, Yellow Springs, OH). Subjects were blinded for their plasma glucose level during the experiment.

Subjects completed two sessions of three runs in the driving simulator, each run lasting a minimum of 8 min. The first driving session was driven with a constant plasma glucose concentration of 5.0 mmol/l. Subsequently, plasma glucose was lowered to a constant plasma glucose concentration of 2.7 mmol/l. Upon achieving this plasma glucose concentration, but after at least 60 min, the second driving session was performed. At baseline and immediately before each driving session, blood was drawn to measure epinephrine levels (high-performance liquid chromatography assay; Chromesystems, Munich, Germany). Also, before each driving session, two questions were posed: *1*) "Do you currently feel hypoglycemic?" with possible answers being "yes," "no," or "maybe" or 2) "Would you currently drive in everyday life?" with possible answers being "yes," "maybe," "no," or "I would first measure my blood glucose." Subsequently, a semiquantitative questionnaire was administered to assess hypoglycemic symptoms. Subjects rated each of the following hypoglycemic symptoms from 0 (none) to 6 (severe): palpitations, anxiety, tremor, sweating, cold hands, numb lips, and dry mouth (autonomic symptoms); difficulty concentrating, blurred vision, impaired speech, and confusion (neuroglycopenic symptoms); and difficulty breathing, painful legs, and seeing yellow halos (dummy symptoms).

Statistical analysis

Assessment of hypoglycemia awareness. Before data analysis, it was established for each patient whether there was a significant rise in epinephrine levels or symptom scores during hypoglycemia compared with euglycemia, defined as exceeding the 95% confidence limit observed during euglycemia, as previously described (13). Patients were identified as having normal awareness of hypoglycemia if there was a significant rise in both parameters. In addition, subjects were rated as hypoglycemia aware or unaware according to Clarke's questionnaire and according to the single question, "To what extent can you tell by your symptoms that your sugar is low? (never, sometimes, often, always)."

Analysis of the decision to drive. In analyzing the question "Would you currently drive in every day life?" the answers "yes" and "maybe" while plasma glucose was 2.7 mmol/l (second driving session) were considered potentially dangerous, as patients would (possibly) drive in a hypoglycemic state. In this situation, "no" and "I would first measure my blood glucose" were considered safe, assuming that patients would take corrective action upon measuring a hypoglycemic value. To determine whether there was a significant difference in answers to the questions posed between various study groups, χ^2 tests were performed. Other data will be presented as means ± SD, with a two-sided 5% level of significance in Student's *t* tests.

RESULTS

Subjects and hypoglycemia awareness

Forty-five patients with type 1 diabetes and 20 patients with type 2 diabetes were enrolled in the study. Subjects were identified as having normal hypoglycemia awareness based on the combined criteria of both epinephrine levels and symptoms scores. Twenty-four type 1 diabetic patients were identified as having normal hypoglycemia awareness (T1Norm group), and 21 type 1 diabetic patients had impaired hypoglycemia awareness (T1Imp group). All 20 patients with type 2 diabetes had normal hypoglycemia awareness (T2 group); 12 subjects used insulin, and 8 subjects used sulfonylureas. The type 2 diabetic patients were older than the subjects in the other study groups (Table 1).

Euglycemia

Before the first driving session, all study groups were euglycemic (plasma glucose 5.12 ± 0.6 mmol/l).

T1Norm group. When asked whether they felt hypoglycemic, 22 patients in the T1Norm group (91.7%) stated that they did not feel hypoglycemic and 2 (8.3%) answered "maybe." Yet, in response to the question whether they would currently drive in everyday life, seven (29.2%) declared that they would first measure their blood glucose before driving. Only one subject answered "maybe" to the latter question (4.5%).

T1Imp group. Four patients answered "maybe" to the question about feeling hypoglycemic (19%), and eight (38.1%) would first measure their blood glucose before driving, whereas one subject (4.8%) would "maybe" drive.

T2 group. One patient answered that he was "maybe" hypoglycemic (5%), and all others answered "no" (95%). Two patients in this group stated that they would first measure their blood glucose (10%), and three (15%) said that they would not drive in their current condition.

Analysis of the decision to drive. During euglycemia, the decision not to drive (or to measure blood glucose before driving) was not made more frequently by patients in the T1Norm than in the T1Imp group ($\chi^2 = 0.11$; $P = 0.74$) or by patients in the T2 group ($\chi^2 = 0.36$; $P = 0.55$). This was no different for patients using insulin ($\chi^2 = 0.26$; $P = 0.61$) or for patients using oral hypoglycemic agents ($\chi^2 = 0.19$; $P = 0.66$).

Table 1—*Subject characteristics*

	T1Norm group	T1Imp group	T2 group
n (men/women)	24 (17/7)	21 (16/5)	20 (16/4)
Age (years)	35.27 ± 8.0	40.4 ± 10.8	51.6 ± 9.0†
Height (m)	1.78 ± 0.10	1.80 ± 0.08	1.78 ± 0.08
Weight (kg)	84.4 ± 14.3	80.2 ± 8.6	89.4 ± 14.5†
BMI	26.5 ± 4.0	24.9 ± 2.9	28.3 ± 4.0†
Diabetes duration (years)	14.8 ± 8.0	19.5 ± 10.0	8.7 ± 5.3†
A1C (%)	8.17 ± 1.00	7.80 ± 1.14	7.90 ± 1.55
Having a driver's license (years)	15.0 ± 8.7	20.3 ± 10.3	28.6 ± 10.3†
Kilometers per year driven	25,458 ± 28,945	21,450 ± 14,849	23,275 ± 14,135

Data are means ± SD, unless otherwise indicated. †$P < 0.01$ for the comparison with the T1Norm and T1Imp groups.

Hypoglycemia

After the first driving session, hypoglycemia was induced with the hyperinsulinemic clamp (2.68 ± 0.29 mmol/l). The subjects' perception of their glycemic condition during hypoglycemia and their decision to drive are shown in Table 2.

T1Norm group. Fifteen of 24 subjects (62.5%) felt hypoglycemic. None of these subjects stated that they would currently drive, but one (6.7%) stated "maybe" he would drive. Three subjects would measure their blood glucose (20.0%), and 11 (73.3%) would not drive. Nine subjects (37.5%) stated that they were "maybe" hypoglycemic. Eight subjects (88.9%) would first measure their blood glucose, and one (11.1%) would not drive.

T1Imp group. Eight of 21 subjects (38.1%) stated that they possibly were hypoglycemic. Five of eight subjects (62.5%) wanted to measure their blood glucose before driving, and three (37.5%) would not drive. Thirteen patients (61.9%) did not perceive hypoglycemia, nine of whom (69.2%) acknowledged that they would drive in everyday life. Three (23.1%) would measure their blood glucose before driving, and one subject (7.7%) would not drive.

T2 group. Of 20 type 2 diabetic patients (all with normal hypoglycemia awareness), 11 (55.0%) answered that they felt hypoglycemic. Five (45.5%) of these patients would measure their blood glucose, and six (54.5%) would not drive at all. Of nine patients who stated they "maybe" experienced hypoglycemia (45%), three (33.3%) would drive anyway in everyday life and two (22.2%) would "maybe" drive. On the other hand, two subjects would measure blood glucose and two would not drive (22.2%).

Analysis of the decision to drive. The answers "yes" and "maybe" were considered unsafe decisions during hypoglyce-

Table 2—*Perception of glycemic condition during hypoglycemia (2.7 mmol/l) and decision to drive*

Do you feel hypoglycemic?	*n* (%)	Would you currently drive?	*n* (%)
T1Norm group (*n* = 24)			
Yes	15 (62.5)	Drive	0 (0)
		Maybe	1 (6)
		Measure glucose	3 (20)
		Not drive	11 (73)
Maybe	9 (37.5)	Drive	0 (0)
		Maybe	0 (0)
		Measure glucose	8 (89)
		Not drive	1 (11)
No	0 (0.0)	Drive	0 (0)
		Maybe	0 (0)
		Measure glucose	0 (0)
		Not drive	0 (0)
T1Imp group (*n* = 21)			
Yes	0 (0.0)	Drive	0 (0)
		Maybe	0 (0)
		Measure glucose	0 (0)
		Not drive	0 (0)
Maybe	8 (38.1)	Drive	0 (0)
		Maybe	0 (0)
		Measure glucose	5 (63)
		Not drive	3 (38)
No	13 (61.9)	Drive	9 (69)
		Maybe	0 (0)
		Measure glucose	3 (23)
		Not drive	1 (8)
T2 group (n = 20)			
Yes	11 (55.0)	Drive	0 (0)
		Maybe	0 (0)
		Measure glucose	5 (45)
		Not drive	6 (55)
Maybe	9 (45.0)	Drive	3 (33)
		Maybe	2 (22)
		Measure glucose	2 (22)
		Not drive	2 (22)
No	0 (0.0)	Drive	0 (0)
		Maybe	0 (0)
		Measure glucose	0 (0)
		Not drive	0 (0)

mia, whereas the answers "no" and "I would first measure my blood glucose" were considered safe. Unsafe decisions were made more frequently in the T1Imp group than in the T1Norm group (χ^2 = 9.70; P = 0.002). Strikingly, the T2 patients also made unsafe decisions (decided to drive) more frequently during hypoglycemia than T1Norm patients (χ^2 = 4.02; P = 0.04).

There was no difference (χ^2 = 0.06; P = 0.81) when comparing the T2 group to all type 1 diabetic patients. In the T2 group, patients using oral hypoglycemic agents answered that they would make an unsafe decision (drive) during perceived hypoglycemia more frequently than patients using insulin (χ^2 = 4.44; P = 0.04). When comparing T2 patients on oral hypoglycemic agents to all insulin users, the same trend was noted, but it did not reach statistical significance (χ^2 = 3.73; P = 0.054).

Hypoglycemia awareness questionnaire. When hypoglycemia awareness was assessed with Clarke's hypoglycemia awareness questionnaire (11), one subject was rated unaware in the T1Norm group. In the T1Imp group, five subjects who answered "maybe" and five subjects who answered "no" to the question "Do you currently feel hypoglycemic?" were rated as hypoglycemia aware according to Clarke's hypoglycemia awareness questionnaire. All subjects in the T2 group were identified as having normal hypoglycemia awareness with the questionnaire. Thus, with this method, 33 type 1 diabetic subjects were judged to have normal hypoglycemia awareness. Of 33, 4 subjects (12.1%) made an unsafe decision. Of 12 subjects with impaired hypoglycemia awareness, 6 (50%) made an unsafe decision. Subjects with impaired hypoglycemia awareness were more likely to make unsafe decisions than subjects with normal hypoglycemia awareness (χ^2 = 6.01; P = 0.01). Similar results were found when patients with type 2 diabetes were excluded (χ^2 = 7.31; P = 0.007). Analysis of awareness with the single question "To what extent can you tell by your symptoms that your sugar is low? (never, sometimes, often, always)" identified 34 subjects with normal awareness and 11 with impaired awareness, with 11.8 and 54.5% unsafe decisions, respectively (χ^2 = 8.80; P = 0.003).

There was no difference in the decisions made by men and women (χ^2 = 0.78; P = 0.38). Similarly, there was no difference in the decisions made by younger patients (under the mean age) versus older patients (over the mean age) either in all study groups (mean age 41.95 years; χ^2 = 0.54; P = 0.46) or in the T2 group separately (mean age 51.6 years; χ^2 = 0.07; P = 0.79).

CONCLUSIONS — This is the first study to examine the decision to drive in diabetic patients according to objectively assessed hypoglycemia awareness and the first experimental study with type 2 diabetic patients. This study led to two important findings. First, a striking finding is that many type 1 diabetic patients with impaired hypoglycemia awareness (43%) failed to decide not to drive during experimental hypoglycemia. As these patients were not conscious of their hypoglycemic condition, this seems comprehensible. However, these decisions may lead to dangerous situations in traffic. Indeed, data of driving simulator studies of our study group indicate that safe driving is maintained at 2.7 mmol/l in type 1 diabetic patients with normal and impaired hypoglycemia awareness (14) and in type 2 diabetic patients with normal hypoglycemia awareness (15). However, it is of no doubt that driving performance will inevitably deteriorate at lower levels of glycemia. Therefore, the decision not to initiate driving or to take appropriate action during driving (pull over and consume carbohydrates) when diabetic patients are hypoglycemic is of paramount importance. In the current study, only 1 of 24 patients (4.2%) with type 1 diabetes and normal hypoglycemia awareness chose to drive while (symptomatically) hypoglycemic.

Second, the perhaps most alarming finding pertains to type 2 diabetic patients. Despite their normal hypoglycemia awareness, 25% of these patients decided to drive while positive or in doubt whether they were hypoglycemic. This was principally the case for patients on oral hypoglycemic agents. This is particularly worrying because of the large and increasing number of patients with type 2 diabetes. Several factors could play a role. First, as patients with type 2 diabetes experience hypoglycemia less frequently than patients with type 1 diabetes, they could be less familiar with the potential dangers. Second, for this very reason, patients may have received less education from doctors and nurses about hypoglycemia and driving (16). These two possible explanations are supported by the fact that mainly patients on oral hypoglycemic agents make potentially dangerous decisions. Third, by the time patients are diagnosed with type 2 diabetes, they are generally older than type 1 diabetic patients and have driven for several decades. Consequently, their driving behavior has been well established and therefore will be less affected by social pressure and education (17).

There are indications that although potentially dangerous decisions were made, the diabetic subjects in the current study were aware of impending hazards. Although legally regulated in some countries, Dutch law does not require self-testing of blood glucose. Nevertheless, during euglycemia, 25–43% of patients stated that they would not drive without measuring their blood glucose first or maybe not drive at all. However, this study meets certain limitations. It must be borne in mind that subjects were familiar with the fact that this was a study about diabetes and driving and perhaps volunteered out of special attitudes toward driving. Furthermore, in some instances, although they were blinded for their plasma glucose, subjects may have given socially desired answers instead of their true beliefs. Thus, the results in this study may underestimate true percentages of potentially dangerous decisions. Finally, in the analysis the answer "I would first measure my blood glucose" was considered "safe," assuming that patients would take corrective action upon measuring a hypoglycemic value. However, from previous research it is known that patients may consider values far below 4.0 mmol/l as safe to engage in driving (10).

In clinical practice, assessment of hypoglycemia awareness with the use of the hyperinsulinemic glucose clamp technique is rarely possible. However, in this study self-reported impaired hypoglycemia awareness as assessed with Clarke's validated questionniare (11), or even with a single question, showed good correlation with unsafe decisions. However, a higher percentage of patients who were identified as having normal hypoglycemia awareness made unsafe decisions when the questionnaire was used (12.1 vs. 4.2%). Therefore, this method appears to be less accurate at identifying patients at increased risk of making dangerous decisions. Moreover, when patients become familiar with the questions and the potential consequences of their answers, they may adapt their answers accordingly. Nevertheless, the questionnaire may be a

helpful tool in clinical practice to estimate the risk of dangerous decision making.

In conclusion, in the current study, most patients with type 1 diabetes and normal awareness of hypoglycemia appear to make safe decisions concerning hypoglycemia and driving. In contrast, patients with type 1 diabetes and impaired awareness of hypoglycemia frequently decide to drive while hypoglycemic, as may be expected. Strikingly, patients with type 2 diabetes and normal hypoglycemia awareness frequently make potentially dangerous decisions as well, particularly when using oral hypoglycemic agents. This is particularly worrying in light of the increasing number of patients. Therefore, early, clear, and consistent education is imperative.

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