

## Short Communication

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# Impaired Awareness of Hypoglycemia and Driving Mishaps in Patients With Type 1 Diabetes Mellitus: A Multi-Center Survey in Japan

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### ABSTRACT

Impaired Awareness of Hypoglycemia (IAH) is a common and serious problem in adult patients with Type 1 Diabetes Mellitus (T1DM). Driving accidents related to hypoglycemia have been previously described. The aim of this study was to determine the prevalence of driving mishaps and confirm the association between IAH and such mishaps among Japanese patients' with T1DM. Clinical data, such as the prevalence of

hypoglycemia, IAH, and patients' behaviors to avoid driving accidents, were surveyed in 133 adult drivers with T1DM at 16 hospitals and clinics in Japan. A stepwise multiple logistic regression analysis of driving mishaps was performed. Driving mishaps were reported in 54.9% of the patients, and 15.8% reported hypoglycemia-related driving mishaps. A stepwise logistic regression analysis found that the presence of IAH (odds ratio [OR]: 5.36; 95% Confidence Interval [CI]: 1.59-18.10;  $P=0.01$ ) was significantly risk factor for hypoglycemia-related driving mishaps, along with age (OR: 1.07; 95% CI: 1.01-1.13;  $P=0.02$ ). Driving mishaps may be prevalent in Japanese patients with T1DM. IAH should be considered as a high risk factor for driving mishaps in this population.

**KEYWORDS:** Driving mishaps; Hypoglycemia; Diabetes; Insulin; Impaired awareness.

## INTRODUCTION

A driver's license is essential for performing various functions in daily life, including access to medical services, in individuals with Diabetes Mellitus (DM).<sup>1</sup> Traffic accidents are associated with the risk of mortality.<sup>2,3</sup> The number of deaths caused by traffic accidents in Japan was 4,863 in 2010, and the Japanese government has set a goal to reduce the annual fatality count to less than 2,500 by 2018.<sup>4</sup> Several studies have reported that drivers with T1DM have an increased risk of driving accidents, with a relative risk ratio of up to 2,<sup>5,6,7</sup> although another study did not support this.<sup>8</sup>

The association between hypoglycemia and traffic accidents has been discussed regarding patients with DM.<sup>9</sup> Patients with Type 1 DM (T1DM) often have an Impaired Awareness of Hypoglycemia (IAH).<sup>10</sup> Little is known about the relationship between IAH and driving mishaps among drivers with T1DM in Japan, even though the prevalence of patients with T1DM is lower in Japan compared with that in Caucasians.<sup>10</sup> The aim of this study, therefore, was to investigate the prevalence of hypoglycemia-related driving mishaps and confirm the association between IAH and driving mishaps among Japanese patients with T1DM.

## MATERIALS AND METHODS

### ETHICS

The study was approved by the ethical committee of the National Hospital Organization Kyoto Medical Center.

### SUBJECTS

We recruited 133 adult drivers with T1DM at 16 hospitals and clinics located nationwide in Japan. Inclusion criteria were: 1) patients had diagnosed and insulin-treated DM, 2) patients regularly attended the hospitals and clinics surveyed, and 3) patients gave written, informed consent. Exclusion criteria were: 1) children and young patients under 20 years old, and 2)

patients who were unable to answer a self-administrated questionnaire for any reason.

## STUDY MEASURES

The self-administrated questionnaire was distributed and retrieved between April 2006 and October 2010. Patients completed a questionnaire to assess their awareness of hypoglycemia, which was based on their ability to recognize hypoglycemia on the basis of symptoms, defining the answer categories "never", "seldom", and "sometimes" as impaired and "often" and "always" as normal hypoglycemia awareness.<sup>11</sup> Driving mishaps are defined broadly, including collisions, citations, losing control, automatic driving, someone else taking over driving, and moderate or severe hypoglycemia while driving.<sup>12,13</sup> Whether such accidents related hypoglycemia happened was determined by the patients with the questionnaire (hypoglycemia-related driving mishaps).

## STATISTICS

Data are presented as the mean  $\pm$  standard deviation or percentage. Student's t-test or chi-square test was used to compare the data between groups. A stepwise logistic regression analysis model was used to identify the related variables. The Statistical Package for the Social Sciences (SPSS 20.0, IBM Corp., New York, USA) was used for these analyses. A two-tailed  $p$ -value  $<0.05$  was considered significant.

## RESULTS

Among the 133 patients, 54.9% (73 of 133 patients) reported at least one driving mishaps, and 15.8% of the drivers (21 of 133 patients) reported hypoglycemia-related driving mishaps, while awake. Overall, the prevalence of IAH was 37.0%. The patients who experienced driving mishaps had a higher IAH, hypoglycemic frequency, and longer diabetes duration than those who did not (Table 1). There were no significant differences in clinical characteristics, such as age, diabetes duration, and the prevalence of hypoglycemia and diabetic complications, between subjects with hypoglycemia-related accidents versus subjects without hypoglycemia-related accidents. There were no significant differences in the prevalence of measuring blood glucose before driving and carrying some sugar sources in the vehicle between groups. A stepwise logistic regression analysis found that the presence of IAH (odds ratio [OR]: 5.36; 95% confidence Interval [CI]: 1.59-18.10;  $P=0.01$ ) was significantly risk factor for hypoglycemia-related driving mishaps, along with age (OR: 1.07; 95% CI: 1.01-1.13;  $P=0.02$ ).

## DISCUSSION

Diabetes mellitus is one of the disease conditions that may lead to traffic accidents.<sup>5,6,7,9</sup> The increased risk of accidents has been suggested to be associated with hypoglycemia in particular.<sup>5,6,7,8,9</sup> The current study showed that IAH

Variables	Drivers with mishaps (n=73)			P value	Control (n=60)	P value (Drivers with mishaps vs. Control)
	All (n=73)	With hypoglycemia- related accidents (n=21)	Without hypoglycemia- related accidents (n=52)			
Age, years	43.3 (11.5)	47.6 (11.6)	41.5 (11.0)	0.04	46.1 (14.4)	0.22
Male, %	41.1	52.4	36.5	0.21	48.3	0.40
Diabetes duration, years	15.3 (9.1)	17.7 (8.7)	14.4 (9.2)	0.17	9.7 (6.5)	<0.001
Continuous subcutaneous insulin infusion, %	6.8	0.0	9.6	0.14	16.7	0.75
Daily insulin dose, units	0.72(0.31)	0.82 (0.42)	0.68 (0.25)	0.10	0.63 (0.23)	0.08
Body mass index, kg/m <sup>2</sup>	21.8 (2.5)	22.2 (2.7)	21.7 (2.5)	0.44	21.8 (2.8)	0.97
Hemoglobin A1c, %	7.9 (1.4)	7.5 (1.4)	8.1 (1.3)	0.11	7.9 (1.1)	0.96
Retinopathy, %	27.4	38.1	23.1	0.19	15.0	0.09
Nephropathy, %	17.8	19.0	17.3	0.86	13.6	0.51
Hypoglycemia, times per month	7.5 (8.7)	8.1 (7.0)	7.2 (9.3)	0.70	4.7 (5.4)	0.03
Impaired awareness of hypoglycemia, %	44.4	66.7	35.3	0.02	27.6	0.048
Measuring blood glucose before driving, %	26.4	35.0	23.1	0.30	23.7	0.73
Carrying sugar sources in the vehicle, %	67.1	81.0	61.5	0.11	64.4	0.74

Data are means (standard deviation) or number.

**Table 1:** Characteristics of patients with type 1 diabetes mellitus

and older age were significantly associated with an increased risk of driving mishaps among Japanese patients with T1DM. In addition, while aging showed a significant correlation with an increased risk of accidents in this study, this likely supports the previous finding.<sup>14</sup> Driving mishaps appear to be prevalent in this population (although appropriate comparative statistics on the accidents are unavailable). IAH and counter-regulatory failure increase the risk of severe hypoglycemia, which links to brain dysfunction.<sup>15,16</sup> The mainstay for treatment of IAH is the strict avoidance of hypoglycemia.<sup>17</sup> A lack of awareness of hypoglycemia is a safety issue for drivers with T1DM and a challenge for health care providers. As prevention, Blood Glucose Awareness Training (BGAT) can be effective for the recognition of hypoglycemia, as shown in American and Dutch studies.<sup>17</sup> Leelarathna et al. reported that IAH and counter regulatory responses may be improved by a clinical strategy aimed at hypoglycemia.<sup>18</sup> In Japan, we also developed a BGAT training site (<http://bgat.jp/index.jsp>) in 2010. Further trials using such BGAT training systems are needed to reduce driving mishaps among patients with T1DM.

Unawareness of a rapid decline in the plasma glucose concentration is an additional issue to be resolved. Drivers with T1DM are obliged to check their blood glucose concentrations before driving. Actually, the prevalence of measuring blood glucose before driving was only about thirty percent in this study. Health care providers can promote the habit of patients checking their blood glucose concentrations before driving, and should strongly advise that patients do not drive until a hypoglycemic condition has been resolved in cases of low blood glucose. Also, continuous glucose monitoring might facilitate identifying and treating patients with a higher risk of hypoglycemia during driving.<sup>19,20</sup>

## STRENGTHS AND LIMITATIONS

The strengths of the current survey include the recruitment of patients at multiple hospitals and clinics nationwide in Japan. Because patients who regularly attended medical centers were recruited, they fully responded to the questionnaire. However, this study has several limitations. First, the sample size

was small and the study was cross-sectional. Second, the data on driving mishaps were from self-administered questionnaires and there were no objective measures of driving accidents. These limitations should be addressed in future research.

In conclusion, Driving mishaps appear to be prevalent in Japanese patients with T1DM. IAH should be taken into consideration as a high-risk factor for driving mishaps in this population.

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