

# Pitfalls of tightening driving regulations for diabetic patients

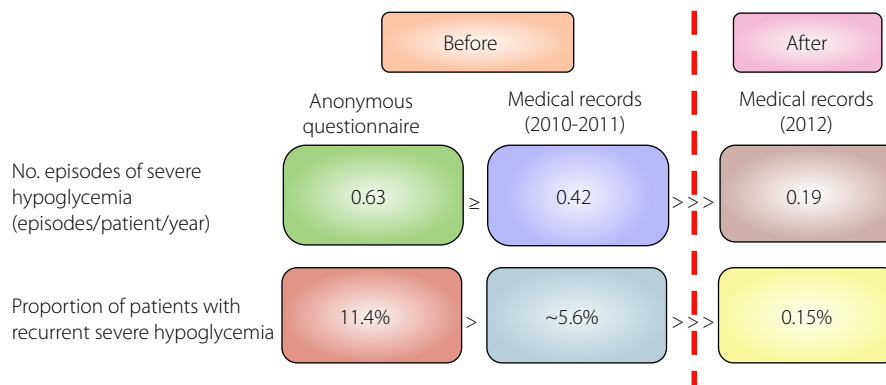
Recently, early introduction of insulin has been recommended for the treatment of not only type 1, but also type 2 diabetes, in relation to pancreatic  $\beta$ -cell protection as well as endorsement of the treat-to-target idea, a concept reinforcing attainment of treatment target levels. Combined with a worldwide increase in the number of patients with diabetes, the number of patients self-administering insulin is unquestionably increasing. The risk of hypoglycemia and frequency of hypoglycemic attacks are also higher in patients self-administering insulin. Diabetic patients self-administering insulin are reportedly prone to causing car accidents by driving during reduced levels of consciousness as a result of severe hypoglycemia, which even if mild, impairs driving performance and decision-making, leading to a higher risk of initiating accidents<sup>1</sup>.

Many car accidents caused by hypoglycemia, along with epilepsy and recurrent syncope, have been reported by the media in Japan. An increasing trend of such accidents, caused by the aforementioned factors, is attracting attention and being discussed in terms of patient and public safety. The road traffic act, revised in Japan in 2001<sup>2</sup>, resulted in the placement of certain restrictions on the acquisition and renewal of a driver's license. The 2001 ordinance designated 'Asymptomatic hypoglycemia (excluding cases where blood glucose levels can be artificially adjusted)' as a disease causing episodes of disturbed consciousness or movement disorder. In June 2013, the Public Safety Commission was allowed to ask questions about certain disease symptoms (including asymptomatic hypoglycemia), therefore authorizing the application of penal provisions consisting of imprisonment of 1 year or less and a fine up to ¥300,000 for drivers whose license was obtained or renewed using false reporting<sup>3</sup>. A system exempting physicians from protecting patient information disclosure and allowing them to voluntarily report medical examination results was also established. These measures show that legal efforts were substantially reinforced in Japan for supervising patients with diseases that could affect driving. In the past, European laws and regulations governing the acquisition of a driver's license varied among countries. Legal revisions instituted in 2006 and 2009, however, establishing that the occurrence of two or more episodes of severe hypoglycemia within a year could result in driver's license disqualification, were reinforced as law for all EU countries (implementation of EU driver's licensing legislation)<sup>4</sup>. Meta-analysis of 15 studies, however, showed that the probability of diabetic patients causing car accidents increased by just

12–19%, as compared with that of non-diabetic patients, showing that the majority of diabetic patients lead normal lives with few daily activities and/or driving problems<sup>5</sup>.

Two positions for tightening laws regulating the acquisition and renewal of a driver's license for diabetic patients exist. One position promoting legal regulation tightening and establishing stricter penalties involves achieving a lower incidence of automobile accidents, whereas the other involves protecting society in relation to the traffic environment. Opinions exist, however, inferring that tightening regulations and establishing stricter penalties could increase the number of patients refusing to visit the hospital for treatment, when necessary, in fear of losing their driver's license; thereby, increasing the number of accidents caused by patients receiving no treatment. It is important and interesting to note whether the objectives of accident reduction and protection of society will be attained by tightening regulations.

An interesting report carried out by Pedersen-Bjergaard *et al.*<sup>6</sup> in Denmark was published in the January 2015 issue of *Diabetes Care* (Figure 1). In January 2012, the law in Denmark was revised, stating that a driver's license will be revoked if more than one episode of severe hypoglycemia occurs within a year. The effect of this legal revision, enacted to improve traffic safety, was studied in the clinical setting. Validation of the hypothesis stating that a reduction in the rate of patients who experienced severe hypoglycemia and self-reported to their primary physicians occurred after legal reinforcement of driving regulations was studied. Severe hypoglycemia was defined as episodes requiring help from other people. They investigated medical charts from 2010 to 2011, before the establishment of driving regulations, and from 2012, after the establishment of driving regulations. The number of severe hypoglycemic episodes recorded in medical charts by primary physicians decreased by 55% in 2012 compared with that in 2010–2011 ( $P = 0.034$ ). The percentage of patients self-reporting two or more episodes of hypoglycemia decreased from 5.6% to 1.5% ( $P = 0.014$ ). Compared with the frequency of hypoglycemia reported in anonymous questionnaires that were continuously carried out, however, the frequency of self-reporting was lower by 70% ( $P < 0.001$ ). Although daily doses of insulin showed a decreasing trend during this survey, glycated hemoglobin levels also showed a decreasing trend. It is unlikely that primary physicians relaxed the target level of blood glucose to prevent hypoglycemia, yet no special treatment change occurred. These



**Figure 1** | Rates of severe hypoglycemia before and after the 1 January 2012 implementation of new EU legislation on driver's licensing in Denmark. Each column represents the data of severe hypoglycemia from an anonymous questionnaire (left), medical records from 2010 to 2011 (middle) and medical records in 2012 (right), respectively. Upper panels show the number of episodes of severe hypoglycemia (episodes/patient/year) and lower panels show the proportion of patients with recurrent severe hypoglycemia (%). Original data were presented by Pedersen-Bjergaard *et al.*<sup>6</sup>

results suggest that the decreased incidence of hypoglycemia recorded by primary physicians is not a true figure. A presumption that patients did not always report the second and subsequent episodes of severe hypoglycemia within a year because they feared losing their driver's license by tightened regulations was therefore made. A conclusion that tightened regulations unintentionally or paradoxically resulted in safety impairment of the patients themselves, and a reduction of traffic safety for the general public was also made. Dømggaard *et al.*<sup>7</sup> from Denmark also reported the results of a cross-sectional study, stating that patients reporting fewer hypoglycemic episodes than actually occurred were more prone to have severe hypoglycemic episodes (odds ratio 3.03, 95% confidence interval 2.42–3.79;  $P < 0.0001$ ).

Accordingly, restrictions and tightening of requirements for acquisition and renewal of a driver's license undermines the relationship between primary physicians and patients. These circumstances also remove the opportunity for preventing severe hypoglycemia through treatment adjustment; thereby, making recurrent risk of severe hypoglycemia continuously present. Furthermore, it might exacerbate the most important treatment outcome of diabetes, glycemic control, a clinical benchmark preventing the onset and progression of chronic complications. These restrictions could also further alienate people in the working environment, who have untreated diabetes, from visiting the hospital.

The aforementioned reports suggest that simply reinforcing regulations might not attain the objective of deterring car accidents, and actually fail to secure traffic safety. Although it is unnecessary to state that certain legal regulations are required, it should be noted that the problem cannot be resolved by enforcing unilateral and uniform regulations.

As described in the position statement of the American Diabetes Association<sup>8</sup>, when driver's licensing restrictions are considered for diabetic patients, diabetes specialists should evaluate the clinical history and treatment of individual patients in order

to protect the safety of society and diabetic patients, as well as achieve better outcomes of diabetes treatment. Patients need to understand the importance of such laws and regulations, and the necessity of complying with them by honestly reporting severe hypoglycemic episodes to their physicians.

How should medical staff including primary physicians at clinical sites respond? Rational interventions for recurrent severe hypoglycemia in patients should include: (i) supplementary food intake during hypoglycemic attacks; (ii) blood glucose self-monitoring reinforcement; (iii) target glucose level relaxation; (iv) insulin therapy changes; (v) preprandial insulin dose optimization; (vi) introduction of the carbohydrate count method; (vii) introduction of continuous subcutaneous insulin infusion; and (viii) use of devices for continuous glucose monitoring. Several reports state even moderate hypoglycemia impairs driving abilities, and time is required for full recovery of driving abilities even when sugar supplementation occurs during hypoglycemic episodes. It is important to provide patients with guidance and understanding for them to recognize and respond to the early stages of hypoglycemia during driving, and realize that they should not resume driving immediately after blood glucose recovery. Without fulfilling this therapeutic guidance, patients run the risk of experiencing recurrent severe hypoglycemia, which could lead to accidents and impairment of quality of life.

In the USA, driving restrictions for diabetic patients fall under the jurisdiction of state and federal governments, and vary among regions. If diabetic patients are not in a diabetic state causing serious consciousness disturbances or cognitive impairment and have no other particular problems, they should be allowed to choose any job whether or not they are receiving insulin. Diabetes status should not uniformly influence employment decisions. For example, employment restriction, based on a patient's glycated hemoglobin level, is inappropriate. If questions regarding a patient's fitness for certain jobs exist, medical diabetes specialists should evaluate individual patients. In 2013, the American Dia-

betes Association announced safe points regarding driving by diabetic patients receiving insulin<sup>8</sup>. Before driving and during long drives, patients should self-monitor their blood glucose at regular intervals to check their blood glucose levels. Patients should carry a blood glucose self-monitoring device and carbohydrates, such as glucose. Patients can drive if the blood glucose level is  $\geq 100$  mg/dL. If patients are showing hypoglycemic symptoms or a blood glucose level  $\leq 70$  mg/dL while driving, they should stop driving, park the car in a safe place and take supplementary food. The blood glucose level should be re-checked 15 min after food supplementation. If the glucose has reached the target level ( $\geq 100$  mg/dL), they can resume driving; however, it is recommended they wait 10 min or more. These statements primarily focused on self-monitoring of blood glucose<sup>5</sup>.

It is anticipated that population aging will progress in Asian countries<sup>9</sup>, increasing the incidence of elderly patients with concurrent diseases, such as dementia, who, therefore, might not be able to carry out self-management treatment(s) including medication management. As many of these patients have a driver's license, diabetes-associated car accidents involving elderly people are expected to increase. It is known that unstable glucose levels and frequent hypoglycemic episodes particularly increase the risk of severe hypoglycemia. Making treatment choices that cause low hypoglycemia and little fluctuation in glucose levels, along with patient guidance, are critical for reducing traffic accidents, and application of the laws and regulations to individual patients.

## DISCLOSURE

The author declares no conflict of interest.

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