POSITION STATEMENT



Diabetes and driving

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Abstract More than 69 million Indians are suffering from diabetes, of which a substantial proportion of the population are currently holding or will seek in the future the license to drive. Driving essentially requires multitasking with visuospatial skills at the same time and thus the management of diabetes in individuals which should demonstrate a proper detection and treatment of diabetes-related hypoglycemia will predict the capacity of driving any motor vehicle. Repeated hypoglycemia-related neuroglycopenia causes increased risk of neurocognitive dysfunction leading to visuospatial skills deficiency. Eight percent of dementia may be attributed to diabetes. Potential causes of driving impairment associated with diabetes are acute hypoglycemia, and its unawareness, retinopathy, neuropathy related to foot that affects ability to use pedals, IHD, cerebrovascular

disease, somnolence and sleep disorder associated with obesity, use of pain relieving medications and antidepressant, and cognitive dysfunction and thus should be reviewed properly before issuing a driving license. Medical evaluation and documentation of acute and chronic complications of drivers by a registered medical practitioner at pre-determined intervals may be considered as a legal necessity to identify at-risk drivers. Secretagogues have a higher incidence of hypoglycemia compared to someone who is on metformin alone. On the other hand, hypoglycemia is more frequent in an insulin-treated patient of both type 1 and type 2 diabetes. In many countries as well as in European Union (EU), it is necessary to review medical fitness in every 3 years by the authority; a person should not have any severe hypoglycemic event in preceding 12 months and a driver must have awareness

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of hypoglycemia and its management. According to Canadian diabetes association consensus statement, review should be done every 2 years; a person should not have any severe hypoglycemic event in preceding 6 months, and according to ADA position statement evaluation should be done every 2-5 years. Medical fitness certificate should be reviewed at frequent intervals; the authorities should enforce strict regulation on suspension and revocation of driving license. Information to the authorities should be promptly done by doctors or patients. Decision should be based on medical evaluation, but hypoglycemia that occurs due to medication change and during sleep does not warrant for disqualification as it may be corrected with proper dietary changes and dose adjustments. Any driver with suspended license should be re-assessed in the next 6 months for their medical fitness and hypoglycemic profile and if found suitable, the license can be revoked. Physicians should participate and should assess patient's physical and mental status, medical condition and treatment, list of medications which may impair driving performance, and any disease-related complication that lead to impaired driving or dangerous driving. Patient education is the most important factor to prevent any motor accident related to their medical condition and should be trained to prevent acute and chronic complications of diabetes.

Keywords Patient education · Hypoglycemic profile · Fitness certificate

Recommendations

- 1. Driving essentially requires proper visuospatial skills, thus repeated hypoglycemia-related neuroglycopenia leading to neurocognitive dysfunction.
- Diabetes-related complications—hypoglycemia and its unawareness, retinopathy, neuropathy, foot-related problems, CVD, IHD, sleep disorders, and side effects of medicines interferes with driving and needs to be evaluated before issuing a license.
- Evaluation and documentation should be done at predetermined frequency by registered medical practitioner.
- 4. Drugs like secretagogue and insulin have an increased risk for hypoglycemia.
- 5. There are no Indian Guidelines, but EU guidelines suggests that every 3 years a checkup is required, person should not have any severe hypoglycemic event in preceding 12 months, and a driver must have awareness of hypoglycemia and its management.
- 6. According to the Canadian diabetes association consensus statement, review should be done every 2 years, a person should not have any severe hypoglycemic event in preceding 6 months, and according to ADA position statement evaluation should be done every 2–5 years.

- Authorities should review medical fitness and can revoke or suspend license.
- Any driver with suspended license should be re-assessed in the next 6 months for their medical fitness.
- Patients' education is of utmost importance, and should be trained to prevent acute and chronic complications of diabetes.

Diabetes mellitus is a chronic metabolic condition that is characterized by persistently elevated glucose in the blood due to insulin secretory defect or defect in insulin action or both. More than 69 million Indians are suffering from diabetes and it is estimated to increase to more than 123 million by 2040 [1]. In a country like India witnessing rapid economic transition, a substantial chunk of India's diabetes population are currently holding or will seek in the future the license to drive.

 More than 69 million Indians are suffering from diabetes, of which a substantial proportion of the population are currently holding or will seek in the future the license to drive.

Driving

For many, it is essential for their daily work, taking care of their family, accessing to public and private facilities, and performing important functions of their daily routine [2].

In most of the instances, people who are highly concerned about the road safety like motor vehicle owners, employers, and other road users link diabetes with unsafe driving but in reality, most of the people with diabetes can operate a motor vehicle without any risk to themselves and others. In this case, the main concern is not being a diabetic but assessing the management of diabetes in individuals which should demonstrate a proper detection and treatment of diabetes-related hypoglycemia which may predict the capacity of driving any motor vehicle [2].

Driving is common in the adult community but it is a highly complex task that involves maneuvering a complex projectile with perfect timing and space at high speed, judging road traffic signals in different weather conditions. It essentially requires multitasking with visuospatial skills at the same time. If a person fails to maintain coordination, it may impair his ability to drive consciously [3].

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Diabetes-related neurocognitive changes

Diabetes-related hypoglycemia is defined as any blood glucose level ≤ 70 mg/dL. Clinically significant hypoglycemia is characterized by < 54 mg/dL in which patient requires assistance for correction of symptoms [4, 5].

Acute hypoglycemic episodes are a rate-limiting side effect in the treatment of diabetes. When severe, hypoglycemia can lead to coma and seizure while mild to moderate is responsible for impairing cognitive function like working memory [6].

There is a longstanding debate on the clinical benefit and associated risk of tight glycemic control in diabetes patients. Nonetheless, it is a matter of fact that hypoglycemia is a major side effect of strict blood glucose control. However, many guidelines are available to minimize hypoglycemia and related mortality and permanent neurocognitive damages. Hypoglycemia-related neuroglycopenia causes increased risk of neurocognitive dysfunction when it occurs repetitively [7]. These patients also have a deficiency in visuospatial skills which are the ability to identify a visual and spatial relationship in objects and measured by three ways namely, imagination ability of objects, making a global appearance by identifying small components, or by understanding the difference and similarity between objects [8].

According to Duarte JMN, neurocognitive dysfunction or dementia is raising in the world. While Alzheimer's disease is most common, it accounts for 60–80% of total cases and among them, about 8% is attributed to diabetes mellitus and is supposed to increase further with the growing diabetes prevalence [9]. Furthermore, cognitive dysfunction impairs the ability to control glucose level in patients with diabetes and is associated with increased risk of severe hypoglycemic episodes and cardiovascular disease when compared with patients without cognitive dysfunction [10].

As previously stated, hypoglycemia is one of the key factors in this situation that leads to decreased blood glucose level in brain which is responsible for neuroglycopenia, that results in decreased supply of energy and this leads to metabolism of another substrate for ATP generation to cover energy demand [9]. Kerr D and Olateju T have reported potential causes of driving impairment associated with diabetes—they are as follows: acute hypoglycemia, hypoglycemia unawareness, retinopathy, neuropathy related to foot that affects ability to use pedals, ischemic heart disease, cerebrovascular disease, somnolence and sleep disorder associated with obesity, use of pain relieving medications and antidepressant, and cognitive dysfunction. In order to maintain seamless driving, it is necessary to correct all the above medical conditions before driving and thereby agencies responsible for giving license to such people should warrant the same before awarding license [11].

 Repeated hypoglycemia-related neuroglycopenia causes increased risk of neurocognitive dysfunction leading to visuospatial skills deficiency. Eight percent of dementia may be attributed to diabetes. Potential causes of driving impairment associated with diabetes are acute hypoglycemia, and its unawareness, retinopathy, neuropathy related to foot that affects ability to use pedals, IHD, cerebrovascular disease, somnolence and sleep disorder associated with obesity, use of pain relieving medications and antidepressant, and cognitive dysfunction and thus should be reviewed properly before issuing a driving license.

Medical evaluation

The evaluation should include an assessment by the treating physician or any physician knowledgeable in the field of diabetes having access to the recent diabetes history of the driver. The input of the concerned physician is essential to decide whether the driving would be safe or practicable. If any concern arises with regard to evaluation of chronic complications of diabetes, it is sensible to refer the individual to a specialist with expertise in assessing the diabetes-related problem for specific recommendations [12].

There are different scenarios which may demand the medical evaluation of the person to demonstrate their driving ability. These include hypoglycemic episodes while driving (even resulting in no motor vehicle accident), severe hypoglycemia, and alteration in vision. The medical evaluation process must include assessment of hypoglycemia risk, evaluation of cataract formation or retinopathy, and neuropathy in feet which may affect the ability to feel and maneuver the brake and clutch pedals. Certain medical conditions which have the propensity of driving mishaps, namely unstable coronary heart disease, obstructive sleep apnea, epilepsy, Parkinson's disease, or alcohol and substance abuse should also be thoroughly checked [12].

It is prudent to frame a questionnaire for identifying at risk potential drivers who may require further detailed evaluation. The questions should inquire for episodes of hypoglycemia leading to loss of consciousness within the past 12 months, required hypoglycemia correction assistance from other person, episodes of hypoglycemia interfering driving, hypoglycemia without warning, loss of visual acuity or peripheral vision, or loss of sensation in the right foot. Any response in affirmative should trigger an evaluation to ascertain whether a restriction on the license or mechanical modifications to the vehicle is required or not [12]. The vital information that has to be gathered during a medical evaluation is enlisted in Table 1.

Medical evaluation of drivers by a registered medical practitioner at pre-determined intervals may be considered as a legal necessity to identify at-risk drivers. These intervals may differ between commercial and non-commercial drivers.



Table 1 Information to be gathered during medical evaluation from a person seeking driving license

- Q1 Episodes of severe hypoglycemia necessitating assistance from another person within previous two years
- Q2 Explanation for the hypoglycemic episode (if available)
- Q3 Whether there is an increased risk of hypoglycemia
- Q4 Ability of the driver to recognize nascent hypoglycemia and ability to correct the same
- Q5 Ability to perform self-monitoring of blood glucose (SMBG)
- Q6 Presence of any diabetes related complication (requiring further assessment) that may affect driving
- Q7 Understanding of diabetes, its management, measures to avoid hypoglycemia while driving, compliance with a suggested treatment plan

Adapted from the American Diabetes Association. Diabetes and Driving. *Diabetes Care*. 2014; 37 (Suppl 1): S97–S103

Licensing authorities may debar the driving permission if medical conditions suggestive of substantially affecting the driving ability of the person. The restricted period may range from 3 to 6 months or even longer. Nevertheless, special considerations must be allowed if the hypoglycemia is attributed to alteration in medications or severe hypoglycemia occurs in sleep [12].

 Medical evaluation and documentation of acute and chronic complications of drivers by a registered medical practitioner at pre-determined intervals may be considered as a legal necessity to identify at-risk drivers.

Driving and anti-hyperglycemic agents

Treatment of any type of diabetes depends upon how the active drug is lowering the blood glucose level, which may act by different mechanisms.

Metformin is used as first line therapy due to fewer side effects and less hypoglycemia risk; subsequently, sulfonylurea is one of the second choice drugs to add to metformin when it fails to control blood glucose alone in patients with type 2 diabetes. Sulfonylureas, the classic secretagogues, increase the risk of hypoglycemia. Another approach is adding insulin to metformin, where the concern of hypoglycemia is further elevated. In type 1 diabetes patients, insulin is the only agent which is used to control blood glucose and any mismatch between carbohydrate intake and insulin may cause a serious hypoglycemia.

Relation between AHAs and driving

Oral antihyperglycemic drugs (OADs) are known to either increase insulin secretion from beta cell or insulin action. Insulin and incretin mimetics are injectable AHAs which are known to fulfill insulin demand in the body. AGIs and DPP4 inhibitors act by a mechanism that regulates glucose absorption in intestinal lumen or nephrons to regulate overall glucose

circulation in the blood. Among these, secretagogues are responsible for having a larger impact on the possibility of hypoglycemia compared to someone who is on metformin alone. On the other hand, hypoglycemia is more frequent in an insulin-treated patient of both type 1 and type 2 diabetes. In a study done by LeRoy and Morse, hypoglycemic medications are stratified by their physiologic action, insulin (OR-1.80), sulfonylureas (OR—1.50), and biguanides (OR—1.49) [13]. In another study done by Heller et al., it was reported that patients with type 2 diabetes initiated on insulin therapy earlier in life, having a similar frequency of hypoglycemic episodes when compared with patients treated with sulfonylureas [10]. Majority of patients with hypoglycemia are on sulfonylurea and biguanide, 38.2 and 56.3% respectively; α-glucosidase inhibitors, sitagliptin, incretin mimetics, and thiazolidinediones were less related to hypoglycemic events. The author concluded that hypoglycemia was related to higher risk of accidents in patients treated with non-insulin agents and require hospital visits related to driving and falls [14].

It is generally stated that the frequency of hypoglycemia in a patient taking insulin less than 2 years is equivalent to non-insulin-treated patient of type 2 diabetes. Around 7% in both groups reported severe hypoglycemia and 39 and 51% respectively, reported mild hypoglycemia [10]. According to Bodmer and colleagues, the ratio of hypoglycemia among the people taking sulfonylurea is more than twice that among those taking metformin [15].

As mentioned above, several studies have revealed that diabetes when treated with insulin and oral drugs has the serious side effect of hypoglycemia which impairs the neurocognitive ability and visuospatial skill to concentrate while driving. As diabetes, if not treated properly, itself cause serious chronic complications like neuropathy and retinopathy and when it come up with the hypoglycemic event, the risk of a road accident can increase several times if not treated within time. It will continue to happen if proper awareness is not created in the community by treating physicians and governing body.

 Secretagogues have a higher incidence of hypoglycemia compared to someone who is on metformin alone. On the



other hand, hypoglycemia is more frequent in an insulintreated patient of both type 1 and type 2 diabetes.

Law stating driving with diabetes

Driving is a very essential and necessary activity in this era to complete time-specific needs in daily life of everyone but when it is compromised with some ailment, the task may become dangerous for driver and others. Hence there should be strict rule by the driving authority to control these mishaps. Unfortunately, there is no such law in India by driving authority or the concerned ministry which can evaluate the medical condition of an applicant or existing drivers. Thus it is very difficult to ensure proper control on road accident. A substantial number of road mishaps can be minimized by those drivers who are taking AHAs.

Countries like Canada, America, Australia, New Zealand, Ireland, United Kingdom, and many more have regulations in their driving department to evaluate diabetes and related complications of hypoglycemia for safe driving. In the European Union (EU), it is necessary to review medical fitness in every 3 years by the authority; a person should not have any severe hypoglycemic event in preceding 12 months and a driver must have awareness of hypoglycemia and its management. Drivers on insulin are advised to carry glucometers and blood glucose strips with them and is required to check blood glucose every time before driving and every 2 h while driving; if hypoglycemia persist, driving must be stopped and restart after 45 min when blood glucose returns to normal; it is mandatory for drivers to carry fast-acting carbohydrate and a personal identification indicating their medical condition [16].

The Canadian diabetes association has released a consensus statement as Diabetes and Driving for their private and commercial drivers in 2015. It has a similar kind of statement as of UK but there are some other points to consider while driving like drivers have to be reviewed every 2 years for medical evaluation of hypoglycemia frequency and other diabetes-related complications; assessment of hypoglycemic frequency in preceding 6 months; while driving SMBG should be performed every 4 h; if a driver experienced moderate to severe hypoglycemia, a driver must refrain from driving at the time and inform their doctor and driving license body immediately within 72 h. For commercial drivers, a complete eye examination should be done by an ophthalmologist or optometrist, assessment of hypoglycemic frequency in preceding 12 months, and a detailed questioner for assessment of diabetes and hypoglycemia awareness [17].

The American diabetes association has also released a position statement in 2012 and in 2014 on driving which is nearly the same as previously stated [18]. Other countries like Australia, New Zealand, and Ireland have a similar kind of

law enforced by driving authority stating that driver should inform about any medical condition, including diabetes, which can impair driving performance; they should be medically evaluated in every 2 to 5 years by authority depending upon medical illness and treatment and if they are found to be hypoglycemic, should refrain from driving until their treating physician gives clarity of their fitness.

• In many countries as well as in EU, it is necessary to review medical fitness in every 3 years by the authority; a person should not have any severe hypoglycemic event in preceding 12 months and a driver must have awareness of hypoglycemia and its management. According to the Canadian diabetes association consensus statement, review should be done every 2 years; a person should not have any severe hypoglycemic event in preceding 6 months and according to ADA position statement evaluation should be done every 2–5 years.

Necessity of law related to diabetes and driving in India

The diabetic population of India is crossing over 69 million and increasing very rapidly over time because of change in culture and routine in daily life of people. Healthcare sector is trying to spread awareness but it is not sufficient to impart all the proper knowledge to every patient. It is a prime responsibility of the healthcare practitioners to inform the patient on their medical condition and also to state driving authority so that mishaps can be minimized. In addition, driving authority should come up with such kind of regulations while giving driving license to people with diabetes with following points.

Screening medical condition in applicants and existing drivers

One should present a proper medical fitness certificate by Diabetologist or Endocrinologist while applying for license and routine submission of medical fitness certificate a regular interval of 2 to 5 years; if diabetes is insulin-treated, the follow-up should be earlier compared to OADs-treated patients. The parameters should include medical history, diabetes and hypoglycemia awareness, duration of existing diabetes, number of hypoglycemic events in preceding 6 to 12 months and management, and diabetic complications like retinopathy and neuropathy. The authority should enforce strict regulation on suspension and revocation of driving license that should depend upon hypoglycemic episodes during driving due to antihyperglycemic medications. Such events should be voluntarily informed to driving authority by



concerned doctor or patient continuously in a smooth and convenient manner.

 Medical fitness certificate should be reviewed at frequent intervals; the authorities should enforce strict regulation on suspension and revocation of driving license. Information to the authorities should be promptly done by doctors or patients.

Decision based upon medical evaluation should be strictly implemented, whether it requires suspension or continuation. It should be based upon driver's hypoglycemic profile and medical condition in case of new application. Since any history of complicated and uncomplicated hypoglycemia does not warrant for unsafe driving unless it is not managed properly to prevent reoccurrence and if reoccur, proper evaluation should be done based upon underlying cause and necessary action should be taken to renew the license. Hypoglycemia that occur due to medication change and during sleep does not warrant for disqualification as it may be corrected with proper dietary changes and dose adjustments. Any driver with suspended license should be re-assessed in next 6 months for their medical fitness and hypoglycemic profile and if found suitable the license can be revoked.

Decision should be based on medical evaluation, but hypoglycemia that occur due to medication change and during sleep does not warrant for disqualification as it may be corrected with proper dietary changes and dose adjustments. Any driver with suspended license should be reassessed in next 6 months for their medical fitness and hypoglycemic profile and if found suitable the license can be revoked.

Role of physicians who are treating diabetes is important for minimizing road accidents

A new regulation can be enforced in which physician participation should be important by sharing patient detail indicating medical condition to driving authority. This should include patient's physical and mental status, medical condition and treatment, list of medications which may impair driving performance, and any disease-related complication that lead to impaired driving or dangerous driving.

Patient education is the most important factor to prevent any motor accident related to their medical condition. One should be properly educated by the treating doctor about patient's medical condition and his driving performance if his treatment includes drugs like insulin and insulin secretagogue that may cause serious hypoglycemia. Patient should be trained to manage hypoglycemia when it is mild or moderate and if severe, a detailed instruction should be given. It may include checking of blood glucose before starting to drive first time in a day and if continuing, should check on regular intervals to prevent hypoglycemia while driving. He should be advised to carry blood glucose meter and immediate source of carbohydrate while driving and if hypoglycemia persist, should inform the doctor immediately.

• Physicians should participate and should assess patient's physical and mental status, medical condition and treatment, list of medications which may impair driving performance, and any disease-related complication that lead to impaired driving or dangerous driving. Patient education is the most important factor to prevent any motor accident related to their medical condition and should be trained to prevent acute and chronic complications of diabetes.

Conclusion

To summarize, diabetic patients seeking driving license should undergo a through medical evaluation by the treating physician to detect any potential risk associated with driving. If found, corrective actions should be taken not only the healthcare professional but also by the licensing authority to ensure minimization of hazards which may lead to road mishaps.

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