REVIEW

Сахарный диабет и вождение автомобиля

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Сахарный диабет – хроническое заболевание, которое не только определяет образ жизни человека, но и оказывает большое влияние на ее социальные аспекты. Одним из таких важных аспектов является вождение автомобиля. Управление транспортным средством – это сложный навык, требующий хорошей зрительно-пространственной ориентации, возможности быстрой обработки информации, бдительности и принятия правильного решения. Проявления сахарного диабета, имеющие отношение к процессу вождения и способные стать потенциальной причиной дорожно-транспортных происшествий у лиц с сахарным диабетом, различны: это гипогликемия и утрата ее предвестников, осложнения диабета – ретинопатия и полинейропатия, ишемическая болезнь сердца. Безусловно, гипогликемии – самая частая и самая непредсказуемая проблема, которая может стать опасным и жизнеугрожающим событием как для самого водителя, так и для других участников дорожного движения. Подавляющее большинство зарубежных исследований подтверждает неблагоприятное воздействие гипогликемии, независимо от степени ее тяжести и выраженности симптомов, на процесс вождения, требующий максимальной концентрации внимания для обеспечения безопасности на дороге. Несмотря на очевидную актуальность вопроса, неутешительные данные касательно отношения самих водителей с сахарным диабетом к контролю за уровнем глюкозы во время движения и мер предосторожности, принимаемых ими до и во время поездки, демонстрируются в российских и зарубежных исследованиях. На данный момент решение этой проблемы, на наш взгляд, предполагает вмешательство как на законодательном уровне, так и в клинической практике – применение адекватных медицинских рекомендаций, регламентирующих возможность, а главное, безопасность управления транспортным средством человеком с сахарным диабетом.

Ключевые слова: *вождение и сахарный диабет; водители с сахарным диабетом; гипогликемия за рулем; управление транспортным средством при диабете*

Diabetes mellitus and driving a motor vehicle

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Diabetes mellitus is a chronic disease, which neither only influences the lives of our patients, nor intervents in social aspects, including such ubiquitous feature of modern life, like driving. Driving a motor vehicle is a complex skill, requiring good visuo-spatial function, rapid information processing, vigilance and rate of making decisions. Potential causes of driving impairment, associated with diabetes, are different: hypoglycemia and it unawareness, complications of diabetes – retinopathy and neuropathy, ischemic heart disease and others.

Nevertheless, hypoglycemia is the most common and the most unpredictable problem that can lead to dangerous and life-threatening event for the driver and those, who can be at risk. Overwhelmed research data confirm impairment affecting driving performance due to any type of hypoglycemia. So, the problem remains quite relevant, not all drivers follow the precautions, measure blood glucose level before and during driving, as many trials and meta-analyses revealed. In our country getting of driving license to persons with diabetes do not properly regulated, even though this problem relates to road safety.

Keywords: *diabetes and driving; hypoglycemia; driving mishaps; drivers with diabetes*

The International Diabetes Federation claims that in 2015, approximately 415 million people between the ages of 15 and 79 years suffered from diabetes mellitus (DM) worldwide [1]. The Federal Service of State Statistics estimated the population of the Russian Federation to be 146,544,710, as of January 2015 [2]. Of these individuals, according to the World Health Organization, nearly 12.4 million are affected with DM, including those who are unaware of the disease [3].

In early 2016, the number of cars registered by the Russian State Traffic Police Inspection was approximately 56.6 million [4]. However, statistics on the number of drivers with diabetes and significant data on how often such individuals are involved in car accidents are unavailable.

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According to the Federal Law of Traffic Safety (Table 1, item 1), all driver candidates and persons renewing an expired driver's license must pass a medical examination. Drivers whose diseases contraindicate vehicle driving must pass additional medical examinations.

The list of diseases that contraindicate vehicle driving has long been regulated by the order of the Ministry of Health and Social Development of the Russian Federation (Table 1, item 2), which was amended on January 1, 2012 (Table 1, item 2). The list was based on the order of the Ministry of Health of the U.S.S.R. (Table 1, item 3) and is not applicable to those with mental disorders.

According to this order, DM is a contraindication for employment as a hired driver of a passenger car lighter than 3,500 kg (category B) and for obtaining a driver's license in categories C (passenger cars heavier than 3,500 kg), D (passenger cars with more than 8 seats), or E (autotrains). For non-hired drivers who apply for a license in category A or B; the order states that "...a motion should be decided individually, on a base of an endocrinological decision; the course of disease, which is accompanied by a disorder of consciousness and tendency to comatose state forbids the driver's license."

There are no concrete recommendations for endocrinologists concerning the frequency and severity of hypoglycemia, abnormal sensitivity to hypoglycemia, or the degree of complications from DM. In addition, doctors commonly rely on blood glucose data reported by the patient or recorded by a glucometer, as well as on laboratory analyses of blood glucose and glycated hemoglobin levels.

The Governmental Regulation of the Russian Federation (Table 1, item 4) does not mention DM in either the list of medical contraindications or among the medical restrictions on vehicle driving. Thus, the recommendations of an endocrinologist are no longer needed to obtain a driver's license. As medical restrictions on vehicle driving, the existing regulation lists various eye diseases, disorders of the nervous system, and permanent impairments of the lower limbs that may occur as chronic complications from diabetes. We believe that any patient with DM (even those unaware of the disease) who wants to obtain or renew a driver's license should be observed and interrogated (a sample questionnaire is shown in Appendix 1) by an endocrinologist to reveal problems that may affect that person's ability to drive a vehicle.

For example, the American Diabetes Association (ADA) [5] recommends that every driver with DM clears a medical examination and answers the following questions:

- Has loss of consciousness due to hypoglycemia occurred during the past 12 months?
- Has a hypoglycemic event occurred that required the help of another person?
- Has a hypoglycemic event occurred while driving that hindered your ability to control the car?
- How do you correct hypoglycemia? What particular means are used? What is the daily intake of carbohydrates (in grams) ingested? When was the glucose level checked the last time?
- Did hypoglycemia occur without signs or symptoms?
- Did you experience changes in visual acuity, a decrease in peripheral vision, or a decrease in the sensitivity of your lower limbs?
- If you have type 2 DM (T2DM), how often do you fall asleep in the daytime? Have you been diagnosed with sleep apnea syndrome?

If a positive answer is given to even one of the aforementioned questions, an additional examination and appropriate glucose-lowering therapy are recommended. If necessary, additional medical consultations should be undertaken before a driver's license is issued or returned. The level of glycated hemoglobin is recognized as an unreliable factor affecting driving impairment because occasional hypoglycemic events present a more crucial risk than does average blood glucose level.

Table 1. Legal regulations on driving rights of people with diabetes

Federal Law of Traffic Safety, November 15, 1995, section 23 (version of the Federal Law, December 28, 2013)

The Order of the Ministry of Health and Social Development of the Russian Federation, April 12, 2011, No 302n "Affirmance of lists of harmful and/or dangerous production factors and works requiring preliminary and periodical medical examinations and Procedure of obligatory preliminary and periodical medical examinations of workers employed in hard works and works under harmful and/or dangerous working conditions," amended January 1, 2012. Since then, the subsections 11 and 12 (except for 12.2, 12.11, and 12.12) have been invalidated.

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The Order of the Ministry of Health of the U.S.S.R., September 29, 1989, No 555 "Improvements of the system of medical examinations of labor and drivers of individual vehicles."
The Governmental Regulation of the Russian Federation, December 29, 2014, "Lists of medical contraindications, medical indications, and medical restrictions on vehicle driving."

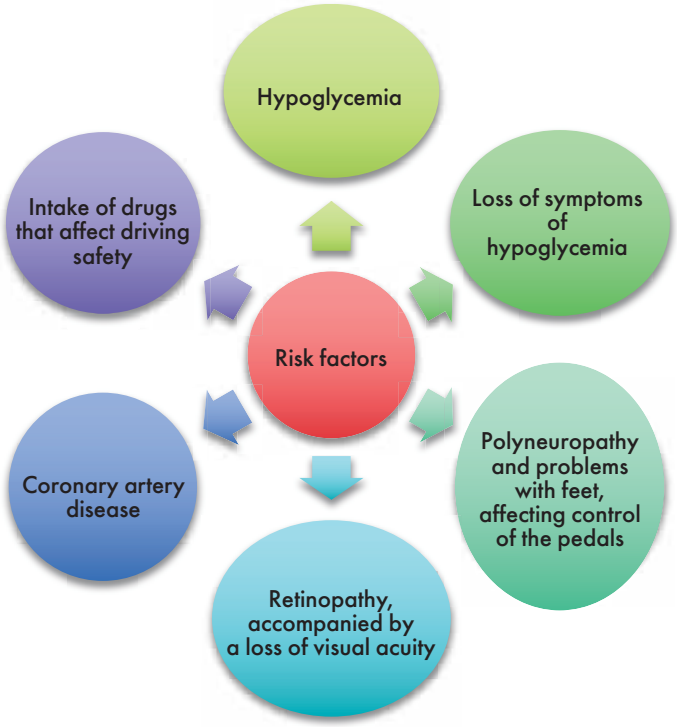

Fig. 1. Diabetes-associated factors that increase the risk of car accidents

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The Governmental Regulation of the Russian Federation, December 29, 2014, "Lists of medical contraindications, medical indications, and medical restrictions on vehicle driving."

A meta-analysis, which was performed in 2011, revealed that the risk of car accidents among people with DM was 12–19% higher than in the healthy population [6]. Another study reported that this risk was approximately twofold higher [7]. For instance, an extensive, multinational, retrospective investigation reported that drivers with type 1 DM (T1DM) have car accidents twice as often as their spouses without diabetes [8].

There are many reasons for the high number of car accidents involving people with DM (Fig. 1), with hypoglycemia undoubtedly one of the most common. Complications from diabetes, such as retinopathy, neuropathy, and cardiovascular problems, may also affect driving skills, even though their effects are more predictable [9].

Driving a motor vehicle is a complex process, requiring good visuospatial function, rapid information processing, vigilance, and quick decision-making skills.

Hypoglycemia causes cognitive and psychomotor disturbances that may negatively influence driving ability [10, 11].

Drivers with DM should be mindful of symptoms of hypoglycemia and accompanying factors that may hinder driving (e.g., trembling, hypotaxia, and visual impairment) [12].

There are several classifications of hypoglycemia; these are based on blood glucose level and a patient's mental state during an episode. Nevertheless, the characteristics of hypoglycemia cannot always be quantitatively determined. Hypoglycemia is a state that can have negative consequences, not only due to a loss of consciousness. Symptoms of hypoglycemia should be recognizable by drivers as they are responsible for their own life and the lives of people nearby.

According to the ADA classification system, ***severe hypoglycemia*** requires another person to administer carbohydrates or glucagon or take life-supportive measures [13]. Obviously, episodes of severe hypoglycemia represent a mortal danger for those with DM and may cause accidents: The results of the Diabetes Control and Complications Trial reported 714 registered episodes of severe hypoglycemia that caused 11 car accidents [14].

Cox et al. carried out a multicenter survey investigation of 452 drivers with T1DM. Over a 12-month period, 23 participants (5%) reported 31 episodes of severe hypoglycemia while driving, such that the driver was unable to correct hypoglycemia without assistance. Furthermore, the authors claimed that every episode of severe hypoglycemia increased 6% the risk of a car accident over the previous 12 months [15].

Furthermore, 185 participants (41%) in this investigation reported 503 episodes of ***moderate hypoglycemia***, which also affects the driving process. In these cases, help from other people was not needed to correct hypoglycemia, but dangerous effects on driving were also noted. For the investigation, Weinger [16], who used questionnaires and neuropsychological tests, determined that most drivers agree that driving is unsafe if blood glucose levels are 2.2 mmol/l.

In addition to severe hypoglycemia, episodes of moderate hypoglycemia increase the risk of car accidents. Many studies confirm that metabolic disorders associated with moderate hypoglycemia can seriously affect driving quality [11, 17, 18]. For example, in one randomized study of the effects of hypoglycemia on driving, 25 patients with T1DM drove in a simulator for two days. The control day included four rides under conditions of euglycemia (a mean blood glucose level of 6.3 ± 0.89 mmol/l) and the experimental day included four rides under the following conditions:

- Euglycemia
- Brief hypoglycemia (blood glucose 3.6 ± 0.33 mmol/l)
- Moderate hypoglycemia (blood glucose 2.6 ± 0.28 mmol/l)
- Euglycemia

The patients were not informed of their blood glucose levels. Driving quality and skill were unaffected under conditions of brief hypoglycemia or during correction of moderate hypoglycemia.

However, moderate hypoglycemia negatively influenced steering, leading to increased risk of side-slip ($P < 0.03$) and turnover ($P < 0.03$), longer remaining on a dividing strip of the road ($P < 0.05$) and out of the road ($P < 0.01$). As a possible counteraction, a driver significantly slowed down a car ($P < 0.04$) These changes were found in 35% of participants; only 50% of these individuals announced that they would not drive under similar, real-life conditions. A measured level of blood glucose between 3.6 and 2.6 mmol/l significantly altered the

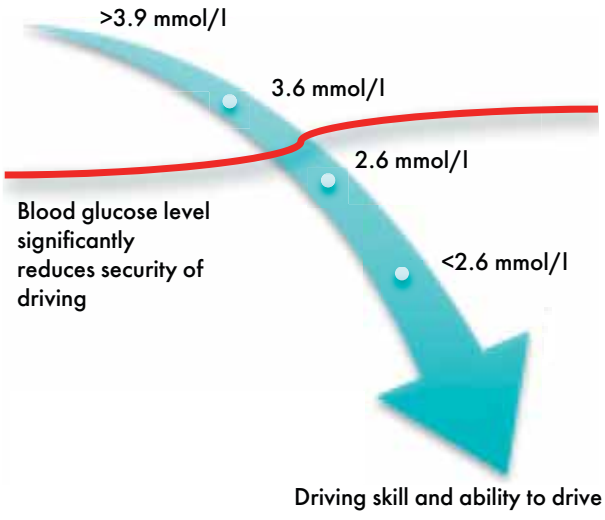

Fig. 2. Effects of blood glucose level on driving quality

driving safety and was not always obvious to the participants (Fig. 2) [11].

These results show that episodes of both severe and moderate hypoglycemia significantly decrease driving safety. The question is whether one should continue driving under such circumstances or stop and correct hypoglycemia [12, 19].

This parameter was highlighted in the work of Graveling that examined 202 drivers treated with insulin (115 and 76 patients with T1DM and T2DM, respectively). The participants were asked whether they would stop driving to correct hypoglycemia. Most (192 persons, 95.0%) answered that they would stop, and 13 drivers (6.4%) reported that they would continue driving.

When asked about safe blood glucose levels, the following responses of the participants were noteworthy:

- 4 mmol/l and higher [151 (74.8%) persons]
- 3.9 to 3.0 mmol/l [42 (20.8%) persons]
- <3.0 mmol/l [9 (4.5%) persons]

Even though 64 drivers (31.7%) had experienced hypoglycemia during driving, and seven participants had been involved in car accidents, most of them answered "***Never***" to the question "***Do you measure blood glucose before a ride?***"

One hundred (49%) participants reported the following experiences:

- Had never measured glucose levels before a drive
- Did not have a source of carbohydrates with them in the car
- Did not stop a driving a vehicle if hypoglycemia was experienced
- Was convinced that driving may be safe if blood glucose is below 3.0 mmol/l [20]

Most drivers who reported not measuring blood glucose levels had an impaired sensitivity to hypoglycemia. Certain investigations did not confirm a significant increase in the number of car accidents involving such drivers [14, 21, 22], but other studies do not deny the importance of this factor in driving safety [23]. The work of Graveling revealed that more drivers have an ***impaired sensitivity to severe hypoglycemia*** (34.8%) than a normal sensitivity to severe hypoglycemia (13.2%; $\chi^2 = 10.8$, P = 0.001). Thus, impaired sensitivity is a critical factor in evaluating accident rates of persons with DM [20].

Data from foreign investigations are supported by those of studies conducted in Russia. Fifty-four patients with DM who were interviewed via the internet community Diabet. Connect were asked "***How often do you measure blood glucose before driving?***" The results of the interviews are shown in Figure 3.

1. Once every time and additionally during a long ride–8 persons (14.8%)
2. Every time before driving–4 persons (7.4%)
3. If it is possible and time is available–4 persons (7.4%)
4. Only if a ride will be long–0 persons
5. Only if I do not feel well–9 persons (16.65%)
6. Never–12 persons (22.2%)
7. Other–17 persons (31.4%)

In response to "Other," a few people provided the comment "If hypoglycemia at the wheel occurred earlier."

It should be noted that both the experience of hypoglycemia while driving and a history of such events are important. This conclusion is supported by a study carried out in a simulator under conditions of a hyperinsulinemic

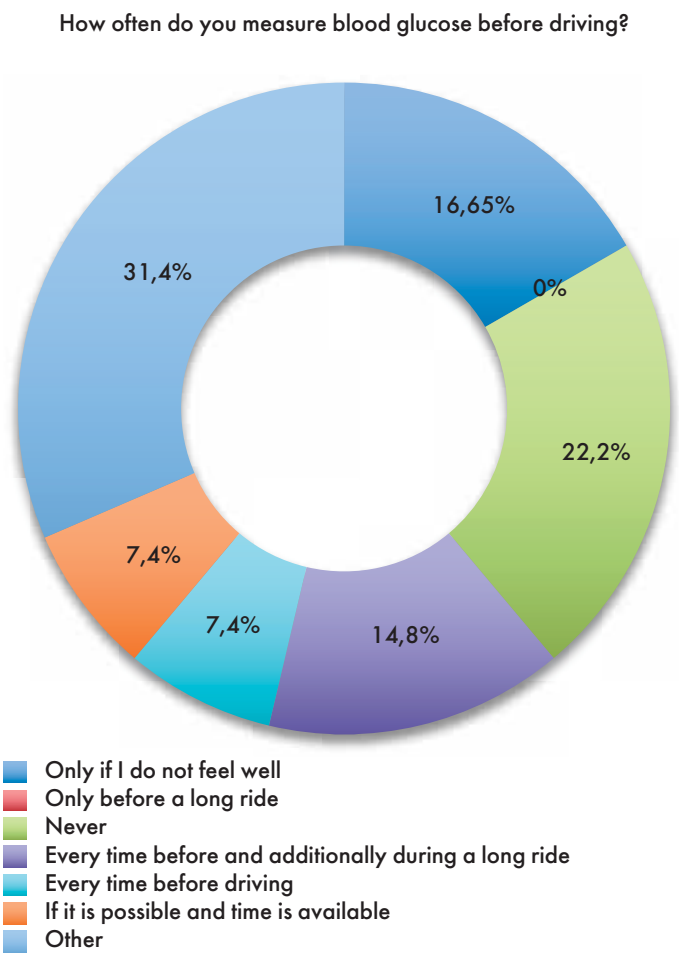

Fig. 3. Frequency of blood glucose measurements before driving (percentage of interviewed patients via the internet community Diabet.Connect; n = 54)

clamp (that controls the hypoglycemic state over a range from 3.9 to 2.5 mmol/l glucose). Two groups of T1DM drivers were compared. In the first group, there was no history of hypoglycemia leading to undesirable consequences while driving. Members of the second group had a history of more than one significant hypoglycemic episode during driving that had led to a car collision or a court trial or required help from another person to continue driving [19].

Under conditions of euglycemia, members of both groups drove equally well. However, under conditions of hypoglycemia, those with a history of car accidents drove much worse; they also had lower responses to epinephrine, were more sensitive to insulin, and exhibited delayed information processing during both conditions of euglycemia and hypoglycemia [5].

Similar results were obtained by Campbell et al. [24]. In this study, patients with T1DM having a history of adverse events while driving exhibited suppressed neurocognitive function and working memory compared with patients lacking such a history. Cox et al. [8], who also examined the same parameter, revealed that such drivers usually decided to stop driving only after a distinct decrease in blood glucose. Such individuals were less prone to measure glucose levels before driving.

Nevertheless, one should not blame only the drivers for the lack of attention to this problem. In fact, a Scottish survey from 2004 found that only 62% of medical workers felt that drivers with DM treated with insulin should test blood glucose levels before driving, whereas 13% of those interviewed believed that driving is safe with a blood glucose level below 4 mmol/l, and 8% did not know that impaired sensitivity to hypoglycemia may be a contraindication to driving [25]. An extensive international investigation showed that almost one-half of patients with T1DM and three-quarters of those with T2DM had never discussed the principles of safe driving with diabetes with their doctors [26].

To conclude, we want to highlight the importance of this issue, which requires a comprehensive approach. At present, solutions to the problem require both legislative and clinical changes, including adequate medical recommendations regarding the ability of a person with DM to safely operate a motor vehicle and safe driving regulations for persons with DM.

Indeed, assessing the risk of car accidents involving those with DM requires reliable evidence. Vehicle driving is potentially dangerous, not only to a driver with DM but also to other people on the road. In addition, DM can negatively affect the driving process. These factors must be taken into account by both the patient and the attending doctor.

Control of hypoglycemia plays a very important role in safe driving as its onset is not always predictable, its manifestations and symptoms are often masked, and drivers may not have time to adequately respond to changes in blood glucose levels while driving. Therefore, the top priority for an attending doctor is to remind a patient to be aware of the symptoms of hypoglycemia while driving and the importance of blood glucose monitoring before driving; the patient should also be aware of any abnormal sensations. The recommendations found in Appendix 2 are a simple example of such a reminder.

The importance of this problem is supported by the current European restrictions on the issuing of drivers' licenses and the results of the investigations presented in this review.

Supplemental information

Conflict of interest

The authors declare to have no conflicts of interest concerning this manuscript.

Contributions of the authors

Patrakeeva E.M.–the concept and design of the review; Dunicheva M.N.–analysis of foreign literature, text writing; Martyanova O.Y.–analysis of Russia-language literature, text writing; Zalevskaya A.G.–final editing, text affirmation

Appendices

Appendix 1. Questionnaire for driver candidates or land-based vehicle driver candidates with diabetes

1. Did you experience severe hypoglycemia over the last year so that help from other people was required?
   - Yes
   - No
2. If 'Yes', describe when it happened and how often. If 'No', skip the question

_____

3. Did you lose consciousness due to hypoglycemia?
   - Yes
   - No
4. Do you feel symptoms of hypoglycemia?
   - Yes
   - No
   - Other (give your answer)

_____

5. Do you measure blood glucose before car driving?
   - Yes
   - No
   - Other (give your answer)

_____

6. Do you feel visual impairment recently?
   - Yes
   - No
7. Do you feel decrease in sensitivity of legs?
   - Yes
   - No
8. The question for patients with type 2 diabetes: did you happen to accidentally fall asleep during while performing any actions in the daytime?
   - Yes
   - No

Appendix 2. Recommendations for drivers with diabetes

- Always keep a glucometer and test strips in your car. They must be easily accessible for an urgent analysis of blood glucose levels.
- Put extra carbohydrates in your car—both "fast-acting" (small package of fruit juice, can of lemonade, dextrose pills or gel, sugar) and "slow-acting" (crackers, bread crisps, cereal biscuits). Keep them easily accessible.
- Attempt to measure blood glucose levels every time before driving. Be advised that your sense of a "good" or "low" blood glucose may not be accurate!
- Do not drive if your blood glucose is above 3.9 mmol/l but beneath 5.0 mmol/l; it is not safe. Eat 1–2 XE (12–24 g) before driving.
- When experiencing hypoglycemia symptoms (as well as inexplicable anxiety or unreasonable aggression against other drivers) during driving, you must park on the side of the road. If it is impossible to do so, switch on the emergency signal and stop the car. Measure your blood glucose level. If it is less than or equal to 3.9 mmol/l, follow "Rule 15": Eat 15 g of "fast-acting" carbohydrates and repeat the measurement after 15 min. If blood glucose levels are still below 3.9 mmol/l, repeat these steps.
- Do not resume driving until the complete restoration of blood glucose levels. This may take 30 to 60 min.
- Abstain from driving if your blood glucose-lowering therapy has been recently modified, for example, if you started using an insulin pump or began insulin therapy after withdrawal of oral glucose-lowering medications.
- If you recently experienced severe hypoglycemia or loss of consciousness because of a low blood glucose level, do not drive until the cause of this state is identified and corrected.
- Remember that safety on the road depends on your actions!

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