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Q1 **Safe driving practices and factors associated with motor vehicle collisions**
 2 **among people with insulin-treated diabetes mellitus: Results from the**
 3 **Diabetes and Driving (DAD) study**

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ABSTRACT

Introduction: The aim of this study was to assess the prevalence of people with insulin-treated diabetes mellitus (ITDM) who have discussed issues related to diabetes and driving with their health care providers (HCPs). We also sought to determine the safe driving practices that are currently employed by this group. Finally, we investigated the factors that might increase the risk of motor-vehicle collisions (MVCs) among this group in Saudi Arabia. *Method:* This cross-sectional study surveyed a representative sample of 429 current male drivers with ITDM using a structured questionnaire in Saudi Arabia. *Results:* Most of the participants (76.5%) never discussed topics regarding diabetes and driving with their HCPs. The majority of the participants (61.8%) reported at least never doing one of the following: (a) carrying a blood glucose testing kit while driving, (b) testing their blood glucose level before driving or during a journey, or (c) having thought of a specific threshold of blood glucose level that would preclude driving. Three factors were associated with a higher risk of MVCs among participants with ITDM: (a) being on a basal/boluses regimen, (b) never having a discussion regarding diabetes and driving with their HCPs, and (c) having experienced hypoglycemia during driving. *Conclusions:* The majority of people with ITDM had not had a discussion regarding diabetes and driving with their HCPs, which was reflected by a lack of safe driving practices. People with ITDM should be encouraged to take precautions while driving in order to prevent future MVCs. *Practical applications:* This research highlights the importance of investing more effort in educating drivers who have diabetes about safe driving practices by their health care providers. Also, it will attract the attention of policymakers for an urgent need to establish clear policies and procedures for dealing with drivers who have diabetes.

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1. Introduction

53 Diabetes mellitus (DM) is one of the most common chronic diseases
 54 in nearly every country in the world. Worldwide, DM has been estimated
 55 to affect 285 million adults (6.4%), and its prevalence is expected
 56 to increase to 7.7%, affecting 439 million individuals by 2030 (Shaw,
 57 Sicree, & Zimmet, 2010). DM is one of the most frequently encountered
 58 diseases in Saudi Arabia. Compared with other parts of the world,
 59 Arabian Gulf countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia,
 60 and United Arab Emirates) are considered to have among the highest
 61 prevalences of DM in the world (Majeed et al., 2014; Ogurtsova et al.,
 62 2017). According to World Health Organization (WHO), Saudi Arabia

63 has the 7th highest rate of DM in the world and the 2nd highest rate
 64 in the Middle East; an estimated 7 million people are living with DM
 65 and more than 3 million are living with pre-diabetes (Abdulaziz Al
 66 Dawish et al., 2016). Moreover, the DM prevalence has increased by ap-
 67 proximately 10-fold over the past three years in Saudi Arabia (Abdulaziz
 68 Al Dawish et al., 2016). Despite the high prevalence of DM, proper
 69 awareness is still a major challenge in Saudi Arabia. Early detection
 70 and a greater awareness of subjects with DM are crucial to minimizing
 71 the risk of developing complications associated with the disease
 72 (Muggeo, 1998).

73 Hypoglycemia is a common complication among people with DM
 74 that puts them at risk for injury and sometimes death (Group UHS,
 75 2007). Hypoglycemia is more obvious among people with insulin-
 76 treated DM (ITDM) because insulin itself can increase the risk of hypo-
 77 glycemia (Leese et al., 2003). Several complications that can occur due

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to hypoglycemia in persons with DM (i.e., altered vision, changes in the level of consciousness, or fainting) could contribute to motor-vehicle collisions (MVCs) (Graveling & Frier, 2015).

Individuals with ITDM who are driving may be impaired by many factors (Skurtveit et al., 2009). During bouts of hypoglycemia, for instance, cognitive functions that are critical to driving (e.g., visual processing, attention) are affected (Graveling & Frier, 2015). Other DM complications can also affect ITDM patients' driving abilities: retinopathy, cataract formation, or neuropathy (Cox et al., 2006). Hence, awareness and knowledge of the effects of DM on driving ability is vital to avoid such complications and minimize the risk of MVCs.

The incidence of hypoglycemia while driving among people with DM has been studied (Cox et al., 2009) and has been directly linked to causing MVCs and even death (Cox et al., 2003; Group DR, 1991). Health care professionals play an essential role in educating people with DM to help avoid any incidents of hypoglycemia while driving. Unfortunately, there are no universal guidelines to be followed by health care professionals to educate people with ITDM before driving. The American Diabetes Association (ADA) recommends that "people with diabetes should be assessed individually, taking into account each individual's medical history as well as the potential related risks associated with driving" (Lorber et al., 2012). In general, most of the guidelines that were established to educate people with ITDM about diabetes and driving shared common aspects, (i.e., carrying glucose meter and strips, checking blood glucose before and during driving, and carrying fast-acting carbohydrates to treat hypoglycemia) (Cox, Gonder-Frederick, Shepard, Campbell, & Vajda, 2012; Graveling & Frier, 2015; Graveling, Warren, & Frier, 2004). In addition, there is a lack of studies about the effectiveness of such recommendations to decrease the risk of MVCs. Moreover, the local literature lacks any studies that have assessed the role of health care professionals in awareness of hypoglycemia and driving among people with DM (Al-Rubeaan et al., 2015).

In Saudi Arabia, hypoglycemia incidents during driving have been vaguely associated with MVCs. Unfortunately, the rate of occurrence is tough to determine, because the evidence can be inconclusive, and it may be difficult to link the accident events to hypoglycemia as a causing factor. This can be attributed to the infrequent measurement of blood glucose at the site of the accident or afterwards (Frier, 2008). As a result, the rate of hypoglycemia and MVC incidence in Saudi Arabia is largely unknown. Therefore, evaluating the association between hypoglycemia and MVCs is warranted to reduce morbidity and mortality among people with DM. Furthermore, assessing the percentage of people with ITDM who have had discussions regarding diabetes and driving with their health care providers (HCPs) as well as its relation to increased risk of MVCs is extremely important.

In this study, we aim to assess the prevalence of people with ITDM who have had discussions regarding diabetes and driving with their HCPs, as well as the safe driving practices that these patients currently used. An additional aim is to determine the factors associated with an increased risk of MVCs among those people in Saudi Arabia.

2. Methods

2.1. Study design and setting

The current research project was part of a cross-sectional study (Diabetes and Driving (DAD) Study) conducted among participants with ITDM in Saudi Arabia to explore different aspects related to diabetes and driving. Data were collected from two specialized diabetes clinics that are affiliated with two different tertiary hospitals in Riyadh, Saudi Arabia.

2.2. Participant enrollment

The participants consisted of adult (i.e., age > 18 years) men with ITDM (type 1 or type 2 DM); these participants had at least one year

of follow up in the diabetes clinic and used cars as their main source of transportation for everyday travel.

The data collection was conducted by four medical students who had significant experience with data collection. The data were collected from August 2016 to February 2017. To ensure that the study group comprised an acceptable representation of our target population, the data collectors went every other day to the data collection site and chose a random interval of 4 h from the day. During these random intervals, all of the participants were approached after they completed their consultations. Then, the data collectors explained the study's objectives to the participants, and anyone that met the eligibility criteria and agreed to participate was included. To ensure the accuracy of our data, the data were obtained by an interview that was carried out by the data collectors. Written consent was also obtained, and confidentiality was assured.

2.3. Instrument development

In the DAD study, the interview questionnaire was developed based on an extensive literature review and available international guidelines about diabetes and driving (Cox et al., 2012; Cox, Singh, & Lorber, 2013; Graveling et al., 2004; Graveling & Frier, 2015; Lorber et al., 2012). The following data were collected:

- Socio-demographic characteristics, including age, highest education level, location of residence, monthly income, current occupation, smoking status, and marital status.
- Diabetes-related information, such as type of diabetes, duration of diabetes, duration of insulin use, regimen of insulin treatment, use of sulphonylurea or glinides, and frequency of measuring blood glucose level.
- Hypoglycemia-related aspects such as receiving any education about the relation between hypoglycemia and driving, and symptoms, time, and frequency of hypoglycemia.
- Practice related to driving and blood glucose monitoring, such as driving distance and duration, whether or not a blood glucose testing kit was carried, and the prevalence of testing blood glucose before and during a journey.
- Practice related to driving and hypoglycemia, such as the experience of hypoglycemia during driving, action taken if hypoglycemia occurs while driving, and carrying carbohydrates to treat hypoglycemia if it occurs during driving.
- The last section was about official regulations in the general department of the traffic and motor insurance companies for drivers with ITDM.

The questionnaire was developed initially in English; it was then translated to Arabic and then back-translated to English. This process was done by two accredited translators, and the original and final English versions were reviewed. Any disagreements were discussed and solved by the principal author and the translators. The final Arabic version of the questionnaire was distributed to our participants.

The content validity of the questionnaire was established by two experts in the field of diabetes medicine to ensure that the items were representative of the outcomes.

To ensure clarity, completeness, and acceptability, the questionnaire was piloted among 20 participants. These participants were selected from the general medicine clinics to prevent contamination with our primary sample. The reliability of the questionnaire was ensured by the test-retest method by redistributing the questionnaire again to the same participants after one month. The correlation coefficient for all items was above 0.7, which indicates excellent stability.

2.4. Study size

The study size was based on the result of the pilot study. Since 30% of the participants with ITDM in the pilot study had experienced a car

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