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Obstructive sleep apnea and driving risk: The current Turkish legislation, controversies, and future perspectives

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ABSTRACT

Motor vehicle accidents (MVA) are one of the leading causes of death and injury in Turkey. Fatality reduction currently targets increasing seat belt use and reducing high-speeding and alcohol usage. However, sleepiness is increasingly recognized as a contributing factor. Sleepiness accounts for up to 20% of MVAs on monotonous roads, especially highways. The most common medical disorder causing sleepiness is obstructive sleep apnea (OSA). Available data suggest that efficient treatment of OSA may reduce MVAs and MVA-related deaths and injuries. Several attempts have intensively been debated during the last decade in order to develop national and international strategies to screen high-risk drivers for sleepiness and OSA. In accordance with the directive of the European Union, the Turkish legislation has recently been revised for regulation of driving license issues for individuals with OSA. There are still many controversies and difficulties in implementation of these rules in practice. A full-night polysomnography (PSG) is recommended, and treatment should be initiated as soon as possible when the OSA diagnosis is confirmed. However, given the limited resources, at-home portable cardiorespiratory sleep monitoring is a reasonable alternative to PSG for appropriately selected patients with high clinical suspicion for OSA, rather than no-PSG, and no treatment. Additional attempts for development of national guidelines for determining the driving risk, development of new screening tools for objective evaluation of sleepiness in drivers with suspected or confirmed OSA, and educating patients about the risks of excessive sleepiness as well as encouraging clinicians to become familiar with relevant laws are urging.

Keywords: Sleep apnea, Driving risk, Legislation

Introduction

Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a chronic disease characterized by repeated upper-airway collapse during sleep, resulting in intermittent hypoxia, fragmented sleep, fluctuations in blood pressure, and increased sympathetic nervous system activity [1]. Population studies in the USA in the early 1990s suggested that the prevalence of OSA - defined by an apnea-hypopnea index (AHI) greater than five events per h was estimated to be 9% in women, and 24% in men, respectively [2]. A later study from the USA showed an increased prevalence, corresponding around 17% in middle-aged (30-70 years) women, and 34% in middle-aged men, which was mainly attributed to increasing body-mass-index in general populations over the last decades [3]. Interestingly, a recent study in Europe, the HypnoLaus Study, based on recent apnea-hypopnea definitions of the American Academy of Sleep Medicine [4] revealed that 84% of men and 61% of women had OSA based on the polysomnographic AHI cut-off level of 5/h in an unselected general cohort of 1525 adults [5]. The authors concluded that the prevalence of OSA was highly dependent on technical procedures such as using nasal cannulas recording more subtle breathing variations as hypopneas (instead of thermistors which were used earlier, and which are known to have less sensitivity) as well as applying the latest hypopnea definitions, which are more liberal compared to the earlier ones (3% desaturations instead of 4% desaturations, and/or arousals). To date, there is no data regarding the prevalence of OSA in Turkey based on sleep recordings. However, the largest questionnaire-based Turkish Adult Population Epidemiology of Sleep (TAPES) study [6] including a nationwide representative sample of 5021 participants suggested a prevalence of OSA around 14% based on the Berlin questionnaire [7].

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Motor vehicle accidents in Turkey

According to a recent report, the total number of motor vehicle accidents (MVA) is continuously increasing in Turkey; there were 1,296,634 registered accidents in 2012 compared to 439,777 accidents in 2002 [8]. The percentage of accidents per registered motor vehicles was also increased from 5.1% in 2002 to 7.6% in 2012. The deaths per general population was almost same (0.006% vs. 0.005%); however, the serious injuries per general population have been increased from 0.168% to 0.354%; corresponding a total number of 3,750 deaths and 268,079 serious injuries in 2012 [8]. According to the accident statistics, the drivers have the biggest defect share with a 95% ratio, and the main components of the driver defects were high speed, alcohol and substance use as well as sleepiness and fatigue [8].

Sleepiness and fatigue

Excessive daytime sleepiness (EDS) at the wheel has been identified as an important risk factor for MVA, and the excess risk of MVA due to sleepiness and fatigue has been estimated at 10-20% [9, 10]. The prevalence of the EDS in Turkey was estimated to be 5.4% in the TAPES study [6]. OSA is an important contributor to the occurrence of EDS in general population [11, 12], and the condition is associated with a two-to sevenfold increased risk for MVA [11, 13, 14]. Crashes due to EDS typically involve running off the road or into the back of another vehicle [15].

Other causes of EDS are insufficient sleep, which is associated with prolonged wakefulness or chronic sleep restriction due to long hours of work or play [16,17], shift work (comprising 7.4% of all those employed), or a variety of medical and neurological disorders [9,18,19].

Epworth Sleepiness Scale (ESS) is the most commonly used tool for subjective sleepiness [20], assessed by eight questions. The total ESS score ranges from 0 to 24; scores below 7 were considered as normal, 8–10 as moderate sleepiness, ≥ 11 –15 was applied to define an elevated risk, whereas ≥ 16 , severe EDS, was considered as high risk of falling asleep in various monotonous situations [11]. Treatment of OSA with continuous positive airway pressure (CPAP) eliminates apneas, reduces daytime symptoms [21], which may reduce the excess MVA risk [12, 22].

Prediction of MVA risk in the European Sleep Apnea Database cohort

The European Sleep Apnea Database (ESADA), started in

2007, is an ongoing clinical and prospective cohort study comprising patients with suspected OSA referred to 25 clinical sleep centers, 21 of them affiliated to universities, in 18 countries [23]. In this cohort, approximately 82% ($n = 6984$ of 8476) were license holders [24]. Of the four previously validated risk factors for MVA history (ESS score ≥ 16 ; habitual sleep time ≤ 5 h; use of hypnotics; annual driving distance $\geq 15\,000$ km), at least one was identified in more than half of the cohort [24]. Predictors associated with severe EDS in a multivariate analysis were age, female gender, BMI, AHI and long driving distance. Importantly, OSA severity was associated weakly with MVA risk factors, and in another validation study from Gothenburg, Sweden, AHI alone did not provide a valid diagnostic marker for MVA risk [22].

New standards and guidelines for drivers with OSA

The increasing awareness about OSA as a risk factor for MVAs, which is reversed by efficient treatment with CPAP, has led to a revision of annex III of the European Union (EU) directive on driving licenses that is subject to mandatory implementation by all member states from December 31, 2015 [25]. This directive was based on the recommendations from a working group established by the Transport and Mobility Directorate of the European Commission in 2012 [26]. As summarized briefly in a recent editorial [27], this directive includes: *a)* Applicants or drivers in whom a moderate or severe OSA syndrome is suspected shall be referred for further authorized medical advice before a driving license is issued or renewed. They may be advised not to drive until confirmation of the diagnosis; *b)* Driving licenses may be issued to applicants or drivers with moderate or severe OSA syndrome who show adequate control of their condition and compliance with appropriate treatment and improvement of sleepiness, if any, confirmed by authorized medical opinion; *c)* Applicants or drivers with moderate or severe OSA syndrome under treatment shall be subject to a periodic medical review, at intervals not exceeding 3 years for noncommercial drivers, and 1 year for commercial drivers, with a view to establish the level of compliance with the treatment, the need for continuing the treatment and continued good vigilance.

Turkish legislation by 26.09.2006

The first legislation regarding OSA and driving license in Turkey was published on September 26, 2006 [28] stating

that: *a)* all driving license applicants with symptoms regarding snoring, witnessed apneas and/or daytime sleepiness; and all commercial driver-license applicants older than 45 years, and those with BMI >25 kg/m² should undergo polysomnography (PSG) before getting a license (and these reports should be renewed every year); *b)* The ones with AHI >15/h should be treated surgically or by CPAP or Bilevel Positive Airway Pressure (BiPAP), and the efficient treatment should be documented on PSG every year [28].

Unfortunately, this legislation has not been in practical use because the number of applicants is substantially greater than the capacity of the sleep centers to test them, and the recommendations have not been realistic.

The revised Turkish legislation by 29.12.2015

In accordance with the EU directive mentioned above [27], the Turkish legislation has newly been revised as following [29]: *a)* Subjects with severe OSA (AHI>30/h), and subjects with moderate OSA (AHI 15-30/h) with documented daytime sleepiness should not get driving license unless this condition is treated; *b)* The efficient treatment should be documented by a committee of 3 medical doctors, of whom one ENT-specialist, and at least one sleep-certified medical doctor (pulmonologist, psychiatrist, neurologist, or ENT-specialist); following issues should be stated in the report: the severity of OSA, response to treatment, compliance with positive airway pressure (PAP) device, and if a commercial driving-license can be given, and if the person can drive ambulance, or official or commercial vehicle; *c)* The applicants with BMI>33 kg/m² should undergo full-night PSG regardless of symptoms; *d)* The applicants with witnessed apneas and daytime sleepiness should undergo full-night PSG regardless of BMI.

Controversies

The increasing awareness about OSA and its consequences on driving is an important step towards increased safety on the road. However, there are several problems with the current, revised legislation in Turkey:

- The practical application of the directive is demanded from the government, and there is yet no standardized approach to implementation of the EU directive through the national legislation in the current form.
- Patients with diagnosed OSA represent only a

very small proportion of a large population with unrecognized and untreated OSA, and the new requirements established by the government would considerably increase the number of requests for specialist evaluation, and lengthen waiting lists for PSG.

- Screening for OSA by using a full-night PSG on a large scale is not feasible. As the legislation from 2006 has not seemed to work in practice, there is a great risk that the situation will be the same even after the current revision, if no concrete, practical steps are taken.
- Although OSA increases the risk of traffic accidents, the disorder is associated with EDS in only one fifth of the patients according to the population studies. The majority of evidence supports the view that driving risk in OSA is more closely related to the degree of daytime sleepiness than the objective severity of OSA in terms of AHI.
- OSA, compared to no-OSA, is associated with a two- to three times increased overall risk for MVAs, but prediction of risk in an individual is too vague.
- In literature, there is no compelling evidence to restrict driving privileges in patients with OSA, if there has not been a motor vehicle crash or an equivalent event.
- Other factors than OSA per se, can contribute to sleepiness in some individuals with OSA, including inadequate sleep time, time of day (early morning and afternoon), shift work, sedative medications, poor sleep hygiene, other sleep disorders, and alcohol intake; and all these additional factors may be particularly important in commercial drivers.
- Subjective EDS in OSA patients is usually assessed by questionnaires, which are subjective, and open for bias by a driver who seeks to underestimate OSA severity, whereas objective evaluation such as Multiple Sleep Latency Test or Maintenance of Wakefulness Test is expensive, time consuming, and not well suited to be performed on a large scale.
- There is no real consensus regarding which ESS score level should be chosen as cut-off for EDS, adapted to Turkish population, in the context of driving risk.
- Patient involvement is particularly important in order to minimize the risk of encouraging OSA patients

to avoid seeking medical attention and treatment because of the understandable concern that such a diagnosis would compromise their ability to continue driving. This risk is particularly important for commercial drivers who depend on a valid driving license for their living.

- In literature, there is no evidence that high BMI is associated with increased risk for MVAs, except its indirect contribution (risk for OSA); and the current BMI cut-off level 33 (instead of the previous 25 kg/m²) for PSG indication is arbitrary, and cannot be justified.

How to define a high-risk driver?

Though there is no consensus regarding the definition of “a high-risk driver”, the report from the American Thoracic Society (ATS) suggests that a high-risk driver is the one who has moderate to severe daytime sleepiness, and a recent unintended motor vehicle crash or a near-miss attributable to sleepiness, fatigue, or inattention [15].

Future perspectives

According to the ATS recommendations [15], all patients being initially evaluated for suspected or confirmed OSA should be asked about daytime sleepiness (i.e., falling asleep unintentionally and inappropriately during daily activities) as well as recent unintended MVAs or near-misses attributable to sleepiness, fatigue, or inattention. Patients with these characteristics are deemed high-risk drivers and should be immediately warned about the potential risk of driving until effective therapy is instituted. It is also recommended that clinicians should routinely inquire about additional causes of sleepiness (e.g., sleep restriction, alcohol, or sedating medications), comorbid neurocognitive impairments (e.g., depression or neurologic disorders), and diminished physical skills as part of the assessment of driving risk. Such factors may additively contribute to crashes due to falling asleep and affect the efficacy of OSA treatment.

In clinical practice, information that should be routinely elicited during an initial visit for patients with suspected or confirmed OSA should include the clinical severity of the OSA, driving risk, and therapies that the patient has received, including behavioral interventions. At subsequent visits, adherence and response to therapy should be assessed, and the drowsy driving risk should be reassessed if it was

initially increased. For patients who have suspected or confirmed OSA, it's also important to educate patients and their families about drowsy driving and other risks of EDS as well as behavioral methods that reduce those risks [15].

For patients in whom there is a high clinical suspicion of OSA and who have been deemed high-risk drivers, a full-night PSG should be performed and, if indicated, treatment initiated as soon as possible. However, due to the limitation of sleep centers with PSGs and waiting lists, at-home portable monitoring is a reasonable alternative to PSG for subjects with high clinical suspicion of OSA. The portable devices are widely used globally, and are recommended according to a final consensus report by the ATS, the American Academy of Sleep Medicine, the American College of Chest Physicians, and the European Respiratory Society [31]. This alternative approach should be considered even in Turkey by the national Social Security Institution. A Turkish study by Firat and colleagues [32] suggesting that portable sleep monitoring is reliable in detecting OSA with AHI>15/h in highway bus drivers is important in this context.

Given the controversies regarding the relationship between OSA severity and MVA risk in clinical cohorts versus the lack of an association between AHI and MVA risk in commercial drivers [30, 33], there is also a need for development of screening tools for objective evaluation of EDS in such individuals. The Oxford Sleep Resistance (OSLER) Test [34] as well as a recently developed neurocognitive test, Gothenburg Sleep Resistant (GOSLING) Test seem to be less time-consuming and reliable tools to detect attention deficits in OSA patients with high MVA risk [35].

Conclusions

Sleepiness is an important contributing factor to traffic accidents, and the most common medical disorder causing sleepiness is OSA. Available data suggest that efficient treatment of OSA may reduce risk for MVA-related deaths and injuries. The Turkish legislation has recently been revised for regulation of driving license issues for individuals with OSA. There are still many controversies and difficulties in implementation of these rules in practice. A full-night PSG is recommended and treatment should be initiated as soon as possible when the OSA diagnosis is confirmed. Portable cardiorespiratory sleep monitoring is a reasonable alternative to PSG for appropriately selected patients with high clinical suspicion for OSA, rather than no-PSG, and no treatment.

Additional attempts for development of national guidelines for determining the driving risk as well as development of new screening tools for objective evaluation of sleepiness in drivers with suspected or confirmed OSA are urging.

Declaration of interest

The author reports no conflict of interest.

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