

## Sleep disorders and driving licence: the current Italian legislation and medico-legal issues

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### Abstract

Road traffic accidents (RTA) are a serious issue in all industrialized countries and have dramatic social and healthcare-related implications. Fatigue (sleepiness) is the principal identifiable and preventable cause of road traffic accidents. Obstructive sleep apnoea syndrome (OSAS) and narcolepsy are two of the leading causes of excessive daytime sleepiness. In this article, the authors analyze the current Italian legislation regarding driving licence issuance and fitness to drive, in order to evaluate the potential implications of sleep disorders, particularly OSAS and narcolepsy. In European Legislation and in Italy, OSAS and narcolepsy are not included among the illnesses or invalidating conditions that limit the fitness to drive for driving licence issuance purposes. In fact, they are not included in the Annex III of the European Council Directive 91/439/EEC of the 29th of July 1991 on driving licences. Some Countries of the European Union (Belgium, France, Finland, Great Britain, the Netherlands, Spain and Sweden) had implemented the 91/439/EEC Directive with national restrictions on driving licence issuance policies in case of OSAS and narcolepsy. Given the well-established scientific evidence available, in Italy, the lack of legislation regulating the assessment of the psychophysical requisites for the issuance and renewal of driving licences of individuals affected by sleep disorders seems extremely worrying. Furthermore, the current lack of legal obligation in Italy for healthcare facilities to disclose such diagnoses to the organs responsible for issuing driving licences (such as the Motorizzazione Civile - the Department of motor vehicles) remains the subject of heated debate. *Clin Ter* 2014; 165(5):e368-372. doi: 10.7417/CT.2014.1766

**Key words:** driving licence, medico-legal evaluation, narcolepsy, OSAS

### Introduction

Road traffic accidents (RTA) are a serious issue in all industrialized countries and have dramatic social and healthcare-related implications. In 2011, 205,638 road traffic accidents resulting in personal injury were recorded in Italy; the number of fatalities within 30 days from the accident was 3,860, while a total of 292,019 injuries were documented (1).

Data collected by the *Automobile Club Italia* suggest that stress, excessive daytime fatigue and sleepiness increase the risk of road traffic accidents. Fatigue (sleepiness, tiredness) is the principal identifiable and preventable cause of road traffic accidents, with fatigue-related accidents surpassing the incidence of alcohol- or drug-related incidents in all types of transportation (2). Recent studies have found that fatigue-related road crashes in the USA account for 1.2 million accidents and 500,000 injuries each year, including 60,000 debilitating injuries and 8,000 fatalities (3). Fatigue can be defined as deteriorating performance over time, with diminished energy and attention levels accompanied by feelings of sleepiness or tiredness. Sleepiness is characterized by a difficulty in remaining awake, even while engaged in activities, and is controlled by the circadian and homeostatic processes (4). Sleepiness can be associated with fatigue, and can therefore affect some, but not all, aspects of the latter. Excessive Daytime Sleepiness (EDS) is defined as an unexpected drowsiness manifesting in a situation in which the sufferer is expected to be alert and awake; it can be caused by physiological factors: shift work, leisure time excesses (physical activities, binge drinking, irregular sleeping patterns), age or pathological conditions (narcolepsy and obstructive sleep apnoea syndrome, voluptuary habits, use of sleep-inducing drugs) (5). The prevalence of EDS is estimated to be between 4 and 20%; the incidence is steadily increasing due to several factors: 1) general lifestyle changes; 2) working hour variations; and 3) the increased incidence of predisposing pathological conditions, such as obesity (6). Epidemiological studies have shown that up to 20% of all road traffic accidents in industrialized countries are sleep-related and driving while drowsy has been identified as the leading cause of fatal road crashes (7). Road traffic accidents involving sleepiness have high morbidity and mortality rates, due to their typical characteristics. Particularly, these types of accidents usually occur around midnight and in the afternoon, corresponding to two circadian peaks in sleepiness. Moreover, such accidents usually happen in high-speed roads and most frequently involve only one vehicle running off the road (8). Studies on sleepiness indicators during driving have revealed sleep intrusions in

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the waking EEG or EOG during driving, mainly associated with night driving or sleep deprivation, as well as subjective sleepiness (9). These findings become even more significant when one takes into account the large number of drivers who fall asleep while driving without causing accidents. Even though the prevalence of driving while drowsy appears to vary substantially between countries, possibly due to geographical differences, the overall rates are notable. In a UK survey of 4,600 drivers, 29% of participants admitted to having been close to falling asleep at the wheel in the preceding 12-month period, and company car drivers were found to be more likely to be involved in sleep-related driving accidents; in the USA, 29% of drivers reported actually sleeping or nodding off during the preceding 12 months, while according to Norwegian drivers who had been involved in road accidents, sleepiness behind the wheel contributed to 1.9-3.9% of the reported accidents (10). In 2003, the EU promoted a meta-analysis that highlighted the finding that narcolepsy and obstructive sleep apnoea syndrome (OSAS) sufferers are at the highest risk of being involved in road traffic accidents (Relative Risk (RR) = 3.7) among the medical conditions, diseases and impairments included in the Council Directive 91/439/CEE of 29th of July 1991 on driving licences, in comparison with subjects who had used sleep-inducing drugs (RR: 1.54) or cannabis (RR: 1.70) (11). In this article, we analyze the current Italian legislation regarding fitness to drive and driving licence issuance, in order to evaluate the potential implications of not having included sleep disorders, in particular OSAS and narcolepsy.

#### **Obstructive sleep apnoea syndrome (OSAS)**

Obstructive sleep apnoea syndrome is a chronic nocturnal respiratory disorder with a prevalence of 1-5% in subjects with normal weight, while in obese subjects the prevalence can be up to 30% (12).

The basic pathogenetic mechanism of this condition involves cyclical interruptions in the subject's breathing pattern, leading to the absence of air flow, caused by obstruction of the upper airways during sleep. OSAS is characterized by the coexistence of daytime (sleepiness, headache and dry mouth in the mornings, concentration difficulties) and nighttime symptoms (snoring, nocturia, feeling of suffocation, fragmentation of sleep) (13, 14). The diagnosis of OSAS involves the evaluation of clinical symptoms, predisposing factors (obesity, acquired or congenital craniofacial malformations, macroglossia) and the results of a nocturnal polysomnography. In the latter, the severity of OSAS is classified using the apnoea-hypopnoea index (AHI), that represents the number of episodes per hour of sleep, as follows: mild, AHI of 5-15; moderate, AHI of 15-30; and severe, AHI of >30 (15). The continuous alternation of respiratory events (apnoeas/hypopnoeas), nocturnal desaturations and arousals (micro- and macro-arousals) are responsible for short-term consequences, such as changes in alertness levels due to non-restorative and fragmented sleep, and potential long-term consequences caused by cardiorespiratory complications (dilated cardiomyopathies, heart attack and stroke, high blood pressure, fatal arrhythmias, respiratory failure) (16-18). Multicentric studies have confirmed that Excessive

Daytime Sleepiness (EDS) that can be measured with the Epworth Sleepiness Scale (ESS) is a subjective symptom that is not correlated with the severity of the disease. EDS may improve significantly with the use of the Continuous positive airway pressure (CPAP) machine (19, 20). A study conducted in Italy and funded by the Italian Ministry of Health estimated that road traffic accidents involving subjects with OSAS cost the public health budget 800,000,000 Euros each year (21).

#### **Narcolepsy**

Narcolepsy is a rare disorder with an prevalence rate of five cases per 10,000 inhabitants. Above all, this is a widely misunderstood illness, often confused with epilepsy, chronic fatigue syndrome, obstructive sleep apnoea syndrome and psychiatric disorders. Patients are correctly diagnosed after an average of seven years from the onset of symptoms (22). The etiology of narcolepsy is currently unknown and the disorder is characterized by excessive daytime sleepiness, typically associated with cataplexy and other phenomena caused by irregular REM patterns, such as hypnagogic hallucinations and sleep paralysis (23). The symptoms include: 1) excessive daytime sleepiness with frequent daily sleep episodes that cannot be avoided and, at times, predicted; 2) cataplexy, a rapid loss of muscle tone caused by emotional manifestations such as laughter, anger, excitement and surprise; 3) hypnagogic hallucinations, intense and vivid sensory experiences, which can sometimes be frightening; and 4) disturbed nocturnal sleep (24). The main neurophysiological aspect, characteristic of narcolepsy, is a rapid and atypical emergence of REM sleep within 15-20 minutes of falling asleep. The daytime sleep attacks typically occur every 90-120 minutes, and the patients often recall dreaming and feel relatively well rested upon awakening from a short, 5-15 minute sleep (25).

#### **Sleepiness evaluation methods**

The current gold standard sleepiness index is the Multiple Sleep Latency Test (MSLT), but this assessment is costly and time-consuming. Another test that requires much less time and expense is the Epworth Sleepiness Scale (ESS), a self-reporting instrument for measuring a patient's perception of sleepiness. Guidelines for the clinical management of obstructive sleep apnoea syndrome (OSAS), narcolepsy, and insomnia recommend the use of ESS, and it has also been employed in various occupational and community-based studies (26). The ESS is a self-administered questionnaire, in which the patient is asked to assign scores ranging from 0 to 3 in response to common occurrences during his/her habitual daily activities, for example sleepiness while driving, reading, watching a play at a theatre or after lunch. A final score of over 10 implies excessive daytime sleepiness. The main limitation of this test, commonly used in the screening of OSAS, is the poor correlation of the score with the severity of the disease. A wide range of variability has been recorded in the questionnaire score in patients with the same disease severity level (27). This variability causes some difficulties in

diagnosing mildly symptomatic OSAS patients. The MSLT, on the contrary, is a test for the assessment of sleepiness mainly used for patients with suspected narcolepsy. The test is carried out on the day following a nocturnal polysomnography of at least six hours, and involves an objective assessment of the quality of nocturnal sleep. The test procedure consists of five electroencephalographic recordings with a duration of 20-30 minutes each, two hours apart, in a quiet and dark environment (28). The sleep onset latency is evaluated by electroencephalographic criteria and expressed as the time elapsed between lights out and the first epoch of sleep. If the patient remains awake, the recording may be stopped after 20 minutes. The International Classification of Sleep Disorders recommends considering the sleepiness moderate/severe if the sleep onset latency of the patient is less than 10 minutes (29).

## Discussion

Several European and international studies have established that individuals with sleep disorders are at an increased risk of being involved in road traffic accidents in comparison with the unaffected population. OSAS, in particular, is associated with this risk more than any other pathological condition (30). Both at the European level and in Italy, OSAS and narcolepsy are not included among the illnesses or invalidating conditions that limit the fitness to drive for driving licence issuance purposes. In fact, they are not included in the Annex III of the European Council Directive 91/439/EEC of the 29th of July 1991 on driving licences, which lists the medical examinations and other measures, including restrictions, to be implemented in cases of drivers affected by illnesses or disabling conditions that may impair their fitness to drive. This directive was adopted in Italy on the 28th of June, 1996 with a Ministerial Decree that endorsed its regulations related to fitness to drive and driving licence issuance as detailed in the prior Presidential Decree 485/92, integrating the content of the latter with some parts of the Annex III of the Directive, without introducing specific restrictions for drivers affected by sleep disorders, such as done by other European countries. Even with the adoption of the 2000/56/CEE Directive through the Ministerial Decree 30th August 2003, and the subsequent adoption of the 2006/126/CE Directive with the Legislative Decree 59/11, these pathological conditions were not currently considered as disabling or limiting for driving licence issuance purposes in Italy. In 2005, a similar legislative oversight subsisted in seven (Austria, Denmark, Germany, Greece, Ireland, Luxembourg and Portugal) of the fifteen member countries of the European Community. The remaining countries (Belgium, France, Finland, Great Britain, the Netherlands, Spain and Sweden) had, by then, adopted the 91/439/EEC Directive with national restrictions on driving licence issuance policies in case of OSAS and narcolepsy, while Germany had introduced similar measures for OSAS. Among the most recent EU members, Hungary and Poland currently have restrictions in place for driving licence issuance to individuals with OSAS, while the Czech Republic and Slovakia have introduced specific regulations regarding subjects affected by narcolepsy. However, a more

careful analysis of the current legislation in all of the aforementioned countries reveals that the regulations are rather generalized and the evaluation criteria for fitness to drive and the validity period of the driving licence for OSAS and narcolepsy sufferers are not very consistent. Above all, the various national regulations include poor details in regards to the criteria and methods, clinical and instrumental, used to not only assess the severity of the disease, but also the potential improvements in the subject's condition after treatment (30). International regulations outside the EU are also affected by such legislative oversights, in some cases related to limited healthcare access, associated with the delay between the initial diagnosis and treatment in some countries, and finally, with the scarce availability of reliable assessment methods for the evaluation of sleepiness (31). In this context, the work carried out by the Italian Association of Sleep Medicine (AIMS), the Ministerial Committee on road safety, sleepiness and transport, and the Association of forensic physicians working in public healthcare (COM-LAS) culminated, in 2010, with the publication of Italian guidelines involving four risk classes based on a clinical assessment for narcolepsy sufferers and on a clinical evaluation, medical history analysis (previous episodes of falling asleep at the wheel), nocturnal polysomnography (severity assessment) and compliance with night-time ventilation therapy (for at least 4 hours per night) for individuals with OSAS (32). For OSAS, these guidelines recommend an assessment of the use of the CPAP (Continuous Positive Airway Pressure) machine, for at least 4 hours per night, to identify at-risk individuals in order to reduce the risk of accidents among the general population. In particular, the guidelines state that an applicant affected by OSAS cannot be considered fit to drive if he/she: has experienced an episode of falling asleep at the wheel of a motor vehicle during the past six months in the case of renewal of driving license has had a road accident caused by sleepiness during the past six months; is being treated with CPAP for less than four hours/night. When OSAS is suspected, according to the guidelines it would be opportune to advise the subject to avoid driving motor vehicles, or even to declare him/her unfit to drive. These restrictions should remain in place until polysomnography results are obtained, and the subject has been treated for at least one month with the CPAP; when an oral appliance is used, the fitness to drive certification may be granted for up to one year. For individuals with narcolepsy, the evaluations proposed by the guidelines are based on the consideration that this is a disorder with a great variability in driving simulation performance among affected subjects, and that narcoleptic subjects, once diagnosed and informed about the risks to which the disorder exposes them, generally take adequate precautions to avoid driving accidents. The guidelines for narcolepsy have been formulated mainly to promote specific restrictions for affected professional drivers, who should be considered unfit to drive, apart from exceptional cases. For all other driving licence categories, the objective is to minimize the risks to the affected individuals and other road users, while guaranteeing an adequate level of independence and the possibility to manage regular working activities (33). In light of these considerations, a recent ruling of the Administrative Court of the Italian Region of Lazio (3<sup>rd</sup> Section of 05/09/2012),

in which the judge reasserted the authority of the relevant organs to re-evaluate the mental and physical fitness to drive of sleep apnoea sufferers, is of particular interest. Specifically, this “historic, innovative, revolutionary and highly prospective” ruling rejected the appeal of a driver who was found by the police while sleeping in his car, which was stopped in the emergency lane of the motorway, posing a significant risk to road safety. The appellant justified his actions to the agents by telling them he suffers from OSAS, and was subsequently obliged to have his driving licence application re-evaluated and to undergo a medical examination, which led to his court appeal against the imposition of these procedures. Therefore, the Molteni bill presented on the 31st of May, 2013, seems particularly timely and urgent. This draft calls for the insertion of a paragraph 2 - c to the Article 119 of the Italian Highway Code, stating that “at the first issue of a driving licence of any class, or the certification for professional driving licences for categories D1 and D (the D1 and D licences are those of bus drivers) and the driver qualification card (DQC) for transporting people, and the certificate of fitness to drive as described in Article 118, the applicant must present relevant certification stating that he/she does not suffer from breathing problems while sleeping and obstructive sleep apnoea syndrome (OSAS), to be issued after a clinical assessment following the regulations established by a decree of the Ministry of Health, in collaboration with the Ministry for Infrastructure and Transports ... the certification must be presented by the applicants identified in this article when reapplying for, or renewing their driving licence”.

## Conclusions

Given the well-established scientific evidence available, the lack of legislation regulating the assessment of the psychophysical requisites for the issuance and renewal of driving licences of individuals affected by sleep disorders seems extremely worrying. Furthermore, the current lack of legal obligation in Italy for healthcare facilities to disclose such diagnoses to the organs responsible for issuing driving licences (such as the Motorizzazione Civile - the Department of motor vehicles) remains the subject of heated debate. The paradox of the current legislation is clear in situations in which the affected individual benefits from the assistance offered by the National Healthcare System for ventilation therapy, while no official report is filed with indications about the subject’s fitness to drive. In the wake of the Molteni bill, the aspiration is to make sleep-related pathology assessments mandatory for professional drivers of all licence categories, and possibly even more generally for the working population, especially shift workers, in order to reduce the number of work accidents in subjects affected by narcolepsy or OSAS.

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