Medico-legal implications of respiratory disorders during sleep

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Abstract: Sleep-related breathing disorders are the most frequent medical cause of daytime sleepiness. Obstructive sleep apnea syndrome (OSAS) has been demonstrated to significantly increase safety and health risks and has been associated with a high risk for motor vehicle accidents, probably the highest of all risks due to medical conditions. Treatment of patients with obstructive sleep apnoea with continuous positive airway pressure (CPAP) is effective as it reduces both apnoeas during the night and sleepiness during the day and improve quality of life. The primary task of the physician is proper diagnosis, therapy and counseling. All professional drivers with excessive daytime sleepiness as well as uncooperative or therapy resistant drivers should be referred to a sleep disorder centre for objective measurements of excessive daytime sleepiness and assessment of driving capability. Given the high prevalence of breathing disorders during sleep in the general population, and the evidence that treatment decreases the risk of accidents, it seems legitimate to try and reduce the occurrence of sleepiness-related accidents in affected patients by regulating the access to a driving license in those patients.

Key words: sleep apnea, driving legislation

The concept of sleep has changed dramatically in modern society. Although sleep problems are experienced as inconvenient, they are often not viewed as a medical problem and only a minority of persons with sleep disturbances consult their physicians and receive medical attention [1]. Poor sleep quality may result in reduced quality of life. Up to 10% of healthy people complain about sleepiness during daytime [2]. Excessive daytime sleepiness is one of the major complaints of people with sleep disturbances since it may be reflected in altered mood and behavioral impairment. Reduced performance becomes of public concern when subjects with excessive daytime sleepiness are involved in potentially dangerous daily activities (reduced productivity and injuries at work or while driving a motor vehicle), which may lead to severe consequences for the afflicted and society in general.

The causes of excessive daytime sleepiness (EDS) are manifold. Otherwise healthy people may suffer from excessive daytime sleepiness due to sleep reduction, shift work or lifestyle-dependent unwise sleep-wake rhythm. On the other hand a number of sleep disorders such as sleep apnea syndrome, narcolepsy and use of sedative drugs are well-known causes of excessive daytime sleepiness [2].

Obstructive sleep apnea syndrome (OSAS) is a condition characterised by repetitive obstruction of the upper airway, often resulting in oxygen desaturation and arousals from sleep. [3,4]. Patients with severe sleep apnoea often tend to fall asleep during the daytime, which is a natural consequence of the sleep disruption resulting from repeated apneas (usually several hundred per night). OSAS represents the most common organic cause of excessive daytime sleepiness.

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The prevalence of OSAS is highest among males aged 40–59 yrs, being 4–8%, and is less common among females (2%) and those in the younger and older age groups [2]. The most significant medical consequences include increased risk of hypertension, coronary disease, congestive heart failure, stroke, glucose intolerance and a significant cardiovascular morbidity and mortality. Also OSAS has been associated with a high risk of automobile accidents and injury in the workplace[4]. The disease is treatable and usually respond very well to the home use of nocturnal continuous positive airway pressure (CPAP).

**Sleep apnea diagnosis**

The presence of certain physical characteristics should heighten the physician's suspicion of upper-airway dysfunction during sleep. An increased body-mass index, hypertension and an increased neck circumference are often characteristic of patients with sleep apnea.

Nocturnal symptoms in OSAS patient are snoring, usually loud, witnessed apneas, gasping and choking sensations that arouse the patient from sleep, restless sleep, frequent arousals, nocturnal esophageal reflux, and nicturia . daytime symptoms are excessive sleepiness , morning headaches, cognitive impairment, depression [4]. EDS is most frequently assessed by a physician using the Epworth Sleepiness Scale (ESS) which is a simple, self administered questionnaire providing a measurement of the subject's level of daytime sleepiness. This questionnaire is used to determine how frequently the patient is likely to fall asleep in 8 frequently encountered situations. An ESS score greater than 12 is associated with a greater probability to fall asleep. Another screening tool is the Berlin questionnaire, used to classify subjects who are at high risk and low risk for OSA by identifying snoring behavior, daytime sleepiness, obesity and hypertension. This tool has reasonable sensitivity, specificity and positive predictive value in a primary care population [3,4,5].

Overnight pulse oximetry is another method to screen sleep apnea. Positive overnight pulse oximetry was defined as greater than 10 short-duration fluctuations of SpO2 per hour of sleep.

The gold standard for diagnosis of OSAS is nocturnal polysomnography. This test measures different physical and physiological parameters while a subject is asleep and includes: electroencephalogram (EEG) - monitors brain waves, an electro-oculogram (EOG) monitors eye movements, electromyogram (EMG) monitors muscle activity, measurement of oral and nasal airflow, chest and abdominal movements, air movements, and blood oxygen saturation, audio recording of snoring and video monitoring. According to the apnea-hypopnea index (AHI), OSAS is classified in mild (5-15/h), moderate (16-30/h) and severe (>30/h) [4,8].

Another option for diagnosing OSAS is the nocturnal respiratory poligraphy with some advantages that includes its convenience (it can be performed in the patient's home or in a hospital room) and its lower costs. A disadvantage is that fewer physiologic variables are measured and it cannot detect arousals from sleep [10]. After completion of one of the mentioned questionnaires, the patient found with a high score should be addressed to a sleep laboratory for further evaluation with a Multiple Sleep Latency Test (MSLT). This test measures how fast someone falls asleep during the day. Normal time would be greater than 10 minutes to fall asleep, while excessive sleepiness is less than five minutes [4].

**Treatment of sleep apnea**

Continuous positive airway pressure (CPAP) is the most effective and most widely used treatment for OSAS. This approach is a treatment, not a cure, and the device must be worn every night. Despite being a very effective treatment for sleep apnea, adherence to CPAP therapy remains problematic. About 50% of people who start CPAP will not use it 1 year later. [11].

CPAP restores a normal sleep pattern and therefore helps protect from the severe health risks: reduce rate of death due to heart disease, may reduce these high blood pressure levels in people with sleep apnea, may help protect from heart problems and reduce mortality, can improve insulin sensitivity in people with type 2 diabetes and OSAS. Treatment with nasal CPAP reduces crash risk to levels seen in the population at large, only when patients are compliant with treatment.
Other treatment options for patients with mild or moderate OSAS are nose, throat and maxillo-mandibular surgery and oral devices [4,8]. In association with the others therapy methods weight loss is mandatory in overweight and obese patients.

**Association of sleep apnoea with road traffic accidents**

Obstructive sleep apnea has been associated with a high risk for motor vehicle accidents, probably the highest of all risks due to medical conditions [13]. Research conducted in countries such as Spain, the United States, Switzerland, Germany, France, Canada, Japan or Australia have all found a significant excess of road traffic accidents caused by patients suffering from OSAS, compared with healthy control subjects (Barbe et al., 1998; Cassel et al., 1996; Findley et al., 2000; George, 2001; Horstmann et al., 2000; Howard et al., 2004; Masa et al., 2000; Teran-Santos et al., 1999; Yamamoto et al., 2000; Young et al., 1997). [14]. Across all studies, the risk of road traffic accidents for patients OSAS, compared to the general population, is increased by about a factor of 3. Treatment of OSAS with CPAP during sleep, if adequately used by patients, reduces the increased risk of motor vehicle accidents (MVA) to the one seen in the general population. [14, 15].

“Fall asleep crashes” have typical characteristics including:
- the problem occurs during late night/early morning or mid afternoon;
- the crash is likely to be serious;
- a single vehicle leaves the roadway;
- the crash occurs on a high speed road;
- the driver does not attempt to avoid a crash;
- the driver is alone in the vehicle.

**Professional consequences of sleep apnea**

Patients with OSAS frequently complain of chronic fatigue, drowsiness impaired concentration and memory, loss of efficiency with the following consequences [4]: falling asleep in meetings, forgetting important calls, loss of documents, misuse and errors, difficulties in attention and career break. It is therefore particularly important to take care of these patients avoid these significant professional implications. Krieger et al. [7] demonstrated a higher frequency of domestic and occupational accidents in patients with OSAS compared to the general population and a reduction in the accident rate following introduction of CPAP therapy.

**Medicolegal aspects**

OSAS is a significant independent risk factor for traffic accidents, with important consequences for public safety, particularly since accidents involving a patient with OSAS are more likely to be associated with major injury.

1. **European Union (EU) legislation**

In the EU, a minimum set of rules for determining the ability to drive was established in 1991, under Annex III to the Directive 91/439/EEC on Driving License Regulations (European Commission, 1991). OSAS is not covered in this document, despite its high association with traffic accidents. A few countries have introduced OSAS in their own Physical Fitness to Drive rules. Between 1998 and 2000, only 6 out of 15 countries had enacted this within their national legislation [3]. More recently, a second attempt for introducing sleep disordered breathing in the driving legislation was undertaken by a working group of COST Action B-26, a European Union financed cooperation project [19]. Nevertheless, only 10 countries had mentioned OSA in their Fitness to Drive national legislation. The Group also discussed the most pragmatic way to implement the screening process for OSA during the driving license renewal process. Ideally, this screening should be every 5 years. The implementation of this scheme is mandatory by 2010 (European Commission, 2003). The Working Group considered it essential to include sleep–wake education in this program [16, 17, 19]. During the diagnostic and therapy, drivers might still be considered able to drive, but with limitations (e.g. short distances, no driving on major highways or at night, etc). On the other hand, they could be declared unfit to drive if sleepiness is judged to be too severe. After effective treatment, with adequate CPAP and / or other therapies, including regular check-ups for symptom control, then driving could continue. A traffic
accident implies different kinds of problem: medical, juridical. Communications problems are present too, when a foreign element appears. In this case, a juridical major problem consists in finding out applicable law. When a traffic accident occurs in a Member State of EU, a problem like this is solved by the Regulation (EC) no.864/2007 of the European Parliament and of the Council on the law applicable to non-contractual obligations (Rome II) [18]. In conclusion, after 20 years of medical and scientific research, the effects of OSA on traffic accidents are apparent. Only a handful of countries have acknowledged the importance of this matter, and have adopted reasonable actions [17].

2. American legislation

In 1991 an expert panel of the Federal Highway Administration recommended that drivers with suspected or untreated sleep apnea "not be medically qualified for commercial motor vehicle operation until the diagnosis has been eliminated or adequately treated" [16]. The panel also recommended that commercial drivers who are being treated for sleep apnea must continue therapy as long as they maintain their commercial driver's licence and undergo a yearly Multiple Sleep Latency Test [19].

In 1994, the American Thoracic Society recommended that as a minimum, physicians treating patients with sleep apnea should report to the state departments of motor vehicles drivers with severe daytime sleepiness who had had a motor vehicle accident or a near miss and who continue to drive without adequate treatment [21]. Some states had no rules for dealing with sleepy drivers. Others, such as California, have tried to integrate the information available from physicians and information on accidents that is available from the motor vehicle department.

| Screening recommendations for commercial drivers with possible or probable sleep apnea |
|---------------------------------|-------------------------------------------------------------------------------------------------|
| **Medically qualified to drive commercial vehicles if driver meets either of the following:** | **In-service evaluation recommended if driver falls into any one of the following five major categories (3-months maximum certification):** |
| No positive findings or any of the numbered in-service evaluation factors | Sleep history suggestive of OSAS (snoring, excessive daytime sleepiness, witnessed apneas) |
| **Out-of-service immediate evaluation recommended if driver meets any one of the following factors:** | 1. Observed unexplained excessive daytime sleepiness (sleeping in examination or waiting room) or confessed excessive sleepiness |
| Diagnosis of OSAS with continuous positive airway pressure compliance documented | Two or more of the following (1) body mass index > 35 kg/m²; (2) neck circumference > 17 inches in men and 16 inches in women; (3) hypertension (new, uncontrolled, or unable to control with fewer than two medications) |
| 3. Epworth sleepiness scale score > 10 | 2. Motor vehicle accident (run off road, at fault, rear-end collision) likely related to sleep disturbance unless evaluated for sleep disorder in the interim. |
| 4. Previously diagnosed sleep disorder; compliance claimed, but no recent medical visits/compliance data available for immediate review (must be reviewed within 3-month period); if found not to be compliant, should be removed from service (includes surgical treatment) | 4. Previously diagnosed sleep disorder (1) noncompliant (continuous positive airway pressure treatment not tolerated); (2) no recent follow-up (within recommended time frame); (3) any surgical approach with no objective follow-up |
| 5. Apnea-hypopnea index > 5 but < 30 in a prior sleep study or polysomno-graphy and no excessive daytime somnolence (Epworth sleepiness scale score < 11); no motor vehicle accidents; no hypertension requiring two or more agents to control | 5. Apnea hypopnea index > 30. |
California requires physicians to report all persons who have "a disorder characterized by lapses of consciousness," a phrase that has been interpreted to include excessive daytime sleepiness. The state evaluates these reports and decides whether the condition is controlled and stable (in which case no action is taken), controlled but unstable (in which case the person is allowed to drive but is reviewed every three or six months), or not controlled (in which case the person's license is suspended).

The message that it is dangerous and irresponsible to drive when one is sleepy should be emphasized in all driver-education courses and publicized by state regulatory agencies. In many states, drivers with known but untreated sleep apnea who have an accident may be liable for negligence [21]. The Federal Aviation Administration has rules requiring pilots with sleep apnea to be treated effectively and to be evaluated annually with overnight polysomnography and the maintenance-of-wakefulness test. The rules specify that acceptable treatment includes surgery or nasal CPAP. Yearly status reports are required for pilots who are treated with CPAP [4].

**Recommendations regarding the evaluation for fitness for duty for commercial drivers with possible or probable sleep apnea**

1. Diagnosis should be determined by a physician and confirmed by polysomnography or poligraphy, preferably in an accredited sleep laboratory or by a certified sleep specialist.

2. First-line treatment for commercial motor vehicles (CMV) drivers with OSAS should be delivered via positive airway pressure machine that is able to measure time on pressure. A minimum acceptable average use of CPAP is 4 h within a 24-h period, but longer treatment would be more beneficial. An apnea-hypopnea index < 5 is acceptable for CPAP treatment follow-up.

**Education and prevention**

Education remains an important point to any risk management. We must continue to educate the public and industry about the dangers of drowsy driving, whatever the cause, and educate governments and insurance companies about the need to support the diagnosis and treatment of sleep apnea [19].

The physician is expected to diagnose sleep apnea and assess the patient’s risk for crashes. The patients must be informed of these risks and institute promptly the appropriate treatment. In addition, the physician must have a follow-up plan in place to determine if the treatment has decreased the patient’s risk for crashes. Because not all patients with apnea are sleepy or have crashes, more data are needed for society to establish and accept a “safe” sleep apnea cutoff for driving, similar to that for alcohol. In simplistic terms, we could reduce crash risk from sleep apnea to zero simply by removing all untreated patients with sleep apnea from the road. In practical terms, however, this is neither possible nor justifiable—either ethically or on the basis of current data. In previous studies, up to two-thirds of clinic patients with sleep apnea never have any objective evidence of crashes.

If we were to restrict their driving simply because of a diagnostic label (their condition may make it dangerous to operate a motor vehicle), then we should surely do the same for every other condition that may cause some impairment in daytime function (e.g., a sleepy nightshift worker). Society has established and accepted a clear cutoff for driving impaired by alcohol, recognizing that a blood alcohol concentration of 0.08% does not have perfect predictive value—some individuals are impaired well below this level whereas a few others are not as impaired at this or a higher level. We must also become comfortable with some sort of cutoff in terms of sleep apnea, recognizing that, in noncommercial drivers, we will reduce but not eliminate the risk completely. The difficulty with this concept is the lack of an accurate metric in quantifying severity of sleep apnea. Despite its imperfection as an overall measure of disease severity, the AHI is an accepted marker for risk of hypertension and other cardiovascular disease. But can we or should we use this as a cutoff marker for driving in sleep apnea? [3].

Specific regulations for licensing that would exclude sleepy subjects from access to a driving license pose many questions. Philosophically, the choice is between individual freedom and the protection of society against a potential risk. This choice of society has been handled in different ways in different countries, but obviously the debate is still open in many places. Morally, such regulations pose the question of how licensing authorities will obtain the relevant information. The choice is
between relying on the driver's honesty, which is open to cheating, or on a third party, usually a doctor, to provide a certificate of medical competence. In this regard, it may be difficult for the patient's own physician to provide a negative certificate or for an external doctor to gather the relevant information. Economic considerations indicate that the cost of sleepiness-related accidents should be compared to the cost of unemployment/decreased quality of life due to the loss of a driving license, but such comparisons have never been made [3].

Ethically, the dilemma of driver certification in OSAS poses the question of medical power versus medical responsibility. Clearly, specific regulations might give doctors the power to prevent sleepy drivers from driving, which might enhance the general recognition of Sleep Medicine and of Sleep Centres. However, the criteria that could be used to decide a driver's medical fitness before or, even more so, after treatment are not yet clearly established, particularly in view of the difficulties in the objective evaluation of sleepiness. Furthermore, the reality is that the diagnosis of OSAS is usually made after months or years of sleepy driving, and often after an accident (or a near-miss). Therefore, education of nonspecialised doctors and the general population in the recognition of the disorder would appear to be at least as important as issuing specific regulations. It also poses the question of the confidence between patients and doctors. The risk exists that if the doctor is allowed to report a given patient to the licensing authorities, patients will be tempted to hide their symptoms and not go to the doctor. One could argue that it is better to treat a confident patient without declaring the disorder to the authorities than to deal with a suspicious and uncooperative patient [3, 14, 17].

It is imperative that primary care clinicians become more familiar with sleep apnea. Not only is it a common disorder, but if sleep apnea is overlooked or the diagnosis delayed, it can lead to long-term health consequences and the propagation of sleep apnea.

References
2. Mathisa J., Seegerb R., Ewert U.: Excessive daytime sleepiness, crashes and driving capability
3. McNicholas W.T. and Krieger J. on behalf of the Task Force members : Public health and medicolegal implications of sleep apnoea
10. Collop N.: Portable monitoring in obstructive sleep apnea in adults; UpToDate, October 14, 2009
17. Rodenstein Daniel on behalf of COST-B26 action sleep apnoea syndrome -Driving in Europe: the need of a common policy for drivers with obstructive sleep apnea syndrome
21. Charles F. P. et all: Sleep Apnea and Commercial Motor Vehicle; Chest 2006;130;902-905