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Driving Risk in Obstructive Sleep Apnoea: Do New European Regulations Contribute to Safer Roads?



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ACCEPTED MANUSCRIPT

Obstructive sleep apnoea syndrome (OSAS) is a highly prevalent disorder that affects at least 10% of adult males and 5% of adult females¹. While the disorder is fundamentally based on recurring episodes of partial or complete upper airway occlusion during sleep with associated sleep fragmentation², the most prominent daytime symptom of the disorder is excessive sleepiness, which may vary in severity from a tendency to nod off in a comfortable chair to a risk of falling asleep in dangerous situations such as when driving a motor vehicle³. Not surprisingly, there is strong evidence that untreated OSAS is associated with a substantial increase in the rate of motor vehicle accidents (MVA), which varies between 2 and 7 times the general population risk in different reports^{4, 5} and the driving impairment in OSAS patients has been reported as equivalent to driving while drunk⁶. A recent meta-analysis of published reports indicated that the overall increased risk of MVA is 2.4 times that of the general population⁷, which exceeds the increased risk of MVA in many other clinical disorders already identified as associated with increased accident risk^{8, 9}.

The role of excessive daytime sleepiness (EDS) in the increased accident risk among patients with OSAS is not fully established¹⁰⁻¹², but the balance of evidence favours EDS as a key factor in this relationship^{11, 13-15}. This uncertainty likely reflects the fact that other factors may influence EDS in OSAS patients such as inadequate sleep time, poor sleep hygiene, alcohol and other drug usage, and co-morbidities such as cardiac disease^{16, 17}, which are particularly relevant in long-distance truck drivers¹⁸. Nonetheless, regardless of the association with OSAS, sleepiness itself is recognised as a major risk factor for MVA and has been reported to account for 5-7% of all MVA¹⁹, with a substantially higher risk in fatal accidents and those occurring on motorways. There are many potential warning signs of accident risk in sleepy drivers

including yawning and head nodding, lane drift, and inability to remember the most recent distances travelled, in addition to missing planned exits ²⁰. In these circumstances, many drivers employ countermeasures such as high caffeine drinks and opening the vehicle window. Pulling into a rest area on the highway for a brief nap can also help reduce the impact of sleepiness. Features of MVA that suggest the likelihood of an accident being the result of driver sleepiness include single-vehicle crash of a lone driver, absence of brake marks on the highway, and accidents that occur at night or during the early afternoon ²¹.

Although OSAS is associated with a substantially increased risk of MVA, there is strong evidence that effective therapy, particularly with continuous positive airway pressure (CPAP), reverses that increase and restores the accident risk to that of an equivalent general population ²². This improvement is particularly well demonstrated in the Canadian report of George and co-authors that compared a cohort of OSAS patients in the Province of Ontario with the general population of drivers in that province for the two 3-year periods before and after initiation of treatment ²³. They found a 3-fold higher MVA rate in OSAS patients before treatment which fell to the same rate as the general population after treatment was commenced. However, despite the reduction in MVA risk consequent to effective therapy, there is evidence that driving simulator performance remains impaired in OSAS patients treated with CPAP

²⁴.

The growing recognition of increased MVA risk in untreated patients with OSAS together with the evidence that effective therapy substantially alleviates that risk has prompted many countries to implement regulations that limit certain categories of OSAS patients to hold a driving license ²⁵. These regulations vary in the degree of restriction imposed but usually permit OSAS patients complying with effective

therapy to continue driving. However, some countries do not have specific regulations regarding OSAS and driving. In the European context, the European Commission has recognised the importance of basic common regulations to be applied throughout the European Union, particularly in the context of open borders between member states where drivers may travel between member states without restriction ²⁶.

In 2012, the Transport and Mobility Directorate of the European Commission established a working group to formally examine the relationship between OSAS and MVA risk and to propose a revision to the Medical Guidelines (Annex III) regarding driver licensing in this disorder. Membership of the group was by nomination from EU member states, thus ensuring a broad European National perspective in the deliberations. Following a face-to-face meeting of the whole group and subsequent detailed discussions among members in sub-groups, a detailed report was submitted to the Commission ²⁷. This report included specific guidelines for the provision of driving licenses to patients with OSAS, and also possible mechanisms to identify subjects at risk for OSAS in the general population. The report also highlighted the importance of educating important stakeholders including police and the transport industry on the importance of OSAS in MVA risk and the potential value to public safety of effective treatment. Following approval by the Driving License Committee of the Transport and Mobility Directorate and subsequent consultation with EU Member States, a revision to Annex III was implemented under EU Directive 2014/85/EU ²⁸. This directive indicates that patients with moderate or severe OSAS (apnoea/hypopnoea frequency >15/hr) associated with sleepiness should not drive until effectively treated. The directive did not specifically indicate the severity of sleepiness required on the basis that this can be difficult to measure on a general population basis but the working group report indicated that sleepiness while driving

represented the most relevant criterion. Similar restrictions are applied to private and professional drivers although the requirements for follow-up of treatment efficacy are more stringent in professional drivers.

Do these new regulations serve to enhance public safety on European Highways? An obvious concern is that such regulations may deter patients with a high likelihood of OSAS from seeking medical attention leading to effective therapy, which could have a negative effect on road safety. For this reason, the directive is presented in the most benign fashion feasible; first, by restricting only patients with moderate-severe OSAS associated with significant sleepiness and second, by indicating that patients can resume driving as soon as effective therapy is demonstrated. This policy represents a classic “carrot and stick” approach where the major emphasis is on the carrot. Nonetheless, a broad education campaign targeting patients, the medical profession, and the transport industry is required to facilitate sensible implementation of this new Directive and to minimize the possibility of driving OSAS patients underground ²⁹. This possibility is a particular concern in commercial drivers who depend on retention of a driving licence for their livelihood, and also represent the group where failure to diagnose and treat OSA carries the greatest risk to public safety on the highways. Further research is required on simplified ways to identify OSAS patients at risk for MVA, particularly measures to better objectively assess sleepiness at a population screening level.

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The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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