

European Respiratory Society statement on sleep apnoea, sleepiness and driving risk

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Drivers with obstructive sleep apnoea and sleepiness are at risk of driving accidents; this is removed by effective therapy, and recent European regulations have been implemented on this topic
<https://bit.ly/3mXDhV1>

Cite this article as: Bonsignore MR, Randerath W, Schiza S, *et al.* European Respiratory Society statement on sleep apnoea, sleepiness and driving risk. *Eur Respir J* 2021; 57: 2001272 [<https://doi.org/10.1183/13993003.01272-2020>].

ABSTRACT Obstructive sleep apnoea (OSA) is highly prevalent and is a recognised risk factor for motor vehicle accidents (MVA). Effective treatment with continuous positive airway pressure has been associated with a normalisation of this increased accident risk. Thus, many jurisdictions have introduced regulations restricting the ability of OSA patients from driving until effectively treated. However, uncertainty prevails regarding the relative importance of OSA severity determined by the apnoea-hypopnoea frequency per hour and the degree of sleepiness in determining accident risk. Furthermore, the identification of subjects at risk of OSA and/or accident risk remains elusive. The introduction of official European regulations regarding fitness to drive prompted the European Respiratory Society to establish a task force to address the topic of sleep apnoea, sleepiness and driving with a view to providing an overview to clinicians involved in treating patients with the disorder. The present report evaluates the epidemiology of MVA in patients with OSA; the mechanisms involved in this association; the role of screening questionnaires, driving simulators and other techniques to evaluate sleepiness and/or impaired vigilance; the impact of treatment on MVA risk in affected drivers; and highlights the evidence gaps regarding the identification of OSA patients at risk of MVA.

Introduction

Obstructive sleep apnoea (OSA) is highly prevalent, with recent general population studies indicating that almost 50% of adult males have moderate or severe sleep disordered breathing (SDB) as measured by an apnoea–hypopnoea index (AHI) of ≥ 15 events·h⁻¹ [1]. The clinical syndrome of OSA, based on an AHI of ≥ 5 events·h⁻¹ along with appropriate daytime symptoms, especially excessive daytime sleepiness (EDS), is reported in up to 10% of the adult male population with approximately half that prevalence in females [2]. EDS while driving is an important factor in motor vehicle accidents (MVA) or work-related accidents. Disorders associated with sleep disturbance and sleepiness are established factors in increased accident risk [3, 4], and OSA is the most prevalent medical disorder associated with EDS. The medicolegal consequences of OSA principally relate to accident risk from OSA with its associated economic implications and legal consequences.

Several jurisdictions have implemented regulations that restrict the ability of patients with OSA to drive until effective treatment is demonstrated [5]. These regulations usually include both objective severity of OSA, demonstrated by measuring the extent of SDB in a diagnostic sleep test, and the level of sleepiness, which is usually assessed in clinical practice using the Epworth Sleepiness Scale (ESS) [6]. The importance of including both variables is underlined by the poor association between AHI in a sleep test and the subjective sleepiness measured by the ESS [7, 8], in addition to the continuing uncertainty regarding the relative importance of SDB severity and level of sleepiness in predicting accident risk [9].

In 2014, the European Union (EU) implemented a directive that introduced regulations regulating fitness to drive in patients with OSA. This directive specifies that patients with AHI ≥ 15 events·h⁻¹ and associated sleepiness should not drive until effectively treated, and physician certification is required to confirm suitability to continue driving [10]. However, considerable uncertainty prevails among clinicians about this evaluation [11], which probably reflects current uncertainties regarding the evaluation of disease severity, particularly the evaluation of sleepiness. The overarching objective of this directive is to prevent patients with untreated OSA who report sleepiness while driving from continuing to drive until the disorder is effectively treated.

As a result of the EU directive and associated uncertainties regarding implementation, the European Respiratory Society (ERS) established a task force to address the topic of sleep apnoea, sleepiness and driving with a view to providing an overview to clinicians involved in treating patients with the disorder.

Methods

The task force members represent experts with established interest/expertise in the topic of driving and OSA, predominantly from respiratory-sleep medicine, but also from neurology, psychiatry and public health. A patient representative was also included. Members were assigned to working groups within the task force covering the relevant topics of epidemiology, mechanisms, screening, diagnosis and treatment. The work of each working group was predominantly by email and teleconference interactions, and physical meetings of the full task force were held during the annual ERS Congress. Each working group prepared a report, which was integrated into a final report by the task force chairs together with a writing committee.

A systematic database search of medical literature (PubMed) was performed by the members of each working group for the years from January 1988 to November 2019, and the respective publications were retrieved. Thereafter, reference lists were systematically examined for relevant articles. Additional relevant references identified from the selected articles were included. Keywords were selected that were appropriate for the relevant working group such as “CPAP” and “drivers”. Then, appropriate search words such as “accidents”, “collisions”, “cognitive impairment”, “vigilance”, “fatigue”, “drowsiness” and “depression” were added. The detailed search criteria and the flow charts of report selection for individual working groups are provided in the supplementary material.

The main inclusion and exclusion criteria were articles published in English; data on human subjects; and no reviews, guidelines or case reports. All studies were identified that were relevant to the respective working group, *e.g.* the evaluation of the effect of nasal continuous positive airway pressure (CPAP) on OSA patients with respect to real and/or near-miss road traffic accidents or performance in the driving simulator, sleepiness, quality of life, cognitive function, vigilance, fatigue, drowsiness and depression. Data were independently extracted and analysed by each working group, and individual study quality was assessed according to the Oxford Centre for Evidence-based Medicine levels of evidence (May 2001)

This ERS statement was endorsed by the ERS Executive Committee on 2 September, 2020, and by the ESRS on 12 October 2020.

This article has supplementary material available from erj.ersjournals.com

Received: 27 April 2020 | Accepted: 25 Aug 2020

(supplementary table E1). All search criteria and tables containing evaluation of individual studies are reported in the supplementary material.

The present ERS statement combines an evidence-based approach with the clinical expertise of the task force members, based on a two-step discussion process: first within subgroups focusing on different sections, and second in the whole group. This statement aims to provide an overview of the literature and current practice and does not make recommendations for clinical practice. All task force members reached a consensus and approved the statements illustrating their common practice regarding the evaluation of sleepy drivers and the evaluation of fitness to drive in OSA patients.

Epidemiology of MVA in patients with OSA

Current knowledge and limitations of existing practice

For several decades, OSA has been reported to be associated with an increased risk of MVA [12], and this risk has been quantified in various studies to range between two and seven times the risk of control populations [13]. The risk is mainly associated with occurrence of EDS, usually assessed as subjective sleepiness by an ESS score ≥ 11 out of 24. However, the comparison of reports regarding accident risk in OSA is complicated by methodological differences, with some studies comparing OSA drivers to a control group, while other reports compare with the general population. Some studies also adjusted for possible confounding factors such as driving frequency and distances, visual difficulties, alcohol consumption and obesity. In addition, the methodology of accident recording differs between reports, with some providing a prospective assessment of a population sample, whereas others evaluate specific driving accidents presenting to the emergency department.

The results of questionnaire-based studies in drivers were analysed separately for noncommercial and commercial drivers (supplementary table E2). Most studies were cross-sectional association studies based on self-administered questionnaires such as Epworth [6] or Berlin [14] and a history of previous MVA, in addition to anthropometric measurements. In noncommercial drivers, sleepiness and OSA risk were associated with increased risk of MVA in some reports [4, 15, 16], but not in others [17–19]. MVA were self-reported, with no objective verification. In elderly subjects, the risk of OSA was not associated with MVA [19]. In commercial drivers, the response rates were low, but self-reported sleepiness was associated with increased risk of MVA [20–22]. The estimated OSA risk was associated with sleepiness in some [23, 24], but not all studies [22, 25, 26]. Only some studies reported an association of OSA risk or sleep disorders and MVA rate [24, 26–28], whereas other studies were negative [29, 30].

In addition, there were three systematic reviews and meta-analyses, as well as 25 sleep study based investigations in the general population, commercial drivers and patients with OSA (supplementary table E3). An increased risk of MVA was reported in untreated OSA (AHI >5 events·h⁻¹), with a median OR 2.83 (95% CI 2.72–3.08) [17]. Dose–effect relationships were reported between OSA severity and risk of MVA in the general population [31–34], but short sleep duration and/or self-reported sleepiness also played a role [31, 35]. According to other studies, sleepiness, but not measures obtained by polysomnography (PSG), was associated with occurrence of MVA [35, 36]. In these studies, documented OSA was associated with a high odds ratio for MVA (range 3.0–8.5). In professional drivers, the same trend was observed [28, 37–39], with some studies underlining a major role for sleep deprivation [40], or sleepiness [41] or nocturnal hypoxaemia [37]. Conversely, STEVENSON *et al.* [42] found no difference in MVA occurrence between heavy-vehicle drivers with and without moderate or severe OSA. In sleep clinic samples, the association between OSA and MVA was confirmed, but some studies found no dose–effect relationship between OSA severity and MVA risk [43–47]. Finally, some studies reported that severe OSA patients were especially at risk [44, 48–50] and young male OSA patients showed a high risk of MVA [48].

The variability in results is partly accounted for by the difficulty in obtaining reliable information on MVA and sleepiness, especially in commercial drivers, the retrospective nature of investigations and possibly the different phenotypes of OSA, since approximately half of OSA patients do not report EDS. Moreover, most data describe male drivers, while few studies assessed MVA risk in female or elderly drivers.

Summary of literature review and current practice

- OSA increases the risk of MVA.
- Studies on professional drivers reported a high prevalence of OSA risk in this population.
- In professional drivers, sleep deprivation is a major risk factor for MVA.

Recommendation for research

There is a strong need for good-quality epidemiological studies, possibly based on large databases and registries, to clarify the relative importance of EDS, SDB severity and other OSA-related variables in quantifying MVA risk.

Pathophysiology and predictors of EDS in OSA

Current knowledge and limitations of existing practice

Sleepiness is a major factor contributing to the occurrence of MVAs. Some studies (supplementary table E4) examined EDS in OSA by PSG plus multiple sleep latency test (MSLT) [51–60] in order to identify variables potentially predictive of objective EDS. Results were variable, but a high sleep efficiency and long sleep duration in sleepy patients were found in three studies [54, 55, 58]. A role for nocturnal hypoxaemia in predicting EDS was suggested by six studies [51, 52, 55–58]. Recently, Li *et al.* [60] reported that mean sleep latency was positively associated with interleukin-6 level, and negatively associated with cortisol levels. In the same series of patients, results of psychomotor vigilance testing (PVT) correlated with the ESS score, but not with the results of MSLT [59].

Studies using the ESS questionnaire to assess subjective EDS were more consistent with regard to the severity of nocturnal hypoxaemia as a predictor of EDS [51, 52, 55–58, 61–70] or poor performance at cognitive tests [71]. ZAMAGNI *et al.* [52] reported that subjective EDS was associated with markers of respiratory effort during apnoeas. Sleep fragmentation was associated with ESS scores in some [54, 57, 58, 61, 62, 72], but not in other studies [4, 55, 64]. Large cross-sectional population studies using more liberal definitions of EDS reported no association between EDS and sleep variables, but an association with several comorbidities [73–75], similar to the study by KOUTSOURELAKIS *et al.* [76] in OSA patients. A strong association between subjective EDS and depression in OSA has been reported in several studies [67, 75–79]; EDS did not appear to differ between males and females with OSA [80]. One study comparing normotensive and hypertensive subjects reported higher AHI and oxygen desaturation index in hypertensive patients, but less EDS in hypertensive compared to normotensive patients with moderate–severe OSA [81]. EDS was associated with insulin resistance or metabolic syndrome in some [56, 82], but not in other studies [66]. Other metabolic changes in OSA, *i.e.* higher hypocretin-1 and lower ghrelin, were reported in patients with EDS compared to patients without EDS [83]. A genetic marker of EDS in OSA has been recently identified in the AMOT gene and the related P130 protein, but these findings need confirmation in larger datasets [84].

Depression and obesity predicted EDS better than AHI in a large cohort of OSA patients at diagnosis, whereas no relationship was found between EDS and AHI in rapid eye movement (REM) or non-REM sleep [85]. In subjects with mild OSA from the general Korean population, slight differences were reported between OSA and non-OSA subjects, but no predictor of EDS could be identified [86].

Two studies reported combined analysis of subjective and objective EDS [57, 87]. SUN *et al.* [57] confirmed the role of both hypoxaemia and sleep fragmentation as determinants of EDS. The study by PRASAD *et al.* [87] in OSA patients reported an independent association of EDS and African-American race, inflammatory markers and short sleep duration.

Other studies analysed the association of obesity and EDS (supplementary table E5). A meta-analysis found that EDS decreased after weight loss with no evident relationship with changes in AHI [88]. In patients undergoing bariatric surgery, EDS was related more to metabolic variables and depression than to AHI [89, 90], or showed no relationship with AHI [91]. Nonsurgical weight loss in obese patients was associated with decreased ESS scores and improved insulin sensitivity [92].

Case–control studies reported 35–57% prevalence of EDS in obese patients without OSA [93, 94], but no relationship between ESS scores and anthropometric or sleep variables [94], confirming previous findings from the same group [95]. A longitudinal study in the general population reported changes in EDS associated with weight gain or loss, and a significant influence of comorbidities and depression over a follow-up of 7.5 years [96]. Analysis of 5-year follow-up data from the Sleep Heart Health Study confirmed the role of weight gain in increasing EDS, but only in females, with OSA severity explaining ~20% of the relationship [88]. In obese OSA patients, nocturnal hypoxaemia predicted EDS [97] or level of alertness at the Maintenance of Wakefulness Test (MWT) [98]. In a sample with heterogeneous sleep disorders, the presence of obesity, but not absolute body mass index values predicted EDS [99].

Summary of literature review and current practice

- No major differences are evident between predictors of subjective and objective sleepiness, although most data relate to subjective sleepiness.
- AHI is not useful to predict EDS in OSA, whereas most studies suggest an association of nocturnal hypoxaemia with EDS.
- Obesity is a risk factor for EDS that is only partly mediated by associated OSA.
- Depression, metabolic variables, comorbidities and genetic background all play a role in EDS pathogenesis.

Suggestions for design of future studies/recommendations for research

The variables obesity, severity of nocturnal hypoxaemia, comorbidities and depression should be considered in future studies on the determinants of sleepiness in OSA patients.

Role of questionnaires as screening tools for OSA in drivers

Current knowledge and limitations of existing practice

Risk stratification in high-risk populations and triage of patients in the context of driving is highly desirable, as the diagnostic capacity of sleep centres is limited and waiting lists are growing [100]. Relevant clinical information should be obtained by a detailed medical history and careful clinical examination of subjects with suspected SDB. However, it may be hard to produce objective, reproducible findings, due to observer and reporter bias. Therefore, several screening questionnaires which incorporate risk factors, clinical symptoms and physical examination parameters have been developed to facilitate the diagnosis of OSA [14, 101–104]. ESS [6], Berlin Questionnaire [14], STOP (snoring, tiredness during daytime, observed apnoea, high blood pressure) [103] and STOP-Bang (STOP-BMI, age, neck circumference, male gender) [105] are most studied in this context. These tools can be considered as an inexpensive approach that is easy to administer with minimal discomfort. However, the discriminant ability of the test for OSA is a concern and is of utmost importance.

In the general population, extreme variation can be found in the sensitivities and specificities for all established questionnaires (ESS sensitivity 18–85%, specificity 22–98% [106–108]; Berlin Questionnaire sensitivity 40–97%, specificity 6–100% [104, 109–114]; STOP sensitivity 33–98%, specificity 10–95% [115]; STOP-Bang sensitivity 0–100%, specificity 0–100% [105, 109, 115, 116]), even taking into account the cut-off thresholds for OSA (AHI ≥ 5 events-h⁻¹, AHI ≥ 15 events-h⁻¹, AHI ≥ 30 events-h⁻¹) (supplementary table E6). A similar pattern can be appreciated visually in figure 1, reporting the results of single studies in different populations. Sensitivity was highest in sleep clinic samples for all questionnaires, while the ESS showed an overall poor predictive value. In clinical population samples (*i.e.* patients admitted or followed for disease other than OSA), on average the Berlin Questionnaire showed a higher sensitivity compared to the STOP-Bang. Clearly, the data indicate that questionnaires do not reliably rule in or rule out the presence of OSA.

Summary of literature review and current practice

- Most studies on screening tools are observational (large cohorts or case series), and show a poor sensitivity or specificity, resulting in an unacceptably high number of missed cases (false negative) and false positive ones.
- The range in reported sensitivities and specificities, even in the same high-risk population and for similar thresholds of AHI, is huge.
- The simplest questionnaire for sleepiness, the ESS, is not able to discriminate patients at risk for OSA.
- In a setting of professional drivers and high-risk populations, in addition to a skilled history and examination, it is the authors' current practice to proceed straight to an appropriate sleep study and perform objective physiological monitoring.

Future research priorities

- Evaluation and validation of new questionnaires in the complete range of OSA severity, and in different target groups (general population, drivers, high-risk groups).
- Combination of screening questionnaires with nocturnal pulse oximetry.
- Development of new questionnaires, with higher sensitivities and specificities, and assessment at which AHI threshold and questionnaire score these questionnaires perform best.

Evaluation of sleepiness

Current knowledge and limitations of existing practice

The objective assessment to identify subjects at high risk of driving accidents, in order to comply with current EU regulations, represents a major problem. While most research on OSA concentrates on sleepiness, driving fitness may relate more to vigilance, *i.e.* the ability of an individual to maintain focus of attention and to remain alert to stimuli over prolonged periods of time [117]. Vigilance decrement is not simply the result of being exposed to repetitive or boring tasks; recent research has shown that vigilance tasks are capacity-draining, resource-demanding and associated with considerable workload and stress [117]. The entire spectrum of sleepiness from complete wakefulness to overt sleep is one of the factors affecting vigilance.

However, vigilance is a complex phenomenon; sleep deprivation and vigilance decrement are unlikely to be functionally equivalent. Over the past three decades, attempts have been made to develop objective and

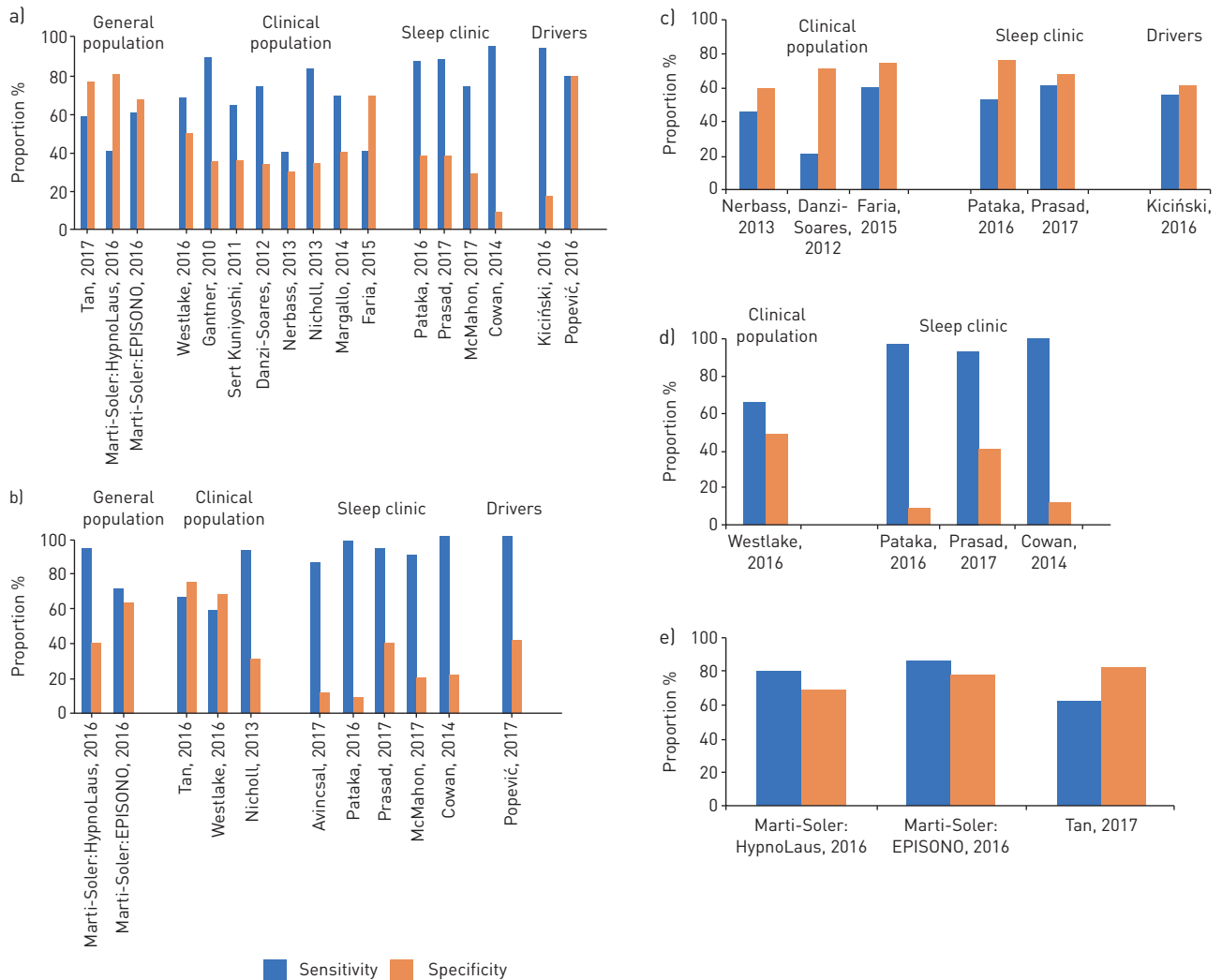


FIGURE 1 Sensitivity and specificity of studies evaluating various questionnaires as screening tools for obstructive sleep apnoea. a) Berlin Questionnaire; b) STOP-Bang (snoring, tiredness during daytime, observed apnoea, high blood pressure; body mass index, age, neck circumference, male gender) questionnaire; c) Epworth Sleepiness Scale; d) STOP questionnaire; e) NoSAS questionnaire (all studies in general population). References cited are TAN *et al.* [219], MARTI-SOLER *et al.* [110], WESTLAKE *et al.* [109], AVINCAL *et al.* [220], GANTNER *et al.* [116], SERT KUNIYOSHI *et al.* [221], DANZI-SOARES *et al.* [222], NERBASS *et al.* [223], NICHOLL *et al.* [224], MARGALLO *et al.* [225], FARIA *et al.* [226], PATAKA *et al.* [227], PRASAD *et al.* [228], MCMAHON *et al.* [229], COWAN *et al.* [230], KICIŃSKI *et al.* [231], POPEVIĆ *et al.* [232].

subjective tests for assessing the effects of sleep deprivation on vigilant attention, then extrapolating the results to driving ability [118]. A description of the most frequently studied tests reported in the literature in relation to sleep disorders is available in the supplementary material.

Studies on tests of vigilance for driving published prior to 2006 are limited by poor methodology, variable patient populations, insufficient information about sleep debt, caffeine/nicotine/drug intake and circadian fluctuation in vigilance/attention, which might affect performance on the day. Furthermore, they are generally not controlled for factors such as age, sex and degree of driving experience. From epidemiological as well as larger-scale surveys in a variety of populations, it remains reasonably clear that MVA rates are likely to be higher in those who drive further after occurrence of sleepiness, have more sleep debt and who also have a sleep disorder (most commonly OSA) disrupting sleep quality [13, 119, 120].

Which type of tests are usually used?

Several tests are available to assess objective vigilance and sleepiness (see the supplementary material for details):

- Psychomotor Vigilance Test (PVT): vigilance [121]
- Divided Attention Driving Task (DADT): vigilance [122]
- Sustained Attention to Response Task (SART): vigilance [123]

- Oxford Sleep Resistance Test (OSLER): vigilance [124]
- Multiple Sleep Latency Test (MSLT): sleepiness [125]
- Maintenance of Wakefulness Test (MWT): vigilance [126]

Most of the available studies involve the effects of sleep deprivation or other diseases with hypersomnia, without a specific focus on driving. For the purpose of this report, MWT is often used in the evaluation of fitness to drive, and many studies regard the interrelationships between different tests and/or sleepiness questionnaires. Several studies analysed the results of MSLT and MWT relative to results of driving simulation, as described in the following section. Similarly, divided attention is usually tested during driving simulation (DADT) and is also reported in the following section.

PVT

PVT is a 10-min test that is easy to perform in the clinical setting. SUNWOO *et al.* [121] compared single administration of several tests at different times of the day, and reported that results of PVT showed good agreement between tests for both reaction time and number of lapses. CORI *et al.* [127] reported that reaction times at PVT were similar in OSA patients and controls, but OSA patients experienced a higher number of lapses, and performed poorly in neurocognitive tests. Importantly, PVT could be used in the occupational assessment of professional drivers [128]. Despite being used extensively in numerous studies over the past three decades in assessing vigilance as related to sleep deprivation in OSA, no absolute parameters have been derived that can be utilised in a predictive manner to assess ability to drive safely.

SART

Only one study on 12 patients with untreated OSA has used the SART and no correlation was found between SART performance and the results of MSLT [123]. To date, there is a lack of normative data and there are large variations in testing depending on circadian influence, age and other variables [123].

OSLER

As with the MWT, the original test comprised four 40-min sessions [124], but other investigators have developed shorter versions with one, two [127] or three sessions [127], or with 20-min sessions, or combined the test with additional testing protocols such as the Multiple Unprepared Reaction Time Tests [118, 129]. A modified version of OSLER revealed associations between poor performance at the test and previous occurrence of MVA [130]. OSLER appears to be a sensitive test for identifying sleepiness in OSA patients and fluctuations in vigilance throughout the day. However, normative data are not available.

Tests assessing sleepiness

MSLT

The MSLT is considered as the “gold standard” for assessing sleep propensity and is used most notably in the diagnosis of disorders of central hypersomnolence, such as narcolepsy and idiopathic hypersomnolence [125]. The test is not designed to measure sleepiness routinely, as it is time-consuming and extremely labour-intensive, relying on a standardised approach and scoring sleep in real time, undertaken by highly trained technical staff [125]. Additionally, it is not available in all centres that care for patients with OSA. However, any patient with a mean sleep latency of <8 min is considered to be pathologically sleepy and this correlates with increased risk of driving accidents [118].

MWT

Several studies have shown that mean sleep latency on the MWT correlates with ability to perform using a driving simulator in patients with untreated OSA [126, 131, 132]. Patients with pathological MWT sleep latency scores (0–19 min) displayed significantly more interline crossings and standard deviation from the centre of the road [126, 133]. Subjects and controls least likely to incur errors had a mean sleep latency of >34 min [126, 133].

Questionnaires and driving

As discussed earlier, a number of sleep questionnaires have been designed and used to assess excessive daytime sleepiness in a clinical setting, including the ESS [6], the pictorial ESS [134] and the Karolinska Sleepiness Scale [135]. However, these tools are subjective and do not correlate consistently with objective measures of sleepiness [136]. Additionally, they were not designed to specifically assess the risk of driving impairment in OSA. One study has shown that an ESS score ≥ 13 out of 24 appears to predict objective sleepiness, which is higher than that which has typically been used in clinical practice (≥ 11 out of 24) [137]. However, there is no correlation with driving safety.

Is there a relationship between real-life driving performance and performance on tests of vigilance and tests measuring sleepiness?

Driving is a complex task, requiring the integration of psychomotor, cognitive, motor and decision-making skills, visual-spatial abilities, divided attention and behavioural and emotional control. Sleepiness will affect a number of these factors to varying degrees, which in turn are determined by individual levels of resilience and resistance to impairment as well as age, sex and baseline neurocognitive function. Many of the tests used to assess driving ability in the context of OSA are unidimensional, do not have established normative data in the overall population with respect to sleepiness and are unable to control for the factors noted earlier. Although many are relatively easy to deploy in clinical practice, they are likely to have value only for intra-individual changes, *e.g.* before and after treatment. Furthermore, testing fitness to drive in terms of sleepiness and vigilance may not be necessary in all patients diagnosed with OSA syndrome, and possibly only a small subset [137, 138]. Taking these caveats into consideration, the following statements can be made.

Summary of literature review and current practice

- The DADT, PVT and OSLEP are currently used in research as objective screening tools for impaired vigilance due to excessive daytime sleepiness in OSA before and after treatment. Results would be specific to the individual only.
- There are reasonable data to correlate performance on the MWT (in respect of mean sleep latency) to driving impairment in a variety of sleep disorders, including OSA.
- A mean sleep latency of 34–40 min using the MWT 40-min protocol reflects good alertness across a day. However, results of MWT do not consider other determinants of driving ability.

Recommendations for future research

- The MWT should be correlated with driving outcomes in real-life situations and in larger groups of patients with OSA as well as controls.
- There is a need to identify cost-effective and reliable ways of objectively assessing driving ability. Sleep debt, circadian influences, driving proficiency, neurocognitive function, drug intake, emotional stability, age and sex should be incorporated into algorithms to establish normative data across a diverse range of populations.

Driving simulators in the evaluation of fitness to drive

Current status and limitations of existing clinical practice

There is significant heterogeneity among driving simulators, ranging from those based on a personal computer (PC), with very simple graphics, using a gaming steering wheel and vehicle controls, through to fully immersive simulators, involving full-size real cars with full visual, motion and audible feedback, which closely replicate the real driving experience. Some studies have evaluated different components of driving in separate neuropsychiatric tests rather than integrated into a simulator or in addition to a simulator [29, 46, 139].

A hierarchy can be considered, from the “steer-clear” test, to divided-attention driving simulators (DASS), to PC-based simulators with realistic graphics and vehicle controls, to highly sophisticated simulators or real-life driving (more details on each of these simulators are available in the supplementary material).

Less realistic simulators are associated with more events, both in patients and normal subjects. For example, in one study using a DASS [131], while patients had more off-road events than general subjects, both still had unacceptably high instances (90 ± 71 versus 40 ± 36 events-h⁻¹), which is not reflective of real-world normal driving. By contrast, the number of events during longer drives on more realistic simulators is much more consistent with real-life driving. GHOSH *et al.* [140] showed that >50% of patients with a moderate-severe OSA syndrome could complete ~1 h of motorway driving without deviating out of the assigned lane, crashing, *etc.* When driving performance is evaluated through quantitative performance measures, simulated driving is generally worse, with higher absolute values compared to real-road test driving [141]. However, the more realistic the driving experience, the greater the cost, which is not realistic for an everyday clinical test. Real-life road driving is not practical nor ethical (it would not be appropriate to test someone in whom there was a high likelihood of an accident).

The most commonly evaluated end-points on the simulator include crashes, near misses, drifting out of lane (inappropriate line crossings), how well the individual maintains their position on the road (tracking error, standard deviation of lane position (SDLP), lane position in centimetres) reaction time and speed adjustment. SDLP most consistently correlates with sleepiness and performance on the simulator [140, 142, 143].

Patients with OSA perform differently to normal subjects on a driving simulator

That patients with OSA perform worse than normal subjects on driving simulators is a consistent finding [29, 46, 131, 133, 144–159] (supplementary table E7). This is true for crashes and drifting out of lane/line crossings, but also for continuously measured variables, such as SDLP, or equivalent. Furthermore, performance on simulators is worse in situations in which real driving performance would be expected to deteriorate, *e.g.* after alcohol or sleep deprivation [152, 156, 160, 161]. However, performance improves following treatment of SDB, as demonstrated in 12 reports that consisted of a mixture of observational, randomised control and case-control studies [36, 139, 146, 153, 156, 161–165] (supplementary table E8). Simulated driving is worse in sleepy patients [126, 132, 133, 166–168] consistently across the whole range of simulator types. Several studies have shown that females perform worse than males on simulators [140, 142, 164].

Relationship between real-life driving performance and performance on a driving simulator

Most of the studies reviewed either used a driving simulator to help understand mechanisms by which OSA might compromise safe driving, as a comparator with sleepiness as measured by MSLT or MWT, or as an end-point to indicate effective treatment. Few studies compared simulated with real-life driving. Relationships, albeit weak, were found with self-reported sleepiness in general (ESS), accidents and episodes of drowsing or sleepiness at the wheel [141, 142, 169–171]. These relationships were seen with steer-clear [142, 169], DASS [170] and more sophisticated PC-based simulators [141, 171], but some studies were negative [46]. Studies involving the most realistic simulators involved too few subjects for meaningful comparison with real-life events.

Can driving simulators be used to help in advising patients with OSA/OSA syndrome as to whether they are safe to drive or not?

The driving performance of sleepy individuals in a driving simulator is partially related to their real-road test driving performance. However, based on the current evidence, simulated driving performance is not able to reliably predict real-life near-misses or accidents on an individual level. When comparing simulated and real driving, the strongest association was found for driving simulation near-misses or accidents with real-life rates of near-misses or accidents, followed by the number of inappropriate line crossings and the SDLP. It is not surprising that the simulator does not accurately predict accident risk; the individual who has a crash in a real car due to sleepiness will very likely have been driving that same car on many previous occasions without incident. Accidents are also caused by other drivers, and due to factors other than driver sleepiness, such as mechanical failure.

Summary of literature review and current practice

- Driving simulators, depending on their degree of sophistication, replicate some aspects of real driving.
- Poor performance on a simulator, across the whole range of simulator types, is associated with subjective and objective sleepiness, due to a variety of causes.
- Poor performance on a driving simulator does not predict accidents or performance during real driving, but may set an alert about whether that individual is safe to drive.
- It remains an open question whether a more realistic driving simulator has more reliable prognostic power compared to the less realistic varieties.
- Females perform less well than males on driving simulators.
- Simulators do have a role in the assessment of whether a patient with OSA syndrome is safe to drive, but this determination requires a multifaceted approach by an experienced clinician.

Priorities for future research

- Standardisation of simulator outcomes: determining which of the many outputs available from a simulator are the best predictors of real-life events; and optimal length of test.
- A consistent definition of accidents and near-misses and whether attributable to driver fatigue (although less subject to recall bias and dishonesty, official records are not widely available and will not pick up near-misses, *etc.*)
- Role of simulators in evaluating fitness to drive in females.

Effectiveness of CPAP treatment in OSA among commercial and noncommercial motor vehicle drivers***Current status and limitations of existing clinical practice******Impact of CPAP treatment on MVA risk among drivers with OSA***

CPAP is the treatment of choice for OSA. However, the question arises of whether it influences the increased risk of motor vehicle crashes in OSA sufficiently [13, 32, 34, 35, 45, 50, 172–174].

Overview of the evidence

There is a lack of randomised controlled trials (RCTs). However, most observational studies indicate that CPAP reduces crash risk [49, 165, 175–177]. Although in an early study, individuals who experienced noninjurious crashes appeared to gain no benefit [178], a more recent study with a longer follow-up reported that the risk of near-miss accidents decreased to normal after treatment for 2 years [177]. In addition, a meta-analysis found a significant reduction in accidents [165]. Furthermore, a meta-analysis showed that CPAP can annually reduce collision costs by USD 11.1 billion, prevent >500 000 collisions and save nearly 1000 lives in the United States [179], suggesting that CPAP is a highly efficient use of healthcare resources [180]. A large number of positive airway pressure-adherent patients studied had crash risks similar to controls, whereas nonadherent patients had a five-fold greater crash risk, 6 years after treatment [181]. Moreover, in the study by KARIMI *et al.* [130], the incidence of MVA in OSA patients recorded over 5 years in the Swedish Traffic Accident Registry was reduced by 70% compared to pre-treatment values among those with good adherence to CPAP, whereas it increased by 54% among patients nonadherent to CPAP treatment.

Summary of literature review and current practice

- Evidence from multiple observational studies suggests that CPAP markedly reduces MVA risk among individuals with moderate–severe OSA.
- CPAP treatment prevents most OSA-related motor-vehicle collisions, costs and deaths.
- The minimum acceptable level of adherence to CPAP is considered >4 h per day.

Effect of CPAP treatment on driving simulator performance in drivers with OSA

Driving simulators enable researchers to conduct driving tests that would be too dangerous to perform in the real world or that require specific driving conditions.

Overview of the evidence

CPAP seems to improve performance in simulated driving [153, 155, 157, 163, 165, 182, 183]. Two studies, a nonrandomised controlled study [164] and a prospective case series [139] indicated significant improvements following only 2 days of CPAP use. Furthermore, CPAP normalised driving simulator performance to the level of controls [155, 175]. Simulator performance remained impaired after treatment in another small study [153], suggesting that some optimally treated patients may have residual deficits that could impair driving. A single night without CPAP significantly worsened driving performance [184]. However, in most of the aforementioned studies the number of patients was limited.

Summary of literature review and current practice

- Simulated driving performance improves significantly within 2–7 days of CPAP treatment.
- The benefits of CPAP on driving performance depend on treatment compliance.

Effect of CPAP treatment on daytime sleepiness among drivers with OSA

Overview of the evidence

A number of studies indicate that CPAP improves sleepiness after as little as 1 night of treatment [129, 139, 157, 164, 165, 49, 178, 179, 185–192]. However, few of them had a randomised design [157, 183, 190, 191]. A self-rating instrument (Sleepiness Wakefulness Inability and Fatigue Test (SWIFT)) was developed [187]; scores were improved after positive airway pressure.

Sleepiness, assessed by MSLT [163, 178, 189, 190], and alertness, assessed by MWT [191, 192] both improved after CPAP.

Summary of literature review and current practice

- Subjective daytime sleepiness improves significantly after as little as 1 night of CPAP treatment.
- Evidence suggests that objective daytime sleepiness improves with CPAP treatment.

Effect of CPAP treatment on cognitive function among drivers with OSA

Overview of the evidence

A limited number of studies [182, 186, 190], including only one RCT [190], evaluated cognitive function with a battery of neuropsychological tests. These tests provided subjective and objective evidence for significant improvement of cognitive function among drivers after CPAP.

Summary of literature review and current practice

- Evidence suggests that cognitive function improves with CPAP treatment.

Effect of CPAP treatment on vigilance among drivers with OSA

Overview of the evidence

Although only five studies were included, improvements were found in the 80-min vigilance test after [189] 1 year and in the “driving simulator” attention test, after 1 night of CPAP [193]. More recently, CPAP resulted in objectively improved reaction times and sustained attention in OSA drivers [129]. Likewise, in two RCT studies, CPAP resulted in significant improvements in three [182] or all domains of the Functional Outcomes of Sleep Questionnaire [183].

Summary of literature review and current practice

- Evidence suggests that vigilance improves with CPAP treatment.

Priorities for future research

- Assessment of causes of residual driving simulator impairment after CPAP treatment and determination whether this is associated with persistent elevated real-life accident risk in OSA patients.
- Identification of acceptable compliance to CPAP treatment regarding driving risk.
- Evaluation of other treatment methods or combinations (surgery, oral appliances, drugs, behaviour modification) in reducing crash risk for drivers with OSA.

Discussion and conclusions

OSA is a widely accepted risk factor for MVA and effective treatment with nasal CPAP substantially reduces this increased accident risk, with several reports indicating that the risk may be reduced to a level similar to the general population [176, 194]. This recognition has resulted in many jurisdictions introducing regulations about fitness to drive in patients with OSA [5], most notably those introduced by the European Commission in 2014 that are now mandatory throughout the EU [10]. While the EU regulations do not distinguish between professional and nonprofessional drivers in the OSA criteria that determine driving restriction (an AHI threshold >15 events·h⁻¹ associated with sleepiness), the requirements for monitoring of professional drivers are more stringent [10]. These regulations can be regarded as a baseline and some European countries have introduced more stringent regulations than those specified in the EU regulations. The risk of MVA has long been recognised as having extra implications for long-haul truck drivers, where drowsiness while driving is common [195], and the MVA risk is enhanced by other factors such as alcohol consumption [172] and short sleep duration [35, 196]. The average increased risk of MVA has been quantified in meta-analyses and several original reports as being ~2.5 times the accident risk of control populations [13, 45, 49, 197] and a recent case-control study of truck drivers reported an even higher MVA risk (OR 3.42) [38]. However, not all reports indicate an increased MVA risk relating to OSA [42]. It is common for OSA patients having an accident to report a preceding history of near-miss events, although the relationship with near-miss MVA differs between reports, with one large cohort study indicating a three-fold increase in MVA risk in OSA patients, but no relationship to near-miss events [198], whereas another report among truck drivers found a two-fold increase in near-miss events, but no relationship to MVA [21]. Furthermore, OSA is associated with a greater than two-fold increased risk of work accidents in general [199].

Many potential contributing factors can be considered in the increased MVA risk among OSA patients, including the severity of SDB as measured by the AHI, the level of EDS typically measured by the ESS, poor sleep quality and related lifestyle factors [200] and comorbidity [17]. Reports differ on the relative importance of AHI and sleepiness as major factors in determining accident risk, which is at least partly a consequence of the poor association between subjective sleepiness and AHI [7, 8]. This discrepancy probably reflects a combination of factors including the fact that many additional factors relating to lifestyle and comorbidity may influence the subjective sense of sleepiness and the relative simplicity of the ESS score itself.

The role of EDS in driving accidents has been the subject of many reports, both in OSA populations and in the context of general driving accident risk. Excessive sleepiness is reported as a contributing factor in 5–7% of MVA, and in up to 17% of accidents involving fatalities [201]. A recent meta-analysis reported that sleepiness at the wheel was associated with an increased risk of MVA with an OR 2.51 [202]. Another questionnaire survey of >35 000 drivers in France found a strong predictive value of EDS for MVA (OR 5.0 for ESS >15), and the strongest predictor of all was sleepiness at the wheel needing to stop (OR 9.48) [17]. Studies using driving simulators demonstrate that the level of impaired performance in OSA drivers is

similar to that seen in drivers with blood alcohol levels above the legal limit or following sleep deprivation [203]. The task force members consider the history of previous MVA to be an important part of current clinical practice in the process of releasing or renewing driving licences (figure 2).

The comparison of AHI and EDS as risk factors for MVA has produced differing results in several studies. EDS has been reported as the principal factor contributing to MVA risk in several reports. ARITA *et al.* [44] found that EDS was the major factor in MVA in OSA patients when compared to snorers. KARIMI *et al.* [39] reported that ESS >15 was significantly related to MVA rate, whereas AHI was not. However, the earlier report of TERÁN-SANTOS *et al.* [172] indicated that AHI was more closely related to MVA risk than ESS in 102 patients presenting to the emergency department following MVA when compared to matched control subjects. Furthermore, the European Sleep Apnoea Database cohort study (ESADA) reported that OSA severity based on AHI was superior to the ESS in predicting MVA risk [119], a finding also supported by an earlier Canadian study [45]. Thus, further research is needed to define the factors relating more clearly to OSA that predict MVA risk.

The problem of fitness to drive has been much investigated in the past 30 years, but the results are far from satisfactory. Since the level of evidence regarding fitness to drive is currently insufficient, the task force chose to summarise the literature, and reports the current practice of the members of the task force. Unfortunately, there is also a large variation in legislation between different countries, in addition to a lack of normative data regarding most tests of vigilance or results of driving simulators. Despite the large number of studies, we still lack simple instruments applicable on a large scale that could reliably indicate that a subject with OSA is fit to drive. OSA is often unrecognised and screening the population of drivers for the presence of OSA is a difficult task. Although several questionnaires have been used, their sensitivity and specificity vary according to the subjects assessed. Thus, documentation of SDB by a recording obtained during sleep remains the only reliable way to diagnose OSA. The panel of experts agreed that it should be the responsibility of the physician to suspect OSA and request diagnostic examination in the case of subjects renewing their driving licence, and the primary responsibility for issuing the driving licence remains with the

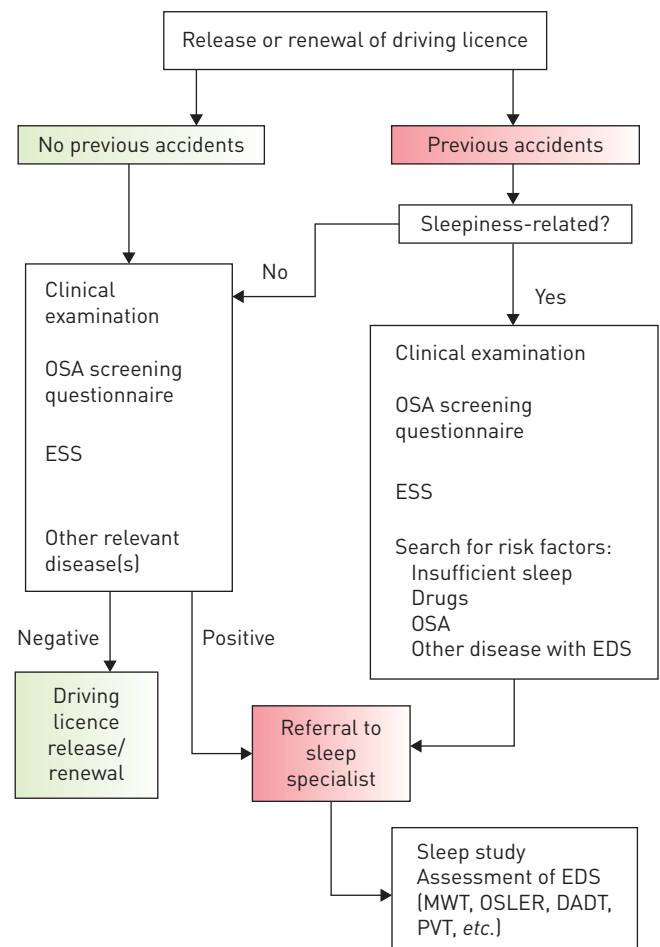


FIGURE 2 The task force members' current practice of advising on fitness to drive according to history of previous motor vehicle accidents. This figure presents the practice of the task force members, and is not intended as a recommendation for clinical practice. OSA: obstructive sleep apnoea; ESS: Epworth Sleepiness Scale; EDS: excessive daytime sleepiness; MWT: Maintenance of Wakefulness Test; OSLER: Oxford Sleep Resistance Test; DADT: Divided Attention Driving Task; PVT: psychomotor vigilance test.

relevant licensing authority. Figure 2 shows the agreed pathway of the task force experts regarding candidates for renewal or issuing of driving licences according to previous history of car accidents. Since European countries have their own national regulations and licensing authorities, more specific guidance cannot be provided. Attention should be paid to potentially important risk factors, such as a history of previous MVAs, especially where sleepiness was a likely contributing factor, the presence of obesity, or a history of snoring. Unfortunately, this is often not the case, as shown by recent surveys of physicians [11, 204, 205]. Stricter criteria for the issuing or renewal of driving licences have been adopted in several countries for commercial drivers, who have a higher exposure to the risk of accidents compared to noncommercial drivers, since long-haul journeys and driving on divided highways are associated with greater risk than short urban journeys. A “fast-track” for sleepy drivers in order to establish CPAP treatment has been tested [206].

Although the 2014 EU directive for the first time considered OSA as a disease associated with driving risk, it is still unclear how OSA patients should be assessed, and which factors may predict an increased driving risk. A reduced sleep latency during the MWT is used in some European countries to document increased sleepiness in OSA patients, but MWT requires a polysomnographic recording the night before the test and repeated recordings during daytime, making it unsuitable to test large numbers of subjects. Conversely, only about half of OSA patients report EDS, and clinical markers that may help identify patients at risk are lacking. Even in patients with OSA and EDS, predicting MVA risk is difficult, since the sense of responsibility of the driver plays a major role in avoiding accidents, *i.e.* very sleepy patients avoid driving, or stop for a nap while driving [168].

In the case of CPAP-treated OSA, the situation is somewhat simpler, since daily use of CPAP can be documented by data download from the device, and studies have shown that CPAP treatment with good adherence effectively decreases MVA risk [176]. Accordingly, the panel of experts agreed that documented use of CPAP for ≥ 4 h for $\geq 70\%$ of nights is considered as enough evidence to consider a treated CPAP patient fit to drive. A flow chart that indicates an agreed pathway of the panel of experts in the evaluation of treatment efficacy in applicants with OSA for release or renewal of driving licence is given in figure 3. However, residual EDS is found in ~ 6 – 13% of effectively CPAP-treated patients [207, 208] and its pathogenesis remains uncertain [209]. Stimulating drugs such as modafinil or armodafinil to counteract

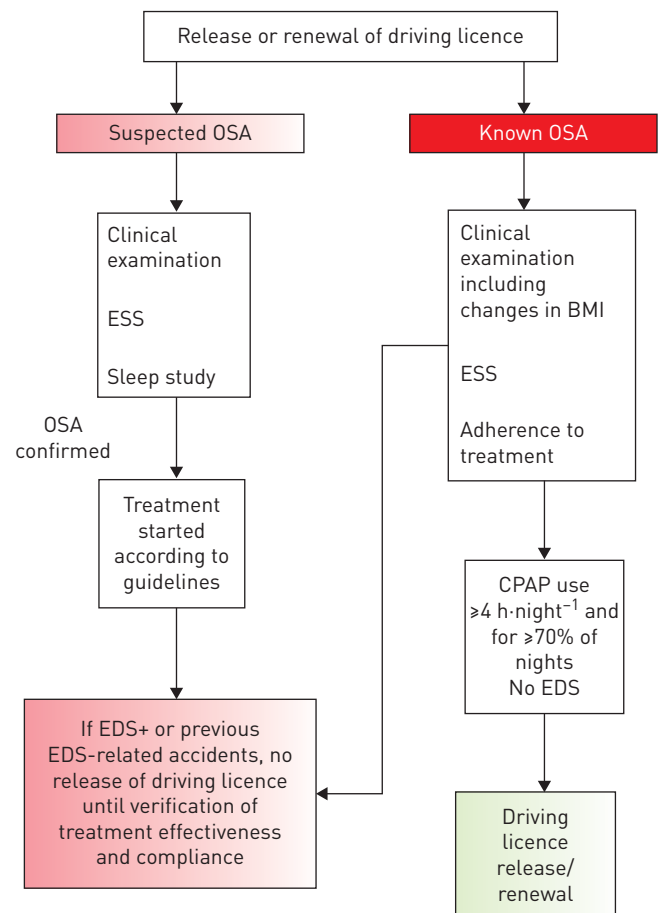


FIGURE 3 The task force members' current practice of advising on fitness to drive in patients with obstructive sleep apnoea (OSA). This figure presents the practice of the task force members, and is not intended as a recommendation for clinical practice. ESS: Epworth Sleepiness Scale; EDS: excessive daytime sleepiness; BMI: body mass index; CPAP: continuous positive airway pressure.

TABLE 1 The task force members' summary statement regarding the assessment of driving risk in obstructive sleep apnoea (OSA) patients

Statement for clinicians advising on fitness to drive in OSA patients

OSA severity assessed as AHI alone does not predict fitness to drive in OSA patients
 Excessive sleepiness is a major risk factor in determining accident risk in OSA, but does not relate to AHI and may be partly due to other non-OSA factors
 Where doubt exists regarding the validity of self-reported sleepiness, further investigation, such as MWT, is warranted, especially in professional drivers
 Effective and compliant treatment of OSA with CPAP largely reverses the increased accident risk and driving can resume once demonstrated

AHI: apnoea-hypopnoea index; MWT: Maintenance of Wakefulness Test; CPAP: continuous positive airway pressure.

EDS, and possibly MVA risk, are effective on residual sleepiness, but were withdrawn from the market due to side-effects [210], while new drugs such as solriamfetol [211, 212], or pitolisant [213] may be useful in patients reporting residual EDS. Whether such drugs could be useful in OSA patients refusing CPAP treatment remains to be further studied [214].

Tests used to date have shown many difficulties in terms of their practical application. Driving simulation, for example, could appear to be an easy test to perform, and experience with driving tests has accumulated over the years. However, it is not yet demonstrated that driving performance on a simulator is predictive of accidents during real driving. Nevertheless, deviations from lane, which are used as indicator of sleepiness during driving simulation, have been used to develop algorithms active in the car to improve safety on the road [215]. Similarly, in-car or driver-worn real-time monitoring for drowsiness may offer some advantage in the real-time detection of subtle changes suggestive of prior sleep loss or circadian effects on alertness. However, such systems could provide a false sense of security in the sleepy or drowsy driver, who may rely on the expectation that the monitoring system would avert a crash.

Despite the abundance of research on the topic, the present report indicates that significant knowledge gaps persist regarding the association of OSA with MVA. Furthermore, the great majority of research in this topic is observational, which diminishes the level of evidence, and thus limits the ability to form firm conclusions. Nonetheless, several statements can be made with reasonable conviction and are indicated in table 1. Current research is moving in an additional direction, with identification of microsleep episodes associated with drowsiness, *i.e.* the intermediate state between wakefulness and established sleep. Indeed, the drowsiness preceding sleep is associated with lack of control and may be a crucial determinant of MVAs [216–218]. Identification of drowsiness may be the new frontier to develop new and more applicable tests to identify risky drivers.

A major limitation of this work relates to the difficulty in defining vigilance, which is a complex psychological construct, including sustained attention, divided attention, focused attention, wakefulness, *etc.* The ESS does not measure vigilance or ability to drive, but only subjective sleepiness, which might be relevant, but reflects only a part of a complex phenomenon, and is open to manipulation by a driver wishing to minimise symptoms, especially where retention of the driving licence is essential for continuing employment. Moreover, sleepiness at the wheel is the result of several factors, which may be unrelated to OSA. In addition, cognitive problems associated with OSA may affect the risk of MVA. The pragmatic approach chosen by the task force members could not address the theoretical assessment of vigilance and cognitive function, which were outside the scope of this work.

General recommendations for future research

- There is a strong need for good quality studies on how to best diagnose OSA and detect sleepiness in drivers.
- Research should focus on biomarkers of sleepiness (including metabolic and genetic markers) that are easily measurable and respond with detectable changes to OSA treatment.
- Sex differences should be better explored regarding variables that affect fitness to drive and assessment methods.
- Results of tests measuring vigilance and sleepiness should be correlated with driving outcomes in real-life situations.
- Further research is needed on how driving simulators can be used on a large scale, and which variables should be used to define MVA risk.
- Whether OSA-associated crash is associated with increased risk of death or injury should be evaluated.

- A clear model applicable in a standardised way in screening for OSA and identifying patients potentially at high risk of MVA is still missing.
- New technologies to prevent accidents and research on new markers, especially focusing on drowsiness-related risk, appear promising.

Conflict of interest: M.R. Bonsignore has nothing to disclose. W. Randerath reports grants and personal fees for lectures from Philipps Respironics, Heinen & Löwenstein and Resmed, outside the submitted work. S. Schiza has nothing to disclose. J. Verbraecken reports grants and personal fees for advisory board work from ResMed and Bioprojet, personal fees for consultancy from Philips, personal fees for lectures from Sanofi, Agfa-Gevaert, Springer and AstraZeneca, grants and personal fees for study participation from Jazz Pharmaceuticals, grants and personal fees for lectures from SomnoMed, grants from AirLiquide, Westfalen Medical, Vivisol, Total Care, Medidis, Fisher & Paykel, Wave Medical, OSG, Mediq Tefa, NightBalance, Heinen & Löwenstein, Accuramed, Bekaert Deslee Academy and UCB Pharma, outside the submitted work. M.W. Elliott has nothing to disclose. R. Riha has nothing to disclose. F. Barbe has nothing to disclose. I. Bouloukaki has nothing to disclose. A. Castrogiovanni has nothing to disclose. O. Deleanu has nothing to disclose. M. Goncalves has nothing to disclose. D. Leger reports grants from Philips (Netherlands), Vanda (USA), Sanofi, Vitalaire International, Merck, Janssen, Jazz and RYTHM outside the submitted work. O. Marrone has nothing to disclose. T. Penzel reports grants from Cidelec and Philips, personal fees for consultancy from Heel Pharmaceuticals, personal fees for advisory board work from Bayer, outside the submitted work; and is a shareholder of Advanced Sleep Research, Somnico, Nukute, and The Siestagroup GmbH. S. Ryan has nothing to disclose. D. Smyth has nothing to disclose. C. Turino has nothing to disclose. W.T. McNicholas has nothing to disclose.

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