American Thoracic Society Documents

An Official American Thoracic Society Clinical Practice Guideline: Sleep Apnea, Sleepiness, and Driving Risk in Noncommercial Drivers

A 2012 Update

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New York, NY

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University of Cincinnati, Cincinnati, OH

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Background: Sleepiness may account for up to 20% of crashes on monotonous roads, especially highways. Obstructive sleep apnea (OSA) is the most common medical disorder that causes excessive daytime sleepiness, increasing the risk for drowsy driving two to three times. The purpose of these guidelines is to update the 1994 American Thoracic Society Statement that described the relationship among sleepiness, sleep apnea, and driving risk.

Methods: A multidisciplinary panel was convened to develop evidence-based clinical practice guidelines for the management of sleep apnea due to OSA. Pragmatic systematic reviews were performed, and the Grading of Recommendations, Assessment, Development, and Evaluation approach was used to formulate and grade the recommendations. Critical outcomes included crash mortality and real crashes, whereas important outcomes included near-miss crashes and driving performance.

Results: A strong recommendation was made for treatment of confirmed OSA. The intended audience is the clinician who encounters patients with sleep disorders.

Conclusions

- OSA versus non-OSA is associated with a two- to three-times increased overall risk for motor vehicle crashes, but prediction of risk in an individual is imprecise.
- A high-risk driver is defined as one who has more than one risk factor for both drowsy driving and car crashes due to falling asleep.
- The purpose of the guidelines is to update the 1994 American Thoracic Society Statement that described the relationships among sleepiness, drowsy driving, and sleep-disordered breathing.
- The most common of which is OSA. The intended audience is the practitioner who encounters patients with sleep disorders.

Discussion: The recommendations presented in this guideline are based on the current evidence, and will require an update as new evidence and or technologies becomes available.

Recommendations

- All patients being initially evaluated for suspected or confirmed OSA should be asked about daytime sleepiness, especially falling asleep unintentionally and inappropriately during daily activities, as well as recent unintended motor vehicle crashes or near-misses attributable to sleepiness, fatigue, or inattention. Patients with these characteristics are deemed high-risk drivers and should be immediately warned.
about the potential risk of driving until effective therapy is instituted.

- Ad d it ional notification should be elicited during an initial visit (or suspected or confirmed OSA in clude the clinical severity of the OSA and therapies that the patient has received including getting b e acquainted with the resources available. The focus is on the less of than 1 month. For appropriate selection of patients (e.g., many comorbidities. high clinical suspicion for OSA), at-home portal monitoring is a reasonable alternative to polysomnography.

- For patients in whom there is a high clinical suspicion of OSA and who have been deemed high-risk drivers:
  - We suggest that polysomnography be performed and, if indicated, treat ment in a timely fashion as soon as possible. mther than delayed until conveni ence (weak recommendation), very low-quality evidence). We recognize that the duration of time that constitutes "as soon as possible" will vary according to the resources available. b m we favor the goal of less than 1 month. For appropria tely selected patients (e.g., high severity), high clinical suspicion for OSA), at-home portal monitoring is a reasonable alternative to polysomnography.

- For patients with confirmed OSA who have been deemed high-risk drivers, we recommend CPT/IP therapy to reduce driving risk. r<1slher than nO lacrimation (sufficient evidence). This suggestion is for CPA! because on ly its effects on driving performance have been well studied: other treatments that could accomplish the same goal have not been evaluated.

- For patients with no suspicion or confirmed OSA who have been deemed high-risk drivers, we suggest NOT using similiar conditions for the sole purpose of reducing driving risk (weak recommendation, very low-quality evidence).

- Opportunities to improve clinical practice include the following:
  - Physicians should develop a practice-based plan to inform patients and their families about the risks of drowsy driving and other risks of excessive sleepiness as well as the options available to reduce driving risk (weak recommendation, very low-quality evidence).

- Clinicians should routinely inquire in patients suspected with OSJ -caused by excessive daytime sleepiness (e.g., sleep restriction, alcohol, and sedating medications), co morbid diseases (e.g., depression or neurologic disorders), and diminished physical skills. Such factors may additively contribute to crash risk and affect the efficacy of sleep apnea treatment.

- Clinicians should familiarize themselves with local and state statutes or regulations regarding the compulsory reporting of high-risk drivers with OSA.
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Scope, Questions, and Outcomes

Community meetings were convened in 2001 and 2012 to identify the scope and framework of the guidelines. It was decided that they needed to be seen by pulmonary specialists and others practicing sleep medicine (commercial licensing vehicle or email was given to specific individuals by email). Initial clinical questions were formulated with the intention of answering the questions with recommendations answering such questions and/or discussions of chronic disease to the degree applicable to driving risks in chronic disease. The quality of evidence indicates the committee's confidence in the direction and magnitude of the estimated effects of each course of action.

Recommendations were developed from the evidence. The strength of each recommendation was rated as "strong" or "weak" (1-5). A strong recommendation indicates that the committee is certain that the decision is best for the public at large and does not consider the benefit to the individual patient. A weak recommendation indicates that the committee is uncertain about the balance of desirable and undesirable consequences. If the desirable consequences and potential benefit is less desirable, the question is reconsidered. When possible, the group used recent evidence-based literature on driving risk. The driving risk assessment tool is the question, "Are you able to drive safely?"

TABLE 1. METHODS CHECKLIST

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<tr>
<th>METHODS CHECKLIST</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td><strong>Panel assembly</strong></td>
<td>Included experts for relevant clinical and nonclinical disciplines</td>
<td>X</td>
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<tr>
<td><strong>Evidence synthesis</strong></td>
<td>Included individual who represents the views of patients and society at large</td>
<td>X</td>
</tr>
<tr>
<td><strong>Evidence presentation</strong></td>
<td>Included a methodologist with appropriate expertise (documented expertise in conducting systematic reviews to identify the evidence base and the development of evidence-based recommendations)</td>
<td>X</td>
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<td><strong>Literature review</strong></td>
<td>X</td>
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<tr>
<td><strong>Search</strong></td>
<td>X</td>
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<tr>
<td><strong>Review of reference lists of retrieved articles</strong></td>
<td>X</td>
<td></td>
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<tr>
<td><strong>Evidence synthesis</strong></td>
<td>X</td>
<td></td>
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<tr>
<td><strong>Applied prespecified inclusion and exclusion criteria</strong></td>
<td>X</td>
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</tr>
<tr>
<td><strong>Evaluated included studies for sources of bias</strong></td>
<td>X</td>
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<tr>
<td><strong>Explicitly summarized benefits and harms</strong></td>
<td>X</td>
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<tr>
<td><strong>Used PRISMA to report systematic review</strong></td>
<td>X</td>
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<td><strong>Used GRADE to describe quality of evidence</strong></td>
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<td><strong>Generation of recommendations</strong></td>
<td>X</td>
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<tr>
<td><strong>Used GRADE to rate the strength of recommendations</strong></td>
<td>X</td>
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**Definition of abbreviation:** GRADE = Grading of Recommendations, Assessment, Development, and Evaluation.

TABLE 2. OPPORTUNITIES FOR GREATER INQUIRY AND RESEARCH

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<thead>
<tr>
<th>OPPORTUNITIES FOR GREATER INQUIRY AND RESEARCH</th>
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<tr>
<td><strong>How often do multiple risk factors for driving crash occur in patients with sleep apnea?</strong></td>
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<td><strong>Is there any relationship between the use of sedatives and the development of sleepiness?</strong></td>
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<td><strong>How are the potential undesirable consequences (i.e., risks) outweigh the potential undesirable consequences (i.e., risks) outweigh the potential undesirable consequences (i.e., risks)?</strong></td>
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Defining abbreviations: ATS = American Thoracic Society; OSA = obstructive sleep apnea.

The high-risk driver with sleep apnea:...
QUESTIONs, EVIDENCE, AND RECOMMENDATIONS

The statements summarized here are based on the prior document (15) and more recent studies and literature surveys. The online supplement discusses some of the topics in greater detail.

**Question 1:** Should driving risk be part of the initial assessment of patients who have suspected or confirmed OSA?

Evidence. Our literature search did not identify any studies that compared the effects of performing a driving risk assessment with the effects of not performing a driving risk assessment; thus, clinical experience was used to address the question. "If OSA is confirmed, the clinician must directly question the patient to identify high-risk drivers. The alternatives—self-reported sleepiness, family-initiated reports of drowsy driving, and a high (i.e., >17 out of 24) ESS score—are insufficient to identify high-risk drivers. Self-report of sleepiness is subject to inaccuracy and bias, and the ESS can <10 be replaced with questions about the effects of various clinical inquiries with the effects of not making those inquiries. Thus, clinical experience was used to answer the question."

**Recommendation 1:** All patients being initially evaluated for suspected or confirmed OSA should be asked about daytime sleepiness (i.e., falling asleep unintentionally and inappropriately during daily activities) as well as recent unintended motor vehicle crashes or near-misses attributable to sleepiness, fatigue, or inattention. Patients with these characteristics are deemed high-risk drivers and should be immediately warned about the potential risk of driving until effective treatment is instituted.

This recommendation is similar to the 1994 ATS statement (15) and is rephrased.

**Question 2:** In addition to the queries about sleepiness, what information should be obtained when assessing driving risk in a patient who has suspected or confirmed OSA?

Evidence. Our literature search identified no studies that compared the effects of various clinical inquiries with the effects of not making those inquiries. Thus, clinical experience was used to answer the question.

**Recommendation 2:** For all patients who have suspected or confirmed OSA, clinicians should routinely inquire about additional causes of sleepiness (e.g., sleep restriction, alcohol, or sedative medications), comorbid neurocognitive impairments (e.g., depression, neurologic disorders), and diminished physical skills. Addressing such risks may reduce driving risk. Even without recognition of the OSA risk assessment should be routinely elicited during routine follow-up.

**Evidence.** Our literature search identified no studies that compared the effects of various clinical inquiries with the effects of not making those inquiries. Thus, clinical experience was used to answer the question.

**Question 3:** What information unrelated to driving risk assessment should be routinely elicited during the initial evaluation of a patient who has suspected or confirmed OSA? And, what information should be obtained during routine follow-up?

Evidence. Our literature search identified no studies that compared the effects of various clinical inquiries with the effects of not making those inquiries. Thus, clinical experience was used to answer the question.
should be held to a higher standard. The clinical management of OSA has been in American Thoracic Society Documents reassessed if it was initially increased. Prior behavioral interventions. If subsequent visits, adherence and response to therapy, comorbidities, high clinical suspicion for OSA, and staff related to rearranging the sleep laboratory schedule to accommodate high-risk drivers, TI1c Committee's impression is based on nonsystematic clinical observations, similar to our previous document (15). Nonsystematic observations provide very low confidence in the estimated effects (i.e., very low quality of evidence). The related recommendation is weak because the very low quality of evidence creates uncertainty about the balance of the desirable and undesirable consequences.

polysonography is the most definitive and, therefore, the preferred diagnostic test. However, (or appropriately selected patient's e.g., no comorbidities, high clinical suspicion for OSA), at-home portable monitoring is a reasonable alternative to polysomnography.

Question 4: Should information on drowsy driving be provided at the initial assessment or a patient who has suspected or confirmed OSA?

Evidence. On ly drivers arc responsible for safe operation of a motor vehicle. However, the public and family members of a participant with sleepiness and sleep apnea can play an important role in mitigating risk, even though most are largely uninformed about sleepiness and driving risk. Counseling about the risks of drowsy driving may identify patients who have already reduced their driving exposure or who will voluntarily stop driving (25, 26). Additional counseling may be appropriate. Alternatives to driving may need to be explored for those who arc unconvincing or unwilling to acknowledge their increased crash risk. Although such educational efforts may be the most important for high-risk drivers, they are also appropriate for those with lesser degrees of sleepiness, even though such patients do not warrant expedited management. There is concern that institution of punitive measures for noncompliant drivers might result in misinformation. Fearful individuals and families who believe that a doctor's intervention can compromise their ability to drive an automobile.

Recommendation 4: For patie nts who had suspected or confirmed OSA, we suggest educating patients and their families about drowsy driving and other risks of excessive sleepiness as well as behavioral methods that reduce those risks.

Question 5: How soon should diagnostic testing occur and, if indicated, should treatment be initiated in patient with suspected OSA who have been determined to be high-risk drivers?

Evidence. We performed a pragmatic systematic review of the literature, which sought studies that evaluated the effects of the duration until diagnostic evaluation and initiation of therapy on crash-related mortality, real crash rate, near crash rate, or driving performance in p-Hnten with suspected OSA (Table F1). Our search identified no studies that met our prespecified selection criteria (figure E1).

Despite the paucity of supporting evidence, the Committee believes that the desirable effects of early diagnosis and treatment outweigh the undesirable consequences in most high-risk drivers with suspected OSA. Desirable consequences include earlier prevention of motor vehicle crashes and, possibly, related mortality. Undesirable consequences include inconvenience to both patients and staff related to rearranging the sleep laboratory schedule to accommodate high-risk drivers. TI1c Committee's impression is based on nonsystematic clinical observations, similar to our previous document (15). Nonsystematic observations provide very low confidence in the estimated effects (i.e., very low quality of evidence). The related recommendation is weak because the very low quality of evidence creates uncertainty about the balance of the desirable and undesirable consequences.

Continuous positive airway pressure (CPAP) can be a reasonable alternative to polysomnography in high-risk drivers with suspected OSA while awaiting the diagnostic evaluation.

Evidence. We performed another pragmatic systematic review of the literature to look for studies that evaluated the effects of empiric CPAP on crash-related mortality, real crash rate, near crash rate, or driving performance in patients with suspected OSA (Table E1). Again, our search identified no studies that met our prespecified selection criteria (Figure E2).

Despite the lack of supporting evidence, the Committee believes that the undesirable effects of empiric CPAP outweigh the desirable effects in most high-risk drivers with suspected OSA. Unlikely consequences include the burden, cost, possibility that some patients will be unnecessarily treated, and possibility that the empiric CPAP will affect the accuracy of the diagnostic test leading to errors with long-term impact. Desirable consequences include the possibility of lowering the driving risk sooner. The Committee’s impression is based on nonsystematic clinical observations. Nonsystematic clinical observations provide very low confidence in the estimated effects (i.e., very low-quality evidence). The recommendation is weak because the very low quality of evidence causes uncertainty about the balance of desirable and undesirable consequences.

Recommendation 6: For patients in whom there is a high clinical suspicion of OSA and who have been deemed high-risk drivers, we suggest NOT using empiric CPAP for the sole purpose of reducing driving risk (weak recommendation, very low-quality evidence).
Question 7: Should patients with confirmed OSA who have been deemed high-risk drivers have their OSA treated for the purpose of reducing the driving risk? Evidence. We performed a pragmatic systematic review of the literature, which sought studies that evdual ted the cff(ce: Of treat- ment on crash-related mortality, reit crash rate, necr crash rate, or driving performance in patients with confirmed OSA (Table E1). Our search identified three systematic reviews that included st udies that at met our prespecified sel.elction criteria (Figure E3) (22, 27, 28). There was considerable overlap among the studies, included, and the findings were similar. J.11 or the systematic reviews evaluated CPAP thepmy and not oral appliances or surgery.

We chose the most recent systematic review to inform our judgment (27). This review included 15 before-versus-after studies and observational studies (I,293 patients) (27). Meta-
analyses found a marked reduction in the incidence of real crashes (odds ratio, 0.21; 95% confidence interval [CI], 0.12-0.35), near-misses (odds ratio, 0.09; 95% CI, 0.01-0.21), and crash-related fatalities. (27). We identified 13 before-versus-after trials that were published after the systematic reviews.

The committee's confidence in the estimated effects was increased by the inclusion of new data in each of the systematic reviews. The findings were similar to the meta-analyses and consistent with the results from the individual studies. The committee's confidence in the results is very low, despite its randomized design. However, the study's small size creates imprecise estimates of effect. The committee judged that the population and outcome of the related recommendation alerting medication is weak. The very low quality of evidence creates uncertainty about the balance of desirable effects (i.e., cost, burden, side effects, and false reassurance) and undesirable effects (i.e., better driving performance).

Recommendation 8: For patients with suspected or confirmed OSA who have been deemed high-risk drivers, we suggest NOT using a stimulant medication for the sole purpose of reducing driving risk (weak recommendation, very low-quality evidence).

Question 8: Can stimulant medications be used to reduce the driving risk among patients with suspected or confirmed OSA who have been deemed high-risk drivers? Evidence. There is interest in using alerting medications (e.g., methylphenidate) to improve driving performance in patients with sleep apnea. However, the evidence is limited by the small size of the randomized controlled trials. In general, any physician owes a duty to the patient to take steps to reduce the foreseeable risk that the patient will harm himself or herself, including the task of operating a motor vehicle (16).

The committee's confidence in the estimated effects was increased by the inclusion of new data in each of the systematic reviews. The findings were similar to the meta-analyses and consistent with the results from the individual studies. The committee's confidence in the results is very low, despite its randomized design. However, the study's small size creates imprecise estimates of effect. The committee judged that the population and outcome of the related recommendation alerting medication is weak. The very low quality of evidence creates uncertainty about the balance of desirable effects (i.e., cost, burden, side effects, and false reassurance) and undesirable effects (i.e., better driving performance).

Recommendation 8: For patients with suspected or confirmed OSA who have been deemed high-risk drivers, we suggest NOT using a stimulant medication for the sole purpose of reducing driving risk (weak recommendation, very low-quality evidence).

Question 9: Is there a legal standard for assessment of sleepiness and sleep apnea for pulmonary specialists and for other health professionals with expertise in sleep apnea? Evidence. Under general principles of malpractice liability, physicians are obliged to adhere to the prevailing standard of care (J.I. 34, 35). The pulmonary physician has the knowledge and skills to perform a history and physical examination, being aware that many conditions, including sleep apnea, confer high functional risk for drowsy driving and need identification as red flags. Steps to mitigate risk can be instituted immediately while awaiting diagnosis and treatment. Once sleep apnea is detected, there needs to be a plan to explain the goal of the therapy and to assess the patient's response, with a goal of reducing risk (22).

In general, any physician owes a duty to the patient to take steps to reduce the foreseeable risk that the patient will harm himself or herself, including the task of operating a motor vehicle (16). This obligation would ordinarily include describing the risks of a medical impairment and warning the patient to take appropriate precautions to reduce the risks of harm to himself or others. This duty has been extended in recent years to cases involving psychiatric patients who present a foreseeable risk of violence to others (16). Liability for third parties has been established in connection with potential impartment in driving performance, such as drowsiness, caused by the side effects of medications (36).

The committee's confidence in the estimated effects was increased by the inclusion of new data in each of the systematic reviews. The findings were similar to the meta-analyses and consistent with the results from the individual studies. The committee's confidence in the results is very low, despite its randomized design. However, the study's small size creates imprecise estimates of effect. The committee judged that the population and outcome of the related recommendation alerting medication is weak. The very low quality of evidence creates uncertainty about the balance of desirable effects (i.e., cost, burden, side effects, and false reassurance) and undesirable effects (i.e., better driving performance).
P. recommendation 9: Clinicians should institutionalize themselves with the presentation and complications of excessive sleepiness as well as local state statutes or regulations regarding the compulsory reporting of high-risk drivers with OSA.

FINAL COMMENTS

Physicians, patients, and regulatory/legal systems ideally would have a mutual understanding of the importance of recognition of sleepiness as a risk factor for safe driving and encourage interventions to reduce risks involved in drowsy driving. Society is responsible for deciding thresholds for tolerance and implementation of policy and regulations. Physicians are responsible for clinical management but also are citizens and opinion leaders. Patients are drivers, workers, family members, and voters. Because the elements in assessments and preventions form a social triad, at any one time, the players can change roles as victim, savior, or persecutor. Communication as the manner and purpose of assessments is essential, as is the physician's character as an advocate for the patient's rehabilitation and health in regard to the management of sleep apnea. Many interesting points might be useful (or discussion or research at a medical mgdgraduate or graduate level were identified during the course of the discussions).

These guidelines were prepared by an ad hoc Committee of the Assembly for Sleep and Respiratory Neurobiology.

Members of the Committee are as follows:

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Author Disclosures: • • • • •

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