

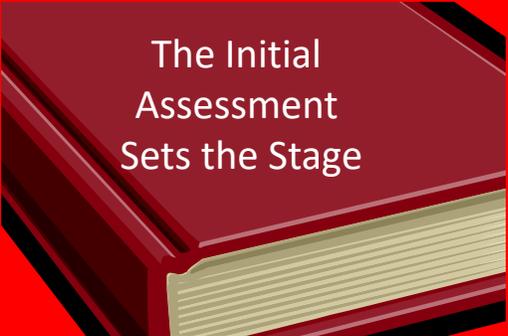
 **University Hospitals**  **CASE WESTERN RESERVE UNIVERSITY**
SCHOOL OF MEDICINE

Managing the Driving Risks of OSA

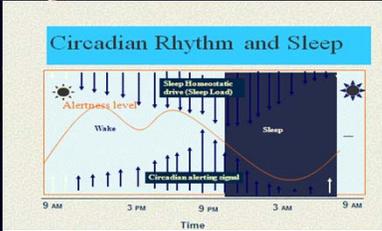
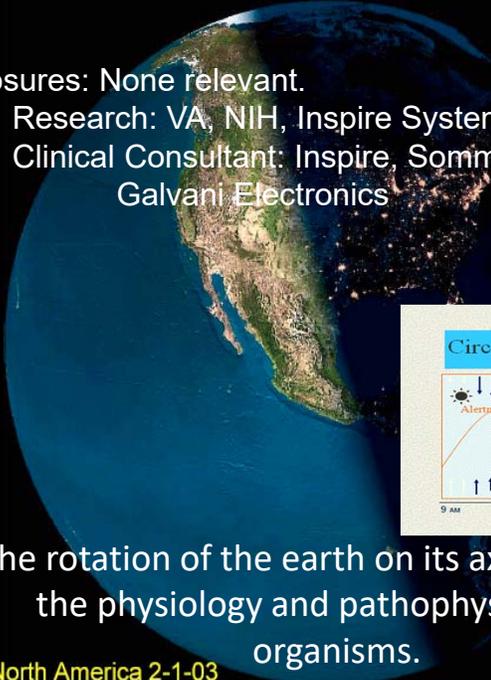
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The Initial
Assessment
Sets the Stage



Disclosures: None relevant.
Research: VA, NIH, Inspire Systems, Sommetrics
Clinical Consultant: Inspire, Sommetrics,
Galvani Electronics



The rotation of the earth on its axis influences
the physiology and pathophysiology of all
organisms.

Sunset over North America 2-1-03

DROWSY DRIVING



SCARY STATS

5000 - 6000 Fatal Crashes
The NHTSA estimates that 5,000 - 6,000 fatal crashes every year may be caused by drowsy drivers.

Two Out of Every Five Drivers
Two out of every five drivers (41.0%) reported having fallen asleep or nodded off while driving.

Cognitive impairment after approximately 18 hours awake is similar to that of someone with a blood alcohol content (BAC) of 0.05%.



After about 24 hours awake, impairment is equivalent to a BAC of 0.10%, higher than the legal limit in all states.



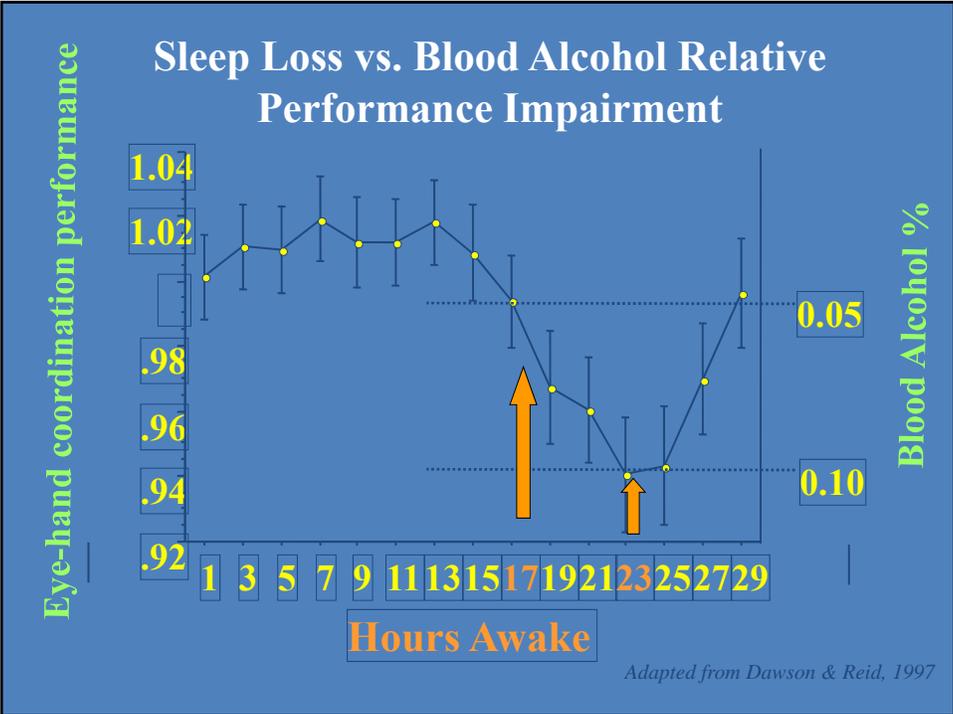
7% 7% of all crashes between 1998 and 2008 involved a drowsy driver.

13.1% 13.1% of crashes that resulted a person being admitted to a hospital involved drowsy driving.

16.5% 16.5% of fatal crashes involved drowsy driving.

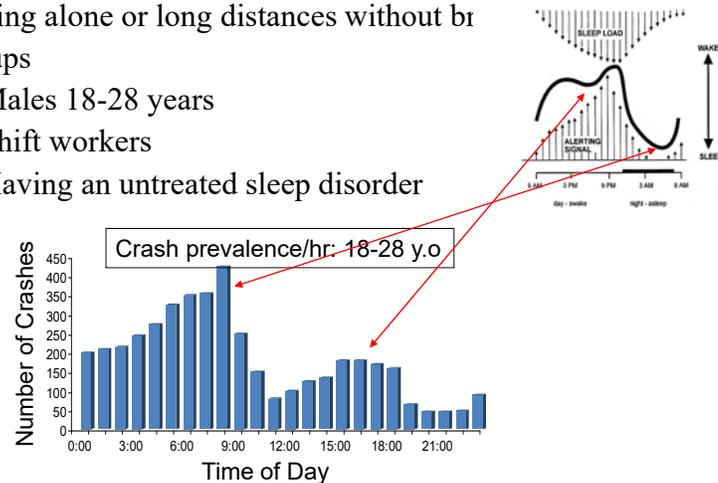


Centers for Disease Control and Prevention and AAA foundation for Traffic Safety



Risk for Drowsy Driving

- <5 hours of sleep at night
- Any sedating medications or small amounts of alcohol
- Driving alone or long distances without br
- Groups
 - Males 18-28 years
 - Shift workers
 - Having an untreated sleep disorder



Pack et al 1995; NIH-NTSA Task Force 1998; NSF Task Force, 2016)

OSA and Crash Risk

- Individuals with OSA are at increased risk for crash
 - Precise estimate of magnitude of this increased risk not calculated for an individual
 - Crash Risk Rate in a range of 1.20 to 4.89
 - Crash risk among individuals with a diagnosis of OSA is higher than comparable individuals without the disorder
 -but ~50% of patients have never had a crash.
 - Crash risk is not outside a normal national distribution.
 - Recognition profile for OSA is similar to that elsewhere
 - Snoring and disturbed sleep
 - Snorts and gasping
 - Waketime cognitive deficits and sleepiness

CPAP AND MOTOR VEHICLE CRASH RISK: REVIEW AND META-ANALYSIS

Continuous Positive Airway Pressure Reduces Risk of Motor Vehicle Crash among Drivers with Obstructive Sleep Apnea: Systematic Review and Meta-analysis

Stephen Tregear, PhD¹, James Reslon, PhD, MPH², Karen Schoelles, MD, SM², Barbara Phillips, MD, MSPH³

¹MANILA Consulting Group, McLean, VA; ²ECRI Institute, Plymouth Meeting, PA; ³Division of Pulmonary, Critical Care and Sleep Medicine, Department of Internal Medicine, University of Kentucky College of Medicine, Lexington, KY

8 studies of crash risk in OSA patients showed that after treatment with CPAP, and one after UPPP:

- Crash risk dropped
 - risk ratio = 0.278, 95% CI: 0.22 to 0.35; P < 0.001
- Daytime sleepiness improved after one night
- Simulated driving performance improved within 2-7 days

....but AHI is not predictive until over 80/hr

funded by FMCSA GS-10F-0177N/DTMC75-06-F-00039

Tregear, Sleep, 33(10):1373, 2010

Neurobiological “exposures” for Crash Risk in OSA

- **Sleep apnea**
 - Sleep fragmentation and acquired sleepiness
- **Behavioral**
 - Short sleep (<5 hours: OR 1.2-1.7)
 - Shift work (OR 1.6-3.32)
 - Inattention (cell phones OR 22)
 - Alcohol and sedating drugs even OTC (OR 6)
- **Co-Morbid Conditions**
 - Diabetes (OR 1.08- 1.3)
 - Depression (OR 1.22-1.9)
 - Neurological diseases (OR 1.5-2.2)
 - Hypertension (1.01-1.3)

RESPONSIBILITIES IN DRIVING RISK

Physician: (does not license drivers.... but has training to assess)

- Determine cause(s) for drowsy driving and treatment options
- Inform patient and family of potential risk
- Create a plan for follow-up
- Act as a physician, knowing applicable state law and regulations

Patient: Act as a responsible citizen for which driving is a privilege

- Acceptance of responsibility
- Be an honest reporter of symptoms

Government: Non-prejudicial re-assessment of driving privileges

- Take responsibility (cost and administration) for directives

A Classic Triangle

ATS position statements 1993 and 2013

Conclusions from the 2013 ATS Position Paper

- OSA Sleepiness is associated with increased risk for motor vehicle crashes.
- *There is as yet no compelling evidence to restrict driving privileges in patients with OSA if there has **not been** a motor vehicle crash or an equivalent level of concern for increased driving risk.*
- The *high-risk driver* is one who has moderate or severe daytime sleepiness that is accompanied by recent history of an unintended motor vehicle crash or a near-miss attributed to sleepiness, fatigue, or inattention.
- *Treatment of OSA improves performance* on driving simulators and might be expected to reduce risk of drowsy driving and drowsy driving crashes.
- *Elements for documentation* during an initial assessment would include clinical severity, driving risk, the type of therapy (including behavioral interventions), the consideration of positive airway pressure or another therapy, adherence to therapy, the response to therapy, reassessment of drowsy driving behavior, and whether the patient could be at high risk.
- *Education and timely diagnostic evaluation and treatment* is likely to decrease the prevalence of sleepiness-related crashes in this population.

ROUTINE INITIAL ASSESSMENT TO PROFILE THE HIGH RISK DRIVER

ATS Guidelines

- In the initial assessment,
 - determining whether the OSA patient is at high-risk for a motor vehicle crash.
 - The profile of a high-risk patient is one who has moderate or severe daytime sleepiness accompanied by recent history of an unintended motor vehicle crash or near-miss attributed to sleepiness, fatigue, or inattention.
- If positive, inquiry about additional causes of sleepiness (e.g., sleep restriction, alcohol, or sedating medications), co-morbid neurocognitive impairments (e.g., depression or neurologic disorders), and diminished physical skills.
- Note: No ESS or AHI or ODI but clinical assessment

2013 ATS Position Paper

POINT-OF-SERVICE ASSESSMENTS FOR “HIGH RISK”

Those high-risk drivers with high probability of OSA:

- Clinical severity (mild, moderate severe)
- The response to a direct question about drowsy driving “Do you drive drowsy?”

This assessment is not be dependent upon outside information to be obtained later.

- We suggest that the diagnostic evaluation and initiation of treatment be performed within one month, rather than later (weak recommendation, very low quality evidence).

2013 ATS Position Paper

ASSESSMENTS IN THOSE WITH OSA AND “HIGH RISK”

For patients with confirmed OSA who have been determined to be high-risk drivers:

- We recommend the treatment of OSA to reduce driving risk (*strong recommendation, moderate quality evidence*). It is reasonable to advise their patients to refrain from driving until treatment reduces risky behavior (*no evidence*).
- We suggest educating patients and their families about the risks of excessive sleepiness and behavioral methods that reduce risk.
- We suggest NOT using modafinil routinely for the sole purpose of reducing driving risk (weak recommendation, very low quality evidence).

2013 ATS Position Paper

GOOD MEDICAL PRACTICE

For pulmonary specialists and other health professionals with expertise in sleep apnea:

- We suggest that clinicians familiarize themselves with.....
- the presentations and complications of excessive sleepiness
- local and state statutes or regulations regarding the compulsory reporting of high-risk drivers. (CA and AZ such state!)

2013 ATS Position Paper

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Question 1

A 46-year-old male presents to your office for evaluation of suspected obstructive sleep apnea (OSA). The patient reports approximately 8 hours of sleep every night. He snores, and his bed partner has witnessed apneic events. The patient wakes non-refreshed on most days, and complains of excessive daytime somnolence. The patient drives for 30 minutes every day from his home to his workplace, where he works as an accountant. He denies ever falling asleep while driving, but admits to drowsy driving. He can recall one occasion when he almost had an accident due to drowsy driving.

On physical examination, the patient is an obese male with an 18-inch neck circumference. Oropharyngeal examination reveals a modified Mallampati class IV airway. The rest of the examination is unremarkable.

You arrange a polysomnography to further evaluate for obstructive sleep apnea. You also counsel the patient about the risks of drowsy driving and urge him to refrain from driving until he can be tested and treated appropriately. The patient understands the risks, but says that he has no other options but to drive. He asks if there is anything he can do to minimize drowsiness while driving.

Question:

Which of the following recommendations is most appropriate to reduce the patient's risk of drowsy driving until he can be tested and treated?

- Answer Choices:
- A. You prescribe modafinil 200 mg for use prior to driving to and from work
- B. You encourage the patient to make a phone call and engage in conversation if he feels sleepy while driving
- C. You recommend that the patient should open his car window 7-8 inches to allow a strong breeze while driving
- **D. You recommend that the patient should pull over and take a nap if he feels sleepy while driving**
- E. You recommend that the patient should run the air conditioner, rather than heater, to keep him alert while driving

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The best countermeasure is sleep. 20 minutes will work for 1-1.5 hours.

Question 2

A 41-year-old male underwent polysomnography for complaints of snoring and excessive daytime somnolence. The study revealed obstructive sleep apnea with an AHI of 15 events per hour. He presents to your office for follow up. He has felt sleepy while at work and while driving. He denies ever being involved in a motor vehicle accident due to drowsy driving, but admits that he has had multiple "near misses." He continues to drive, as it is his only means of getting to work. He is concerned about drowsy driving and requests treatment to help prevent falling asleep while operating a motor vehicle.

Question:

In addition to warning the patient against drowsy driving, and starting CPAP therapy, what other steps should be taken at this time?

- Answer Choices:
- A. Ask about other non OSA causes of daytime sleepiness.
- B. Perform a MSLT to assess daytime sleepiness.
- C. Start stimulant therapy (e.g. Modafinil)
- D. Perform a MWT to assess ability to stay awake.
- E. Report to the local Department of Motor Vehicles that the patient has a medical impairment that may render it unsafe for him to operate drive.

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Question 3

A 50-year-old male has recently been diagnosed with obstructive sleep apnea (OSA) after undergoing overnight polysomnography. He sees you in your office for further management and to initiate treatment. The patient is accompanied by his wife. He has a medical history of hypertension and pre-diabetes, both of which are managed with lifestyle modifications. The patient is quite active and denies any daytime somnolence. Physical exam is notable for a modified Mallampati class III airway. The Epworth Sleepiness Scale score is 9. After discussing the diagnosis and treatment options, you consider risk stratifying the patient for drowsy driving.

Question:

Which of the following is the best approach to assess this patient's risk for drowsy driving?

• Answer Choices:

- A. An assessment should not occur during this visit because the patient does not complain of daytime somnolence and the Epworth Sleepiness Scale is less than 10.
- B. An assessment should not occur during this visit. It should occur 6 weeks after the patient has started treatment for OSA.
- C. An assessment should occur during this visit. It should consist of directly asking the patient about falling asleep while driving, including actual crashes and near misses due to sleepiness.
- D. An assessment should occur during this visit. It should start as a discussion with his wife, if the patient is agreeable, which will allow a more objective view of his day to day sleepiness.

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- D. An assessment should occur during this visit. It should start as a discussion with his wife, if the patient is agreeable, which will allow a more objective view of his day to day sleepiness.
- Correct Answer:

Use any and all sources of information during the visit.

Question 4

A 44-year-old male with a history of untreated obstructive sleep apnea falls asleep while driving and gets into a motor vehicle accident.

Question:

Which of the following statements is most accurate regarding drowsiness and motor vehicle accidents?

Answer Choices:

- A. Motor vehicle accidents due to falling asleep commonly involve multiple vehicles.
- B. Review of crashes due to drowsy driving reveal evasive maneuvering just prior to the crash.
- C. Serious injury and death occur less commonly in crashes due to drowsiness compared to crashes in which drowsiness is not a factor.
- D. Sleepiness related crashes occur most commonly at night and in mid-afternoon.
- E. The majority of motor vehicle accidents are due to drowsy driving.

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