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Editorial

Getting Serious about Excessive Sleepiness☆

Sleepiness is a very common patient complaint and is more widespread than previously thought, affecting as many as 20% - 30% of U.S. adults. Disorders of excessive sleepiness of central origin such as idiopathic hypersomnia and narcolepsy are much less prevalent but not uncommon. I suspect historical prevalence data underestimate the number of patients affected. Sadly, way too many patients with sleepiness do not discuss symptoms with their physician or do not recognize sleepiness as the cause of their fatigue, neurocognitive impairment, mood changes or even fatigue related accidents. The strong circadian drive for wakefulness supports daytime function and often disguises functional impairment. In other words, the patient can get by but is not normal. We have personal, family, community, and work obligations that siphon off our necessary hours of quality sleep. Living life constantly in a daze and suffering the attendant co-morbidities should not be the norm in our society, and yet it is. We need to put this issue on our radar and use the latest in sleep science to address it.

Fortunately, our scientific understanding of the sleep-wake process has improved, as has our ability to safely and effectively treat sleep problems. Wearable technology has intrigued our patient population as to total sleep time and indirect measures of sleep quality, including the importance of" dipping" of heart rate during sleep. Basic research, advanced technologies and big data along with analytic tools, such as artificial intelligence, are enhancing our understanding of brain states and biological processes. Traditional stimulants that act on the central nervous system, particularly the monoaminergic system, had been commonly prescribed for excessive sleepiness for decades. These drugs (i.e., methylphenidate, amphetamines) are very effective at keeping you alert, but they can cause serious side effects and can be addictive.

Thankfully, we have made progress and have more options today. Safer wake-promoting agents such as modafinil, and later armodafinil, hit the U.S. market in 1998. These medications have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of sleepiness in narcolepsy, shiftwork sleep disorder and persistent sleepiness in treated OSA. Once a day dosing, perhaps less tolerance and rebound, lower side effect profile, less abuse potential and schedule IV status all offer clinical advantages. They are non-habit forming and are less likely to cause excess locomotor activities, anxiety, jitteriness, or rebound effects than the traditional stimulants. Sodium oxybate was approved in 2002 by the FDA as the first drug approved to treat cataplexy in narcolepsy. Subsequently, sodium oxybate was shown to improve excessive daytime sleepiness in adult narcolepsy and now is considered a standard of care by the AASM.

Just this year, the FDA approved solriamfetol, the first dual-acting dopamine and norepinephrine reuptake inhibitor approved to treat excessive sleepiness in adults with narcolepsy or obstructive sleep apnea. Last year sodium oxybate was approved to treat pediatric narcolepsy age 7 or greater. Pitolisant is the first alerting agent acting on the important central histamine (H1) receptors mediated by an antagonist/inverse agonist effect on H3 receptors. It is approved in the E.U. for narcolepsy, and is being evaluated by the FDA for approval in the U.S. Current pivotal trials have just been completed in narcolepsy with low salt oxybate. Once nightly dosing in an extended release formulation of sodium oxybate is in phase 3 trials. GABA-A antagonists, norepinephrine reuptake inhibitors, and orexin agonists are being studied. And now finally there are trials evaluating pharmacologic intervention for idiopathic hypersomnia.

Understanding the burden of excessive sleepiness and disorders of primary central nervous system sleepiness has helped clinicians and health care professionals to refine strategies for clinical management to include behavior modification, counseling and family support.

Despite these advancements, recognizing and treating patients' excessive sleepiness is still a challenge for many primary care providers. One way to combat this issue is by ensuring health care providers ask about sleep during each patient visit. The National Sleep Foundation (NSF) has championed sleep as a vital sign since 2013. Primary care physicians also need continuing medical education on excessive sleepiness for proper diagnosis and treatment, as well as training on clinical tools (i.e., Epworth Sleepiness Scale, Functional Outcomes of Sleep Questionnaire) and objective tests that can help with identifying excessive sleepiness. NSF is committed to getting primary care physicians the education and training they need to recognize, evaluate and treat this pervasive problem.

As a community, we need to meet head on the challenge of addressing excessive sleepiness and encourage everyone to prioritize their sleep. While we continue to make scientific progress in understanding sleep-wake biology, let's also ensure that we are promoting the benefits of good quality and quantity of sleep; and making it attainable for everyday people.

Disclosures

Dr. Richard Bogan has been a consultant for Harmony Biosciences and Jazz Pharmaceuticals. He served on the speakers' bureau for Jazz Pharmaceuticals and Merck. He has participated in industry sponsored research with Axsome, Fresca, Jazz, Balance, Harmony, Merck and Philips. He is employed by SleepMed Inc. as Chief Medical Officer and is a shareholder of SleepMed Inc.

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