Sleep Apnea Treatment:

Is it Effective?



November/December 2023

What is the definition of an effective sleep apnea treatment? In a word, its duration. Emerging scientific literature indicates that what matters most is how long treatment is used during the night and how long untreated apneas last. Until one year ago, four (4) hours of CPAP usage per night for 70% of nights was considered by the Centers for Medicare and Medicaid Services (CMS) to be adequate for insurance coverage.

Then, on December 1, 2022, a <u>report</u> entitled "Long-Term Health Outcomes in Obstructive Sleep Apnea" was published for CMS by the Agency for Healthcare Research Quality (<u>AHRQ</u>). The report found that four hours per night, 70% of nights is not an adequate duration of use to prevent the <u>diseases</u> and negative impact on the quality of life associated with untreated sleep apnea.

The AHRQ report also reviewed the validity of breathing measures as surrogates for long-term health outcomes. In particular, the Apnea-Hypopnea Index (which expresses the number of <u>apneas</u> and <u>hypopneas</u> per hour) was found to be a weak and arbitrary indicator of sleep apnea severity and long-term health outcomes.

For years, the effectiveness of treatment has been measured by the Apnea-Hypopnea Index (AHI). For example, the FDA has approved surgically implantable obstructive sleep apnea treatment devices that have proven safe and that reduce AHI by 50% with no more than 20 apneas and hypopneas per hour – assuming a full night's use. However, the AHRQ report found that the *duration* of apneas using blood oxygen (Sp02) desaturation as a proxy for health outcomes is a more relevant metric than the frequency because the longer an apnea lasts, Sp02 drops <u>logarithmically</u>, and the more damaging it is to a patient's health.

Therefore, the difference in a patient that has an AHI 20 with apneas lasting an average of 5 seconds (for a total of 3 missed breaths since the end of the last exhalation), is not nearly as severe as an AHI 20 with apneas lasting 20 seconds (the median duration observed in the Heart Health Study with a range of 11 - 58 seconds), or at least 4 missed breaths in a row. This is often accompanied by a drop in Sp02 to well below 90%, and a graduated adrenergic response to increased CO2 levels, triggering the release of epinephrine, production of glucose, and arousal of the fight or flight mechanism, in proportion to the duration of the event.

For some, the usage of treatment all night, every night is essential. Otherwise, they report waking up tired and unable to function properly during the day from repeated episodes of unconscious near-suffocation and struggling to breathe against an <u>obstructed airway</u>. However, not all of those with sleep apnea wake up too tired to function, possibly because some of their apneas are <u>central apneas</u> during which no attempt was made to inhale, even though the airway was open. About half with sleep apnea do not suffer <u>excessive daytime sleepiness</u>, and report using treatment just enough to get by. For many this means only 4 hours per night, 70% of nights – and in some cases, only because they are required by their employer to meet this minimum adherence threshold for safety reasons.

But is this an effective treatment?

What happens each time an obstructive apnea lasts 20 seconds or longer? And how many of those happen in a night? Taking the prior example of AHI 20 with an average duration of 20 seconds, which would be 160 apneas in an 8-hour sleep session, for a total time spent in apnea of 3,200 (vs. 800) seconds. At a breath every 5 seconds, that would be approximately 640 attempts to inhale against a closed airway vs. 160 attempts that night (if all events were obstructive apneas).

The AHRQ report further determined that the total duration of exposure to reduced air flow while asleep as measured by Sp02 (using a finger-worn pulse oximeter), is a legitimate proxy for

determining nightly hypoxic load and lifetime burden, and these are the metrics most closely associated with poor health outcomes. The Sp02 metrics cited in the report appear to be more meaningful than AHI and express event *duration*. They include:

- T90 (desaturation time spent below 90%)
- P90 (percent of total sleep time below 90%)
- DO3 (desaturation time spent 3% below baseline)
- PO3 (percent of total sleep time 3% below baseline)
- DO4 (desaturation time spent 4% below baseline)
- PO4 (percent of total sleep time 4% below baseline)

If these metrics appear to be more accurate predictors of health outcomes associated with obstructive sleep apnea than AHI, perhaps we could consider a 50% improvement over baseline in these metrics would be a legitimate minimal goal for the effectiveness of treatment. Additionally, reducing the average duration of apneas by 50% to an average of 10 seconds could be another metric to target in seeking to establish the effectiveness of treatment.

As research continues, motion and heart rate variability may emerge as additional legitimate proxies for long-term health outcomes associated with obstructive sleep apnea and for measuring the effectiveness of treatment. For example, a reduction in heart rate spikes of over <u>40 beats per minute</u> during apneic events detected using a pulse oximeter, and an improvement in time spent laying still detected using a chest-positioned accelerometer, could add critical insights needed to assess the effectiveness of sleep apnea treatment at home with the minimum number of sensor and patient discomfort.

The current status quo of only a 10% diagnosis and a 5% sleep apnea treatment rate cannot continue. We need a material positive change, considering the health and economic consequences for the people, employers, and health insurance companies impacted. A new year often creates new opportunities. The emergence of more sophisticated medical-grade wearable sensors will likely bring true improvements in sleep apnea treatment, as well as scientific advances in the methodology used to determine effectiveness. Now that's a change we can all be excited about.

About the Author

<u>Michael G. Nathans</u> is the CEO and Co-Founder of WhisperSom Corporation, a medical device and informatics company. He holds a degree in Biology and Pre-healing Arts from Franklin & Marshall College and has a 35-year business background that includes 5 years at PwC, two U.S. patents, and two grants from the Ford Foundation. Follow WhisperSom on <u>LinkedIn</u> and <u>Facebook</u> and visit <u>whispersom.com/library</u> for more discussions about sleep apnea and raising the 10% diagnosis and 5% treatment rates through awareness and technology.