PRO/CON DEBATE

ANALYSIS AND PERSPECTIVES

JCSM
Journal of Clinical Sleep Medicine

http://dx.doi.org/10.5664/jcsm.2324

PRO: Sliding into Home: Portable Sleep Testing Is Effective for Diagnosis of Obstructive Sleep Apnea

Douglas B. Kirsch, M.D., F.A.A.S.M.

Clinical Instructor, Harvard Medical School, Regional Medical Director, Sleep HealthCenters, Brighton, MA

Whether you call it home sleep testing (HST), out of center sleep testing, portable monitoring, or something else, the debate about the use of medical devices to assess patients for obstructive sleep apnea outside the sleep laboratory setting has been ongoing for almost 20 years. In the last few years, the discussion has intensified as many United States-based insurance providers, including the government-run Center for Medicare and Medicaid Services (CMS), have approved the use of these devices for diagnosis of obstructive sleep apnea (OSA).[1] This article will briefly review the epidemic of OSA, the history of home sleep testing, and the reasons that home sleep testing is likely to play an increasingly large role in the practice of sleep medicine in the next several years.

Obstructive Sleep Apnea (OSA)

The medical community has been increasingly aware of sleep disorders over the last several years, and in particular, OSA evaluations have been occurring at an increasing rate; CMS data demonstrates that payments for polysomnography alone increased from $62 million in 2001 to $235 million in 2009.[2] These payments do not include the cost of medical consultations or the treatments for these patients. This 4-fold increase over 8 years may be explained by several factors: increasing availability for testing as sleep medicine has grown as a field (more than 2,000 centers were listed as accredited by the American Academy of Sleep Medicine in 2010),[3] the worsening epidemic of obesity in the United States (in 2010, no state had a prevalence of obesity [defined by a BMI of 30] < 20%; 12 of these states had a prevalence ≥ 30%),[4] and increasing knowledge that untreated OSA has medical and societal consequences (such as the potential to increase the risk of motor vehicle crashes, morbidity, and mortality).[5,6] Though the total amount of money used for polysomnography is small on a percentage basis when looking at the budget for CMS, it is probable that the rate of increase was particularly of concern. In the current US budget climate, many methods for reducing cost while maintaining quality were reviewed, including procedures for OSA diagnosis.

Home Sleep Testing and Auto-titrating Positive Airway Pressure (PAP) Therapy

Studying sleep objectively has generally required a laboratory, given the large amount of signals needed for a full polysomnogram (EEG, respiratory parameters, leg/chin movements, EKG, oxygen saturation), as well as the amplifiers, output methods (in recent years, computers), and technical staff. A diagnosis for OSA is typically given when a patient has an apnea-hypopnea index (AHI) ≥ 15 events/h, or an AHI ≥ 5 associated with sleep symptoms or medical disorders.[7] OSA is a relatively common disorder (data from 1993 suggests that 4% of middle-aged men and 2% of middle-aged women have the disorder[8]), and it is one of the most commonly diagnosed problems in a sleep laboratory. As well, sleep laboratories are typically localized to sites with larger populations, making testing of scattered or rural populations more difficult. Thus, portable methods have been evaluated for diagnosis of OSA.

Testing for OSA in the home only solves half of the problem. Prior to the last few years, after a diagnosis of OSA was made, an attended in-laboratory PAP titration study was also necessary to ensure the appropriate pressure was chosen for treatment. At times, both a diagnostic study and a titration study were performed in the same night as a "split-night" protocol. However, the creation, validation, and clinical use of the auto-titrating PAP device minimizes the need for an in-laboratory titration study. While there are still some lingering questions regarding the equivalence of continuous use of auto-titrating PAP therapy and standard PAP therapy, the algorithm of HST for diagnosis and auto-titrating PAP for treatment clearly allows for cost-effective patient management.

The History of Home Sleep Testing

Scarce data about home sleep testing in the early 1990s limited the use of the devices on a larger scale. A review was performed by the American Sleep Disorders Association (a precursor to the American Academy of Sleep Medicine) in 1994,[9] which suggested that home sleep testing be used only in the following situations:

1. Patients with severe symptoms or when treatment is urgent and PSG is not readily available
2. Patients unable to be studied in the laboratory
3. Follow-up study after diagnosis established by polysomnography to evaluate response to therapy

A repeated review in 1997 repeated those recommendations, suggesting that there was not enough validated data for unattended use of home sleep testing devices.[10] A Tri-Society (formed of the American Academy of Sleep Medicine, American Thoracic Society, and the American College of Chest

Physicians) Practice Parameter in 2003 stated that type 3 studies (limited channel home sleep tests) were acceptable in the *attended* setting, but that these testing methods were not recommended in unattended settings, for general screening, or for patients with comorbid conditions.[11]

An AHRQ (Agency for Healthcare Research and Quality) task force performed a technology assessment in 2007, this time with additional data from newer studies and a different viewpoint.[12] Not only did they compare baseline AHI on an in-laboratory polysomnogram to the AHI from a HST, but also they recognized that AHI data did not support that a precise AHI predicted PAP use. Thus, they evaluated outcomes of positive pressure use comparing patients who had been tested in and out of the laboratory. The major findings:

1. Type 3 home testing devices have the ability to predict AHI suggestive of OSA with high positive likelihood ratios and low negative likelihood ratios, particularly when manual scoring is employed.
2. For people with a high probability of OSA, use of laboratory-based PSG does not result in better outcomes over an ambulatory approach in terms of diagnosis and PAP titration

Studies from the last 4-5 years have examined the outcomes from home testing algorithms versus standard in-laboratory polysomnography. One of the pivotal studies used by CMS as evidence for approving HSTs was Mulgrew et al. in 2007, which demonstrated that in subjects with high pre-test probability of obstructive sleep apnea (demonstrated by oximetry and questionnaire), an ambulatory approach (portable monitoring and auto-titrating positive pressure titration) was at least equivalent to in-laboratory testing in terms of adherence of positive pressure therapy and resolution of sleep apnea symptoms after 3 months.[13] One year later, Berry et al. examined 106 Veterans Administration Medical Center (VAMC) patients with excessive daytime sleepiness and a high risk of OSA and randomized them to either portable monitoring with a 2-3 day titration via auto-titrating positive pressure therapy or in-laboratory polysomnography. Both groups were then placed on standard CPAP with no difference in adherence rates to CPAP or improvement in sleep symptoms after 6 weeks.[14] The study of Kuna et al., published in 2011, evaluated 260 VAMC patients and demonstrated that a home testing pathway was not inferior to a laboratory-based pathway for treatment of OSA. Lastly, the 2012 HomePAP study by Rosen et al., assessed 373 subjects, testing the utility of an integrated clinical pathway for obstructive sleep apnea (OSA) diagnosis and continuous positive airway pressure (CPAP) treatment using portable monitoring devices. The findings determined that there was clinical equivalence between the pathways from a standpoint of PAP adherence (in fact, PAP adherence was higher in the ambulatory group) and that a cost analysis favored the ambulatory approach.[15]

Home Sleep Testing: What Is It?

At the heart of home sleep testing is the ability to accurately make a correct diagnosis of OSA while minimizing false positives and false negatives. Most devices will rely on 3 primary signals to assess a patient's sleep-disordered breathing:

1. Aiflow (nasal-oral thermistor, nasal pressure, or preferably both),
2. Respiratory effort (ideally with respiratory inductance plethysmography)
3. Oximetry (with a standard maximum signal averaging time $\leq$ 3 sec at a heart rate $\geq$ 80 beats per minute)

Additional factors on home testing devices may include cardiovascular measurements (such as pulse rate or rhythm strips), positional monitoring, and measurement of sleep time. There are several devices which use alternative metrics: venous pulsation substituting for respiratory effort (ARES device, currently under FDA review), arterial tonometry instead of nasal airflow and respiratory effort (WatchPAT), or the analysis of EKG rhythms as a surrogate for respiratory channels.

A home testing device should be validated against in-laboratory polysomnography to ensure that it functions at an adequate level. The American Academy of Sleep Medicine constructed a technology evaluation in 2011, updating their 2007 Clinical Guidelines paper.[16,17] The 2011 paper suggested that an out of center testing device should have a positive likelihood ratio (LR+) $\geq$ 5 coinciding with an in-lab- polysomnography (PSG)-generated apnea hypopnea index (AHI) $\geq$ 5, and an adequate sensitivity ($\geq$ 0.825). A review of many of the currently available devices can be found in this 2011 article.

Home sleep testing though generally effective, has some important limitations. Many portable tests underestimate OSA severity because of the differences in methods to detect obstructive events and amount of sleep. The numerator of the AHI (respiratory events) is lower for a portable test than an in-laboratory test, as subtle sleep-disordered breathing not as easily identified as it would on an in-laboratory test because of the inability to detect arousal-related events. Also, the denominator (time) is larger with portable tests because recording time is assessed rather than sleep time (EEG signal for sleep scoring is not available in many home testing devices). As well, many devices are prone to artifact and have a failure rate that ranges from 3% to 18% depending on study and device.[17]

Why Home Sleep Testing Is Here Now and Why It Might Not Be All Bad?

At this point in time, HSTs are going to play an increasing role in the practice of Sleep Medicine. That is in large part due to the changes in insurance practices around the use of HST. In the northeastern United States, particularly in Massachusetts, prior authorization programs run by utilization management companies have begun to proliferate, shunting many patients from the sleep laboratories and into home testing. Though these programs have not clearly been built exactly on the existing 2007 Practice Parameters from the AASM, it is clear that many patients who are seeking evaluations for OSA will be first evaluated in the home setting; one utilization management company's (American Imaging Management) estimate is as high as 70%.[18] Clearly, the view of these insurance companies is that money will be saved in this process as a home sleep study costs about $200-$300, whereas a sleep study may be $800 and up. Other health insurance companies, such as Aetna and United, have begun utilization management programs applying prior authorization protocols on a national level. Home sleep testing cannot be replaced back into Pandora's box.

Though viewed with much suspicion by some sleep practitioners, HSTs may actually help the field of Sleep Medicine. Certainly, adopting this method of evaluation will result in many changes in physician habits and sleep laboratories. However, as we adjust our practice styles to the new world ahead of us, we may reach a larger number of patients when not limited to a physical location of a sleep laboratory. Patients who might be intimidated by an in-laboratory test may be more willing to consider testing in the home environment. Pre-surgical sleep testing with portable sleep monitors may become a more practical method of patient assessment. Large-deductible insurance programs are proliferating as businesses try to rein in costs, and in a struggling economy, patients may see an expensive in-laboratory test as an unnecessary expense but might view a home sleep test as a more economical option. In order to maintain the cost-effectiveness of use of home studies and promote better adherence to PAP therapy, many insurance programs are limiting testing and interpretation to qualified, high-quality providers. This system provides an opportunity for sleep specialists with comprehensive management and treatment programs to increase the number of patients directed their way.

Essential Points

1. Limited channel testing outside the sleep laboratory can appropriately diagnose OSA in patients with high pre-test probability for OSA
2. Portable monitoring appears to be a cost-efficient diagnostic measure at a time when medical costs are being closely scrutinized
3. In combination with auto-titrating PAP and with proper standards for use, testing and treatment of OSA may be done outside of the laboratory setting.

Closing

Regardless of your personal viewpoint on home testing, all sleep medicine clinicians should begin to evaluate their practices, assessing how they might integrate home sleep testing. Developing a reasonable home testing plan will likely involve several steps: becoming familiar with the HST devices and each device's pros and cons, learning how to interpret these studies carefully and appropriately, and finally, developing a business plan for your centers, which may include shrinking the size of the physical sleep laboratory. Many coaches say that preparation is the key to victory; for the field of sleep medicine to continue to be successful, we will have to organize and adapt to new circumstances.

CITATION

Kirsch DB. Pro: Sliding into home: portable sleep testing is effective for diagnosis of obstructive sleep apnea. *J Clin Sleep Med* 2013;9(1):5-7.

REFERENCES

1. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=226&ncdver=3&NCAId=204&NcaName=Continuous+Positive+Airway+Pressure+(CPAP)+Therapy+for+Obstructive+Sleep+Apnea+(OSA)&IsPopup=y&bc=AAAAAAAAIAAA& (Accessed 7/1/12)
2. http://oig.hhs.gov/publications/workplan/2011/FY11_WorkPlan-All.pdf (Accessed 7/1/12)
3. http://www.aasmnet.org/articles.aspx?id=1728 (Accessed 7/1/12)
4. http://www.cdc.gov/obesity/data/adult.html/ (Accessed 7/1/12)
5. Tregear S, Reston J, Schoelles K, et al. Continuous positive airway pressure reduces risk of motor vehicle crash among drivers with obstructive sleep apnea: systematic review and meta-analysis. *Sleep* 2010;33:1373-80.
6. Young T, Finn L, Peppard PE, et al. Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. *Sleep* 2008;31:1071-8.
7. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=226&ncdver=3&NCAId=204&NcaName=Continuous+Positive+Airway+Pressure+(CPAP)+Therapy+for+Obstructive+Sleep+Apnea+(OSA)&IsPopup=y&bc=AAAAAAAAIAAA& (Accessed 7/1/12)
8. Young T, Palta M, Dempsey J, et al. The occurrence of sleep-disordered breathing among middle-aged adults. *N Engl J Med* 1993;328:1230-5.
9. Ferber R, Millman R, Coppola M, et al. Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. *Sleep* 1994;17:378-92.
10. Chesson, AL Jr, Ferber RA, Fry JM, et al. The indications for polysomnography and related procedures. *Sleep* 1997;20,423-87
11. Flemons, WW, Littner, MR, Rowley JA, et al. Home diagnosis of sleep apnea: a systematic review of the literature: an evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. *Chest* 2003;124:1543-1579
12. AHRQ Technology Assessment, 2007 (https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads//id48TA.pdf) (Accessed 7/1/12)
13. Mulgrew AT, Fox N, Ayas NT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med* 2007;146:157-66.
14. Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep* 2008;31:1423-31.
15. Rosen CL, Auckley D, Benca R, et al. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: The HomePAP Study. *Sleep* 2012;35:757-67
16. Collop NA, Tracy SL, Kapur V, et al. Obstructive sleep apnea devices for out-of-center (OOC) testing: technology evaluation. *J Clin Sleep Med* 2011;7:531-48.
17. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2007;3:737-47.
18. http://www.npr.org/blogs/health/2012/01/16/145182935/the-sleep-apnea-business-is-booming-and-insurers-arent-happy (Accessed 8/30/12)

SUBMISSION & CORRESPONDENCE INFORMATION

Submitted for publication August, 2012
Submitted in final revised form August, 2012
Accepted for publication August, 2012
Address correspondence to: Douglas B. Kirsch, M.D., 1505 Commonwealth Ave., 5th Floor, Sleep HealthCenters, Brighton, MA 02135; Tel: (617) 783-1441; Fax: (781) 430 5861; E-mail: Doug_Kirsch@sleephealth.com

DISCLOSURE STATEMENT

Dr. Kirsch has indicated no financial conflicts of interest.