Portable Monitoring for Diagnosis of Sleep Apnea

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Abstract Economic and access issues are driving the use of portable monitoring for primary diagnosis of obstructive sleep apnea (OSA) in selected adults. Its applicability has been demonstrated for adults at high risk of sleep apnea, but many caveats and research questions remain. For technical reasons, most limited-channel diagnostic devices tend to underestimate the severity of the disease. In addition, portable monitoring is of little value for sleep disorders other than OSA and has not been advocated for children or the elderly. Similarly, auto-continuous positive airway pressure (APAP) is an alternative to in-laboratory continuous PAP titration. The cost-effectiveness of portable diagnostic testing and APAP titration in actual practice is yet to be determined, but will be a critical question in the years ahead. Future research should examine their use for extended populations, and the economic effect of these modalities, to determine the best use of these techniques as alternatives to traditional in-laboratory testing.

Keywords Sleep apnea · Portable monitoring · Home monitoring · Polysomnography · Diagnosis · Auto-positive airway pressure · APAP

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Introduction

Advances in digital technology combined with economic pressure to reduce the cost of healthcare are revolutionizing diagnostic and treatment for adults with obstructive sleep apnea (OSA) as the historical recommended method, in-laboratory-attended multiple channel polysomnography (PSG), is being replaced by portable sleep testing. Concerns about appropriate application, and the decrease in reimbursement for home studies, have limited broad acceptance of this technology in the field of sleep medicine. However, despite the overall economic and logistical advantages of portable testing being debated by specialists, portable home testing is increasing in use by primary care, otolaryngologists, and other sleep physicians, and diagnosis of OSA is now often determined on the basis of portable limited cardiorespiratory testing [1, 2]. In addition, initiation of positive pressure therapy is now increasingly being performed by auto-adjusting positive-pressure devices instead of the traditional in-laboratory technician-attended titration study [3, 4]. The long-term effects of these changes on healthcare outcomes are hotly debated and ultimately uncertain, but highlight the fact that appropriate clinical use of sleep testing requires that the clinician understands the scope and methodological differences of each sleep testing method, and how each of these diagnostic devices affects treatment decisions and outcomes.

Scope of Sleep Testing

Both in-laboratory and portable sleep testing are the primary tests used to diagnose sleep disordered breathing and OSA. The tests, as currently performed, may assist in diagnosis, but independently are not diagnostic of other

sleep disorders, for example insomnia, hypersomnia, circadian rhythm sleep disorders, or narcolepsy [5]. Although in-laboratory studies may be useful for identifying selected parasomnias and movement disorders, many of these sleep disorders are uncommon, rarely the indication of the test, and are often diagnosed clinically without the need for PSG.

Sleep testing is, by definition, a method of measuring multiple physiologic variables, which may be normal or abnormal, during sleep. Abnormal physiology must then be defined as either pathologic or non-pathologic. For example, snoring is clearly an abnormality of upper airway function but is often regarded as non-pathologic and not believed to represent a disease by many sleep physicians. In addition, most measured sleep metrics have been determined to be pathologic or non-pathologic by consensus without the benefit of clinical data. The results of sleep testing are therefore confounded not only by the method of testing, but also by the metrics measured and the definition of pathology of these metrics.

Until recently, in-laboratory technician-attended PSG was essentially the only accepted method for accurate diagnosis of OSA. However, there are now several tools and methods that can technically measure selected metrics of the disease which separately, or in combination, can serve as alternative methods of diagnosis. OSA diagnosis can be determined using measures that include airflow, ventilatory effort, snoring sounds, pulse oximetry, heart rate variability, peripheral arterial tomography, and motion and movement detectors [6]. Many of these measures are now incorporated into clinically available full or limited channel diagnostic devices, and are advocated or approved for accurate diagnosis of OSA. A major indicator of the value of portable home testing was the use of portable monitors for patient evaluation in the Sleep Heart Health Study—a pioneering study evaluating cardiovascular disease associations and sleep apnea [7].

In addition to the many physiological factors that can affect the diagnosis of OSA, technological issues exist that effect sensitivity and specificity of diagnosis. In addition, different tools may be used to measure similar physiology in vastly different ways; the most common example of this is the use of thermistors versus pressure sensors as surrogates for airflow [8•]. In this case thermistors have lower sensitivity in identifying changes in airflow compared with pressure sensors. Pressure sensors are often overly sensitive in assessing apnea when compared with pneumotachograph measurements of airflow. The result is that different diagnostic devices vary in sensitivity and specificity in identifying disease and virtually no comparative data exist to enable the clinician to assess the true severity or presence of disease [9]. Despite these uncertainties, portable sleep apnea monitoring is now a firmly established method of

testing and research needs to shift focus from whether portable testing can be utilized to how best to utilize it.

In recognition of this shift, the American Academy of Sleep Medicine (AASM) published a consensus statement defining nomenclature for types of sleep study [10]. Four categories were described. Type I are in-laboratory attended polysomnograms with a minimum of seven channels, including measures of electroencephalography, electrooculography, electromyography, and EKG, plus measures of airflow and respiratory effort. Type II are PSG with a minimum of seven channels like Type I devices, but are non-attended. Type III are multiple channel cardiorespiratory tests with a minimum of four channels, including ventilation or airflow with at least two channels of respiratory movement, or respiratory movement and airflow, plus heart rate or EKG, and oxygen saturation. Last, Type IV devices are single-channel measures of airflow or pulse oximetry. This classification is critical because it established a historical precedent for both device development and clinical assessment.

Similar to all diagnostic tests, in-laboratory and portable testing require knowledgeable interpretation to best apply results and optimize patient care. Because of the increased accessibility and reduced complexity of portable testing, there are valid concerns that they may be increasingly used and interpreted by non-sleep trained physicians who may not recognize their limitations, and result in incorrect diagnosis with resulting delayed or unnecessary care [11•, 12•]. Future algorithms will need to account for how the tests are actually used in clinical practice, and may require greater sleep physician input for the care of patients who inadequately respond to initial therapy.

Device Comparison

The purpose of sleep apnea testing is often multifactorial. In its simplest form, sleep testing identifies the presence or absence of OSA. A higher standard requires that testing assesses not only the presence or absence of OSA but also its severity. At its best, diagnostic testing can be assessed on how well it predicts patient outcomes. Most studies assessing and comparing diagnostic sleep testing have focused on their ability to identify the presence or absence of sleep apnea on the basis of thresholds of the apnea–hypopnea index (AHI), which is the most common surrogate metric used to measure the disease. Thresholds of AHI to define the presence of OSA vary widely with studies using 5, 10, or even 15 incidents/h as a cut-off.

Comparative studies and systematic reviews of portable sleep apnea testing to traditional in-laboratory PSG have commonly found high sensitivity but a lower specificity [13•]. Portable devices and PSG agreed best for patients at

high risk for OSA but were less sensitive for lower risk populations. Some of this disparity is based on the fact that portable devices lack measures of sleep leading to overestimation of time asleep along with failure to identify incidents scored on the basis of EEG arousal.

Because of these issues, the 2007 AASM clinical guidelines suggest restricting portable testing to narrowly defined populations with strong clinical history, low medical risk, and only when considering non-invasive treatment [14]. It was recommended that result be reported as only positive ($AHI \geq 15$) or negative ($AHI < 15$) rather than in terms of AHI.

Part of the difficulty in assessing diagnostic agreement between in-laboratory and portable testing is the high variability in in-laboratory sleep testing [15, 16]. Only recently have studies assessed the reproducibility and concordance of the test with itself. Most of these studies used longitudinal data in untreated or placebo-treated patients from device treatment studies. Correlation of in-laboratory PSG with itself is only 0.6 and is lower than some portable types of tests. Portable monitors demonstrate a higher precision than in-laboratory studies when repeated studies are done. This may be because of less effect of body position on AHI in a portable than the in-laboratory test (where position may be artificially adjusted at the discretion of the technician). There is a trend for some types of portable monitor to provide a lower AHI than in-laboratory PSG but whether this represents an error in accuracy is unknown.

A recent exhaustive review of diagnostic sleep apnea testing types demonstrated that facility-based PSG and portable monitors can differ substantially in estimates of abnormal breathing incidents [13]. These discrepancies may affect clinical interpretation for some patients. AHI cut-offs from the Type III monitor of 5, 15, and 30 incidents/h resulted in respective sensitivity of 83–97 %, 64–100 % and 75–96 %, and specificity of 48–100 %, 41–100 %, and 79–97 %. Although substantial differences exist, the diagnostic ability of Type III monitors remains very good with high positive likelihood ratios and low negative likelihood ratios.

Treatment Effects

Measurement of treatment effects is tricky by PSG, even though it is described as an objective test, because of reliance on traditional sleep scoring, which is based upon pattern recognition, and is often subjective, resulting in different results for the same study when there are changes in the people scoring and reading the studies. Although the field has advocated accreditation standards to reduce variability, differences still exist and are exacerbated by the fact that there are currently three different definitions of

hypopnea which further confound results and interpretation. In addition, significant night-to-night variability has been shown to exist. Thus, the final result is that the primary outcome of PSG, the AHI, does not correlate to metrics of patient outcome. Thus, disease severity is based upon PSG-derived AHI is consensus-based with very little evidence to support it.

Positive airway pressure (PAP) therapy is routinely recommended to treat OSA, and advocates of continuous PAP (CPAP) note that pressures based on in-laboratory study routinely reduce AHI to fewer than 5 incidents/h. In-laboratory-attended titration of CPAP or bi-level PAP has been regarded as the ideal method for determination of optimum PAP levels for home therapy, and remains a major incentive for maintaining algorithms of in-laboratory diagnostic testing. However, with the development of auto-titrating PAP (APAP) devices, the need for in-laboratory titration (even independent diagnostic testing) has been questioned [17]. Early AASM practice guidance advocated that APAP machines were not to be used for unattended titration, only for supervised in-laboratory use or to enhance CPAP comfort and compliance [2•, 3].

Several studies have demonstrated that unattended APAP result in similar titration pressures to in-laboratory PSG along with similar clinical outcomes, although they have failed to demonstrate that APAP universally improves outcomes. In addition, treatment algorithms utilizing APAP have not found improvements in CPAP adherence, which continues to average 50 % or below for adults. Similarly, recent randomized studies of a selected population of low risk-patients revealed that non-attended testing, combined with APAP, have equivalent adherence results to traditional in-laboratory testing and attended titration.

As mentioned earlier, there is concern that altering the methods of diagnostic testing will further reduce clinical outcomes if non-sleep specialists are more involved in directing care of these patients. A recent, large study suggests that patients treated by sleep specialists have higher levels of CPAP use, and better outcomes; however, the conclusions are limited as only 40 % of the patients diagnosed with OSA had any measurable follow-up or evidence of any treatment [2•]. Of the remaining group, only 36 % used the device for the minimum criteria of 4 h/night for 70 % of nights. Although the study advocated that residual AHI was reduced to 4.7 events/h, these data do not account for adherence, which if included, would actually raise the average AHI for the population “successfully” treated to over 11 events/h.

Conclusion

Advocates of both facility and non-facility-based testing, argue for cost effectiveness. No outcome data support

either argument at present. Outcomes of models are highly dependent on the baseline assumptions of the model. A recent study comparing different diagnostic and treatment algorithms in an economic analysis concluded that in-laboratory testing was the most cost-effective means of treating patients; however, the study's conclusions were based on the assumption that portable testing would eliminate only 22 % of in-laboratory studies. Much work must be done to determine the optimum method to improve outcomes in adults with OSA; however, portable monitoring is quickly being promulgated as economic incentives push insurers to recommend their use for first-line diagnostic testing. Future research should examine their use in extended populations to determine how they can best be used as an alternative to traditional in-laboratory testing.

Disclosures BT Woodson: scientific advisor with honorarium for Inspire and Medtronic ENT, receives honoraria for academic presentations, has hyoid and tongue suspension patents, receives royalties for hyoid patent, has stock/stock options with Siesta Medical, has surgical bias as a surgeon; SL Ishman: consultant for First Line Medical.

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