REVIEW ARTICLE

A Review of the Current Status of Home Sleep Apnea Testing *vis-à-vis* In-lab Polysomnography: Is Old Still Gold?

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Abstract

Obstructive sleep apnea (OSA) affects almost one billion people worldwide and is a major cause of morbidity and mortality. However, most patients with OSA remain undiagnosed and untreated. In-lab polysomnography attended by a sleep technologist is the gold standard intervention for the diagnosis of OSA and titration of positive airway pressure (PAP) therapy. However, in-lab polysomnography is expensive, labor-intensive, and associated with long wait times. Further, patients are observed for only one night outside their normal sleep environment which may adversely affect the quality of sleep and not capture night-to-night variability. Hence, various portable devices have been developed to perform home sleep apnea testing (HSAT) at lower costs than in-lab polysomnography. In this review article, we compare the relative merits and demerits of HSAT *vis-à-vis* in-lab polysomnography. We delve into the current evidence for the efficacy, shortcomings, and costs of the different types of sleep studies. We summarize the current guidelines for sleep apnea testing. We conclude with the Indian perspective on the various types of sleep studies available.

Keywords: Home sleep apnea testing, Obstructive sleep apnea, Polysomnography, Portable sleep study, Sleep-disordered breathing.

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Introduction

Sleep-disordered breathing (SDB) is a major cause of morbidity and mortality worldwide. The common types of SDB include OSA, central sleep apnea (CSA), obesity hypoventilation syndrome (OHS), and the overlap syndrome of OSA and chronic obstructive pulmonary disease (COPD). Specifically, OSA is estimated to affect almost 1 billion adults globally.[1] It is associated with daytime sleepiness, cognitive decline, and poor quality of life. It may also increase the risk of cardiovascular disease, stroke, road accidents, and death.[2,3] However, most patients with OSA and other SDBs remain undiagnosed.

In-lab polysomnography is considered to be the gold standard diagnostic test for OSA. It may be performed over two nights, comprising a whole night diagnostic test on the first night followed by positive airway pressure (PAP) therapy titration on the second night. Alternatively, it may be performed as split-night polysomnography, wherein the first half of the night's test is the diagnostic component, and the second half is the therapeutic component.

However, in-lab polysomnography has several limitations. First, it has to be performed in a sleep laboratory with sophisticated equipment under the supervision of a trained sleep technologist. Hence, in-lab sleep studies are expensive and labor-intensive. Second, as a limited number of studies can be performed each night, there may be a long waiting period for in-lab polysomnography. Finally, the in-lab study is performed outside the patient's usual sleep environment. This results in the "first night effect" with unsuitable sleep quality on the night of testing.[4] Also, the night-to-night variability of the sleep disorder is not captured.[5]

To overcome these limitations, HSAT or portable sleep studies were developed. In this review, we discuss the relative merits and demerits of HSAT *vis-à-vis* in-lab polysomnography. We delve into the current evidence for the efficacy, shortcomings, and costs of the different types of sleep studies. We summarize the current guidelines for sleep apnea testing. We conclude with the Indian perspective on the various types of sleep studies available.

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Home Sleep Apnea Testing (HSAT) – An Overview

The development of HSAT has been ongoing for the past four decades. A wide variety of tests have been developed, which differ in their methodologies and the variables captured. Traditionally, sleep studies have been classified into four types, where type I is an in-lab-attended polysomnography, and types II–IV are various forms of HSAT (Table 1).[6] Newer HSAT modalities which are based on peripheral arterial tonometry (PAT) defy this classification. Irrespective of the type, all portable devices lack electroencephalography (EEG) and do not capture cortical sleep. Further, manual titration by laboratory personnel is not possible with HSAT.

HSAT vs In-lab Polysomnography

Diagnostic Accuracy

The primary purpose for the development of HSAT was as a substitute for the gold standard test, i.e., in-lab polysomnography. Accordingly, HSAT has never been studied as a replacement for

Table 1: The classification of sleep studies

	Type I	*Type II*	*Type III*	*Type IV*
Number of channels	≥7	≥7	≥4	≥1
Included channels	EEG, EOG, EMG, airflow, respiratory effort, oximetry, ECG	EEG, EOG, EMG, airflow, respiratory effort, oximetry, ECG	Airflow, respiratory effort, ECG (or heart rate), oximetry	Oximetry or airflow or respiratory effort
Body position	+	±	±	–
Leg movements	Usually, +	±	±	–
Laboratory staff	In attendance	Absent	Absent	Absent

ECG, electrocardiogram; EEG, electroencephalogram; EMG, electromyogram; EOG, electrooculogram

in-lab testing in superiority studies. In a systematic review and meta-analysis of 19 studies enrolling patients with a high pretest probability of moderate-to-severe uncomplicated OSA, HSAT was found to have a diagnostic sensitivity ranging from 0.79 to 0.97 and a specificity ranging from 0.60 to 0.93 in comparison with in-lab polysomnography.[7] Hence, at best, HSAT is a noninferior modality to in-lab polysomnography for the diagnosis of uncomplicated OSA with a high pretest probability of moderate-to-severe disease.

On the other hand, HSAT is inferior to in-lab polysomnography in various settings. Firstly, HSAT tends to underestimate mild OSA. This is because most HSAT devices do not assess EEG or sleep–wake. Hence, the denominator for calculating the diagnostic index is the total recording time rather than the total sleep time. Accordingly, this index is termed the respiratory event index (REI) to distinguish it from the apnea–hypopnea index (AHI) obtained from an in-lab sleep study. As the REI has a larger denominator and misses out on hypopneas scored in association with cortical arousals, it usually underestimates the AHI. The multicenter European Sleep Apnea Cohort study found that HSAT may underestimate the AHI by around 30%.[8] In another study, Zeidler et al. found that when subjects with normal HSAT reports underwent in-lab testing, one-fourth were found to have OSA, which was mild in most cases.[9] Detecting mild OSA is important because the treatment of mild disease with PAP therapy has been found to improve the quality of life.[10]

Second, HSAT is likely to have a high rate of technical failure as it is unsupervised by laboratory staff. In a study enrolling over 1157 patients undergoing HSAT, Zeidler et al. found that 111 subjects (9.6%) had a technically inadequate study. When these patients underwent a repeat in-lab study, 71% were found to have OSA.[9] Hence, the authors concluded that patients with suspected OSA who have a negative or technically inadequate HSAT report should undergo subsequent in-lab testing.

Third, HSAT has not been tested for patients with complicated OSA, i.e., those patients with comorbidities, including congestive heart failure, chronic respiratory disease, stroke, neuromuscular disease, and opioid use disorder. These patients are more likely to have CSA or hypoventilation that may not be adequately detected by HSAT.[11] Furthermore, most HSAT devices cannot be used to diagnose other comorbid sleep disorders like periodic limb movement disorder, narcolepsy, and parasomnias.

Newer PAT-based tests have a few advantages over previous HSAT devices. They can differentiate between sleep and wake and detect arousals using a proprietary algorithm based on the sympathetic tone of the peripheral arteries. However, a recent meta-analysis of 17 studies enrolling over 1,300 participants found a clinically significant discordance in the AHI detected by PAT-based devices and in-lab polysomnography.[12] In this study, the WatchPAT device was found to have a high sensitivity (94%) but low specificity (43%) for the diagnosis of mild OSA. In contrast, WatchPAT had a comparatively lower sensitivity (74%) and higher specificity (87%) for severe OSA.

PAP Titration

The traditional model of OSA management involves an in-lab diagnostic study combined with an in-lab PAP titration. The patients have been prescribed a fixed pressure delivered by a continuous positive airway pressure (CPAP) device. However, the usual paradigm for PAP therapy among patients diagnosed with HSAT involves home titration using an autotitrating PAP (auto-PAP) device. The home titration may be done over 3–14 nights. Unlike in-lab titration, there are no standardized guidelines for home titration. Following home titration, the patients may be prescribed a fixed pressure using CPAP by estimating the pressure that eliminates obstructive events for either 90% or 95% of the time (P90 and P95, respectively) from the auto-PAP device data. Alternatively, many patients are treated with the auto-PAP device on a long-term basis.[13]

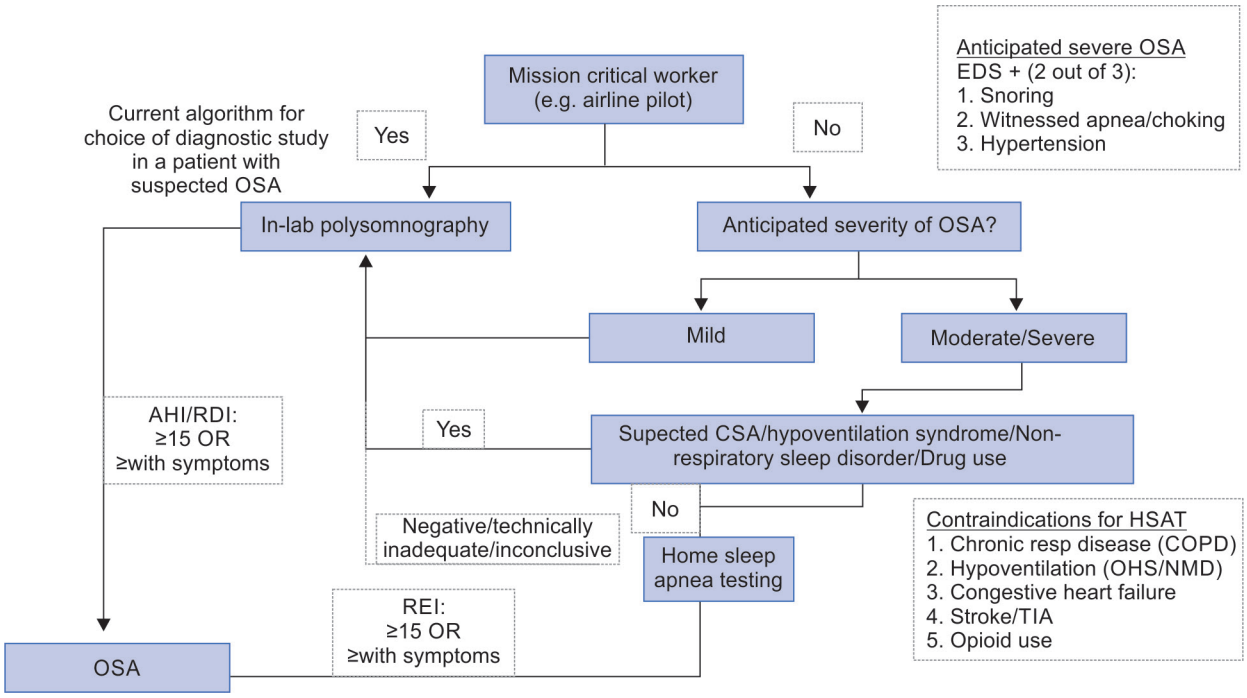
Based on the results of two randomized controlled trials, HSAT combined with home-based auto-PAP titration is noninferior to in-lab diagnosis and titration in terms of treatment acceptance, adherence, and functional improvement.[14,15] However, there are a few important caveats to these results. First, the aforementioned studies ensured early and close follow-up at the clinic in the weeks after initiating therapy using home titration. As personnel intervention is not possible during home titration, early follow-up is imperative to ensure troubleshooting and optimal adherence. Second, patients with complicated OSA who do not qualify for HSAT were excluded from these studies and are not candidates for home titration either. Finally, neither of the above studies used auto-PAP in an open 4–20 cm H_2O window for long-term treatment. While Rosen et al. used a fixed CPAP device after titration, Berry et al. used a narrower PAP window that was individualized to patient needs.[14,15]

Polysomnographic Phenotypes of OSA

There is a growing recognition that OSA is not a homogeneous disease. The phenotyping of disease provides us an opportunity to recognize clusters with distinct prognoses and management strategies. Various phenotypes of OSA have been described based on clinical and polysomnographic manifestations.[16] The discrimination of polysomnographic phenotypes is possible by the wealth of data acquired during in-lab studies, which simply cannot be captured by HSAT.

Zinchuk et al. performed one such polysomnographic phenotyping study to identify those OSA patients at increased risk of cardiovascular disease.[17] They analyzed over 65 polysomnographic variables covering four broad domains: sleep fragmentation,

Flowchart 1: Algorithm for the choice of diagnostic sleep study in a patient with suspected OSA



AHI, apnea – hypopnea index; COPD, chronic obstructive pulmonary disease; CSA, central sleep apnea; EDS, excessive daytime sleepiness; OHS, obesity hypoventilation syndrome; OSA, obstructive sleep apnea; RDI, respiratory disturbance index; REI, respiratory event index; TIA, transient ischemic attack

breathing events, oxygenation, and autonomic dysregulation. Based on cardiovascular risk, they found 7 different polysomnographic phenotypes. The risk was the highest in those assigned to the periodic limb movements during sleep (PLMS) and the hypopnea and hypoxia groups. Further, the benefit of PAP therapy in reducing the risk was also maximum in these groups. Additional research into polysomnographic phenotypes is ongoing and may facilitate tailored therapy for OSA in the future.

Economic Aspects

The costs of any disease can be expressed in terms of the sum of the direct costs levied by the disease management and the costs incurred by treating complications of the disease. Alternatively, the cost-effectiveness of treatment can be expressed, which refers to the impact of therapy on the reduction of costs of adverse clinical outcomes. Furthermore, these costs can be borne by different parties in varying healthcare settings, namely the patients, the providers, or the insurers.

The direct cost of undiagnosed OSA in the United States has been estimated at 150 billion US dollars.[18] Furthermore, the costs of managing OSA represent one-third of this estimate, while the costs of complications of OSA represent the remaining two-thirds. This suggests great savings if all patients with OSA are diagnosed and treated. In terms of management strategies, Western literature has shown that the utilization of HSAT combined with auto-PAP has lower direct costs compared with in-lab polysomnography combined with CPAP therapy.[19]

However, studies examining the cost-effectiveness of different management strategies have conflicting results. An analysis by Deutsch et al. compared the cost-effectiveness of full-night polysomnography, split-night polysomnography, and HSAT at varying levels of insurers' willingness to pay.[19] Although HSAT had lower direct costs, it was less efficient compared with polysomnography for managing OSA. Hence, HSAT was more cost-effective only at the lower end of the insurer's willingness to pay. Split-night or full-night polysomnography was more cost-effective at higher amounts of willingness to pay. A more recent study by Pietzsch et al. found that full-night polysomnography with CPAP treatment was more cost-effective than HSAT at any level of the insurer's willingness to pay.[20]

Current Guidelines for HSAT

The American Academy of Sleep Medicine (AASM) laid down the guideline for portable testing in 2007.[11] Although the guideline requires an update considering the evolution of HSAT technology, its broad tenets are still relevant. Accordingly, HSAT has been promulgated as an alternative test for in-lab polysomnography in carefully selected patients with a high pretest probability of moderate-to-severe uncomplicated OSA. Among patients with suspected OSA, a negative or technically inadequate HSAT should be followed up by in-lab polysomnography. Importantly, all HSATs must be performed under the supervision of a qualified sleep physician, who is responsible for comprehensive patient evaluation and follow-up. A simplified algorithm for the choice of diagnostic study in a patient with suspected OSA is depicted in Flowchart 1.

The guideline also comments that HSAT devices should provide raw data which can be manually scored or edited by a qualified sleep specialist. Although manual validation of HSAT results is desirable, newer PAT-based HSAT devices use proprietary algorithms for scoring sleep and respiratory events that cannot be manually verified.

Indian Perspective

There are many ways in which the Indian scenario differs from the advanced countries where HSAT technology has been developed and tested. First, a major impetus for the development of HSAT in

Western countries has been the growing public recognition of OSA, which led to a high demand for sleep studies that could not be met by the existing laboratories. Further, the high costs of in-lab testing led insurers to develop algorithms for portable testing in selected patients. However, public awareness of OSA remains low in India.[21] There is a lack of information on the busyness of existing sleep labs in India. Further, there are no insurance or regulatory frameworks for guiding the choice between HSAT and in-lab management pathways in India.

Second, the lack of a formal residency program in sleep medicine in India has resulted in a dearth of sleep practitioners in India. Anecdotally, at least some proportion of HSAT in India is prescribed by personnel who are not trained to perform a comprehensive sleep evaluation. Hence, there are no safeguards to ensure the rational use of HSAT in the country.

Third, there are no economic assessments of in-lab polysomnography or HSAT from India. Extrapolation of Western literature is challenging due to the differences in our healthcare systems. For instance, in-lab polysomnography is performed at minimal costs in governmental institutions in India. Also, in most cases, the cost of PAP machines is borne by the patients and not by insurers. As fixed CPAP devices are less costly than auto-PAP devices, one may argue that the direct costs of the in-lab polysomnography combined with fixed CPAP pathway may not be much greater than HSAT combined with auto-PAP pathway in India.

Keeping these points in mind, it is essential to develop trained clinical manpower to comprehensively evaluate sleep disorders in India. There is a need to perform studies into the burden of overall and unrecognized OSA in India. Further, cost-effectiveness studies of different management pathways need to be performed in the government and private healthcare sectors in India. Such studies will help us prepare for the sleep laboratory and HSAT needs of the country. Finally, there is a need to introduce a regulatory framework for the proper use of sleep diagnostics and therapeutics in India.

Conclusion

In-lab polysomnography is still the gold standard diagnostic test for OSA. However, HSAT is a vital tool in the armamentarium of the astute sleep physician as an alternative test in selected cases with a high pretest probability of moderate-to-severe uncomplicated OSA. However, indiscriminate use of HSAT is not cost-effective and should be avoided among patients with complicated OSA. The wholesome growth of sleep medicine in India depends on the concomitant development of holistic diagnostic infrastructure and clinical manpower that is adequately trained to use this infrastructure.

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