

Portable monitoring devices in the diagnosis of obstructive sleep apnea: current status, advantages, and limitations^{*}, ^{**}

Monitorização portátil no diagnóstico da apneia obstrutiva do sono: situação atual, vantagens e limitações

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Abstract

Recent years have seen a growing interest in the use of portable monitoring devices for the diagnosis of obstructive sleep apnea syndrome. These have the potential to be used in lieu of the more complicated and uncomfortable alternative, polysomnography, which has long been considered to be the gold standard for the diagnosis of this relatively prevalent condition. Following their approval in 2008 by the Center of Medicare and Medicaid Services, the federal agency which administers Medicare and Medicaid in the United States, there has been extensive discussion about the utility and validity of these devices for use in the diagnosis of obstructive sleep apnea syndrome. Although there are various models of portable monitoring devices, the literature contains little information regarding how each device should be used in specific age groups, patients presenting comorbidities, and asymptomatic patients. Additionally, studies about the cost-effectiveness of this diagnostic method are scarce and conflicting. Therefore, this objective of this study was to review what has been learned about portable monitoring devices over time, as well as to examine the recent progress, advantages, limitations, and applications of these devices in the diagnosis of obstructive sleep apnea syndrome in different groups of patients.

Keywords: Sleep apnea, obstructive/diagnosis; Polysomnography; Diagnostic equipment; Monitoring, ambulatory.

Resumo

Nos últimos anos, é crescente o interesse pela utilização de aparelhos de monitoramento portáteis para o diagnóstico da síndrome da apneia obstrutiva do sono, como uma alternativa mais simples e confortável à polissonografia, que é o exame considerado o padrão ouro para o diagnóstico dessa condição relativamente prevalente. A liberação do uso desses equipamentos pelo *Center of Medicare and Medicaid Services*, agência federal que administra os serviços médicos nos Estados Unidos da América, em 2008, resultou em ampla discussão sobre a utilidade e validade desses equipamentos para o diagnóstico de síndrome da apneia obstrutiva do sono. Apesar de haver vários modelos de equipamentos de monitorização portátil, há pouca informação na literatura a respeito de como cada equipamento deveria ser utilizado em grupos etários específicos, portadores de comorbidades e pacientes assintomáticos. Além disso, estudos de custo-efetividade desse método diagnóstico são escassos e conflitantes. Portanto, o objetivo do presente estudo foi revisar a evolução dos conhecimentos no uso de equipamentos de monitorização portátil, bem como examinar os avanços recentes, vantagens, limitações e aplicações desses equipamentos para o diagnóstico de apneia obstrutiva do sono em diferentes grupos de pacientes.

Descritores: Apneia do sono tipo obstrutiva/diagnóstico; Polissonografia; Equipamentos para diagnóstico; Monitorização ambulatorial.

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Introduction

Obstructive sleep apnea syndrome (OSAS) is a highly prevalent condition that is observed in 1.2% to 7.5% of the general population,⁽¹⁻⁹⁾ mostly in adults and primarily in obese males.⁽¹⁰⁾ The definition of OSAS is an apnea-hypopnea index (AHI) above five events per hour of sleep, together with excessive daytime sleepiness.⁽¹⁻¹⁰⁾ A recent epidemiological study conducted in the city of São Paulo, Brazil,⁽¹¹⁾ showed a high prevalence of OSAS in the adult population (32.8%).⁽¹²⁾ In that study, OSAS was defined according to the criteria of the most recent International Classification of Sleep Disorders, published by the American Academy of Sleep Medicine (AASM) in 2005,⁽¹³⁾ which state that a diagnosis of OSAS can be confirmed if the subject has an AHI of 5.0-14.9 events per hour of sleep and presents with at least one of the following complaints: loud snoring, excessive daytime sleepiness, and fatigue. In addition, subjects with an AHI equal to or greater than 15, with or without any additional complaints, can be classified as having OSAS. Because of the high prevalence of OSAS, it is unlikely that there will ever be enough sleep laboratories to screen and diagnosis all of the cases.

There is a well-established association between OSAS and excessive daytime sleepiness, which leads to traffic accidents,⁽¹⁴⁻¹⁷⁾ as well as between OSAS and hypertension.⁽¹⁸⁾ In addition, OSAS is a harbinger of the aggravation or the onset of heart diseases, such as arrhythmia, coronary insufficiency, heart failure, and stroke.⁽¹⁹⁻²⁴⁾

Although polysomnography is considered the gold standard for the diagnosis of OSAS, it is costly and involves a technically complex examination.⁽²⁵⁾ There is some evidence that OSAS is underdiagnosed because neither physicians nor patients have sufficient information about the syndrome. In addition, there are few laboratories that specialize in polysomnography.^(26,27) Consequently, in recent decades, there has been an increased interest in exploring cost-effective methods of diagnosing OSAS, and greater attention has therefore been focused on portable monitoring devices (PMDs).⁽²⁸⁾

Although the use of PMDs has been proposed for the diagnosis of OSAS, most studies attempting to determine the accuracy of these devices have not followed the best practice guidelines for diagnostic test validation. Two

recent, well-designed studies conducted in Brazil evaluated the accuracy of in-home recordings using PMDs, compared with polysomnography recordings made in a sleep laboratory.^(29,30)

There has been much discussion surrounding the utility, advantages, and limitations of using PMDs for the in-home diagnosis of OSAS, without the supervision of a trained professional. The fact is that the use of such devices not only facilitates access to polysomnographic data but also improves the quality of the data, since they are collected within the comfort of the habitual sleep settings, thus aiding in the diagnosis of OSAS. Studies conducted in the USA, Brazil, and Canada, as well as in a number of other countries, have shown the efficacy of in-home monitoring in diagnosing OSAS in patients with a high suspicion of the syndrome.⁽³¹⁻³³⁾

Here, we review what is known about the use of PMDs in the diagnosis of OSAS, including recent findings, as well as the advantages and limitations of the applications of this technology.

Types of monitoring used in the diagnosis of OSAS

According to the American Sleep Disorders Association (ASDA),^(34,35) the methods of investigating OSAS can be classified by the type of sleep study employed.

Full-night in-laboratory polysomnography: type 1 sleep studies

Full-night polysomnography is used as the standard to which other types of sleep studies are compared. It records at least seven bioparameters, including electroencephalography (EEG), chin electromyography (EMG), electrooculography (EOG), airflow, respiratory effort (measured by recording movements of the thorax and abdomen), pulse oximetry, and electrocardiography (ECG). The position of the body must also be established in an objective manner and duly documented. Periodic leg movements can be recorded, although this is optional. In-laboratory polysomnography requires a specialized laboratory, as well as a trained professional who intervenes if there is an adverse event during the recording.

Comprehensive in-home polysomnography: type 2 sleep studies

Type 2 sleep studies measure the same seven bioparameters measured by type 1 devices (EEG, chin EMG, EOG, airflow, respiratory effort, pulse oximetry, and ECG). Body position can be objectively established, and the measurement of periodic leg movements is desirable, but optional. The examination is not supervised by a trained professional.

Modified in-home sleep apnea testing: type 3 sleep studies

Type 3 sleep studies record data related to at least four bioparameters, including ventilation (at least two bioparameters of respiratory movement; or respiratory movement and airflow), HR or ECG, and pulse oximetry. Monitoring can include EMG of the legs, and the presence of a trained professional is not required.

Continuous single- or dual-bioparameter in-home recording: type 4 sleep studies

Most of the PMDs employed in type 4 sleep studies record data related to only one or two bioparameters (airflow, pulse oximetry, or both). Even sleep studies conducted with devices that record three or more bioparameters are classified as type 4 studies if the device employed does not record airflow. Type 4 sleep studies do not require the presence of a trained professional.

Validation of the use of PMDs: historical perspective

The first attempts to review and standardize the use of PMDs in the diagnosis of OSAS were made in 1994 by the ASDA.^(34,35) The authors concluded that there was no standardization of PMDs and that they varied widely in complexity, ranging from the recording of only one bioparameter to full polysomnography. At the time, there had been few studies on the topic, and there was little evidence to recommend their use over the standard method. Although the convenience for the patient, lower operational costs, potentially better treatment adherence, and increased accessibility were considered advantages, the main limitation of the unsupervised use of PMDs was their unsupervised nature, translating to an inability

to correct faults that tend to occur during the test. Therefore, at that time, the ASDA did not recommend the use of PMDs by unstable patients, by patients with mild symptoms, for the screening of asymptomatic high-risk patients, or for the titration of continuous positive airflow pressure (CPAP).⁽³⁴⁾ The supervised use of PMDs was indicated for patients with severe symptoms of OSAS for whom treatment was urgent and for patients who were unable to reach a sleep laboratory, as well as for those who had been previously diagnosed with OSAS by means of polysomnography. However, the use of type 4 devices was not considered acceptable for the assessment of OSAS.^(32,33)

In 1997, the ASDA assembled a new task force in order to establish the effectiveness of polysomnography and related procedures.⁽³⁶⁾ The resulting study revealed that the sensitivity and specificity of PMDs for the diagnosis of OSAS was lower than was that of polysomnography. That study mentioned the need for better establishing and validating the bioparameters recorded by this kind of equipment. The supervised use of type 3 sleep studies continued to be indicated for patients in whom there was a strong suspicion of OSAS. If the results collected from type 3 sleep studies were negative for OSAS in asymptomatic patients, the indication for complete in-laboratory polysomnography was upheld. Type 4 sleep studies continued to be contraindicated in such cases. A systematic review and meta-analysis of the literature conducted in 2000 drew the same conclusions.⁽³⁷⁾

In 2003, another group of authors⁽³⁸⁾ assessed the effectiveness of PMDs in confirming or excluding the diagnosis of OSAS. Type 2 sleep studies, whether supervised or unsupervised, did not produce any evidence to support either function. Supervised type 3 sleep studies produced a great deal of evidence to either exclude or confirm OSAS, whereas unsupervised type 3 sleep studies produced very little. In supervised sleep studies, the potential advantage of PMDs was a decrease in the time spent by the technician and physician when compared with polysomnography. The loss of data was also assessed, and it was found that there was a 20% loss related to type 2 sleep studies,⁽³⁹⁾ compared with 3-18% related to the unsupervised in-home use of type 3 sleep studies.⁽⁴⁰⁻⁴²⁾ When supervised type 3 sleep studies were performed in a sleep laboratory, the loss of data ranged from 3% to 9%.^(43,44) The need for studies examining specific

groups, including those with comorbidities associated with OSAS, has also been discussed.

In 2003, the AASM⁽⁴⁵⁾ published practical guidelines for the use of PMDs in the diagnosis of OSAS, in which the use of PMDs for the screening of OSAS was not recommended in patients without symptoms suggestive of the disease. The use of PMDs was also not indicated for patients with associated comorbidities, such as heart failure, lung disease, hypoventilation syndrome, and stroke. The indication for the use of PMDs was restricted to cases in which patients had severe symptoms of OSAS, in which they could not be examined in a sleep laboratory, or in which there had already been a definitive diagnosis of OSAS using polysomnography. In addition, manual scoring was determined to be more accurate (i.e., automatic scoring was rejected). Type 1 sleep studies (full-night in-laboratory polysomnography) were recommended for cases in which type 3 studies had yielded negative results for OSAS in symptomatic patients. Type 3 sleep studies, whether split-night or full-night, were not recommended for CPAP titration. Type 4 sleep studies continued to be contraindicated for OSAS diagnosis. In 2005, the AASM⁽⁴⁶⁾ published new practical guidelines for the indication of polysomnography and related procedures, maintaining the recommendations that it had put forth in 2003. Those guidelines reiterated the statement that if type 3 sleep studies produced negative results for OSAS, the patient should undergo type 1 sleep studies. However, in 2007, the AASM revised its recommendations on the use of PMDs in the diagnosis of OSAS, particularly with respect to the use of unsupervised type 3 sleep studies in individuals over 18 years of age presenting OSAS symptoms.⁽²⁵⁾ The standard put forth therein was that the sleep studies should, at the least, record airflow, respiratory effort, oximetry, and HR. Additional recommended uses of and contraindications for the use of PMDs were as follows:

- Their use was considered acceptable for the diagnosis of OSAS in patients who are very likely to present the syndrome, based on a pre-test for OSAS and after a thorough clinical assessment.
- They should be used in adult patients only, since, at the time, there were no related studies in children and elderly individuals.
- Their use was considered acceptable for the diagnosis of OSAS whenever type 1 sleep studies cannot be performed due

to immobility or critical conditions of the patient.

- They were recommended as a way to monitor the response to treatment with an intraoral device (although not for CPAP) or to surgical procedures involving the upper airways.
- Their use was considered an acceptable means of monitoring weight loss.
- They were approved for selective use in patients who had OSAS symptoms but no comorbidities.
- Their use was not considered acceptable for the diagnosis of other sleep disturbances, such as central apnea, periodic leg movement, parasomnia, alterations in the circadian rhythm, and narcolepsy.
- They were not recommended for the screening of asymptomatic patients.

Despite the practical recommendations set forth by the AASM about the use of PMDs in the diagnosis of OSAS, some third-party health care companies, such as CIGNA (Philadelphia, PA, USA)⁽⁴⁷⁾ and Blue Cross of California (Thousand Oaks, CA, USA),⁽⁴⁸⁾ covered the use of PMDs, but only under the specific conditions laid out by the AASM. Therefore, the American Academy of Otolaryngology – Head and Neck Surgery filed a request with the Centers for Medicare and Medicaid Services (CMS) asking that the CMS reconsider its positions on PMD studies. The American College of Chest Physicians, the American Thoracic Society, and the AASM, all motivated by the previously noted lack of evidence to indicate greater efficacy and cost-effectiveness, coordinated rebuttal arguments to dissuade the CMS from altering its position. In contrast, a significant number of practitioners, the National Sleep Foundation, and Apria Health Care (Lake Forest, CA, USA) argued that PMD studies would be beneficial in the diagnosis and management of OSAS.⁽⁴⁹⁾

In 2007, based on the reports produced by the Agency for Healthcare Research and Quality,⁽⁵⁰⁾ the CMS approved the use of unsupervised PMD sleep studies for the diagnosis of OSAS, with the objective of determining whether treatment with CPAP was warranted.⁽⁵¹⁾ The fully accepted PMDs were those capable of producing type 2 or 3 sleep studies. Type 4 sleep studies were accepted if they recorded at least three bioparameters (those that recorded oximetry alone were not endorsed). This decision will most likely result in a more widespread application of PMDs for the purpose of diagnosing OSAS. Still,

the advantages and limitations of these devices must be considered in order to ensure the most accurate results.^(52,53)

Limitations to the validation of PMDs

Validation of PMDs makes for a challenging task since they are generally compared with polysomnography. Despite being held as the gold standard, polysomnography also has limitations that must be taken into consideration: variability of AHI results when the subject is observed over different nights or by different observers⁽⁵⁴⁾; longer time spent in the supine position when compared with habitual sleep⁽³¹⁾; and difficulty in sleeping in an unfamiliar environment.⁽⁵⁵⁾ Of note, it is relevant to highlight the impact of a given polysomnography result on quality of life, morbidity, and mortality, since some studies have shown that the AHI correlates poorly with quality of life and daytime sleepiness, parameters that weigh heavily in the management of OSAS patients.⁽³⁸⁾

Another difficulty that arises when comparing polysomnography and PMD results is related to the calculation of the rate of abnormal breathing events during each kind of recording. Traditionally, polysomnography provides the average number of breathing events per hour of sleep, that is, the calculation is made by dividing the total number of breathing events by the total sleep time, in hours. In contrast, because PMDs do not measure the total sleep time, the calculation of the average number of abnormal breathing events is based on the total recording time, which could underestimate the rate of those events when compared with polysomnography.^(52,53)

When considering the identification of breathing events by polysomnography, hypopnea is in part scored if associated with EEG arousal or oxyhemoglobin desaturation.⁽⁵⁶⁾ As PMDs do not allow for the assessment of arousal, the number of hypopnea events might be underestimated, a possibility that impairs the estimation of the severity of the disease.

Several devices that fall under the denomination "PMD" require individual validation, since they record different numbers and types of bioparameters.^(52,53) Therefore, there should be no generalized conclusion about the validity of different devices drawn from studies involving only a particular device or a particular situation. Studies examining such validation often make use of a population that is

predominantly at high risk for OSAS. In addition, there are few studies on the use of PMDs for the diagnosis of OSAS in women, since they normally develop milder forms of the disease or are asymptomatic.^(52,53)

Despite the validation of some PMDs, there is currently no evidence to support the use of in-home OSAS screening of children, the elderly, or individuals who have comorbidities, such as severe lung disease, neuromuscular disease, and heart diseases. These groups are of significant importance due to the greater difficulty that they face in going to a sleep laboratory, and further studies will be required in order to assess their diagnostic needs.

Cost-effectiveness of the use of PMDs

The analysis of the cost-effectiveness of the use of PMDs for the diagnosis of OSAS is particularly dependant on clinical studies. However, there have been only a few randomized clinical trials involving different strategies for the diagnosis and treatment of OSAS that include the collection of data about quality of life, health, and economic aspects.⁽⁵⁷⁻⁶⁰⁾ One review,⁽⁵⁷⁾ using a model for the cost-utility analysis, comparing laboratory polysomnography, in-home monitoring, and no testing for five years after the initial evaluation for OSAS, including CPAP therapy, involved a hypothetical cohort of individuals suspected of having OSAS. Quality of life, survival, and charges for (as proxies for costs of) each diagnostic method were considered. In the five years following the initial diagnostic evaluation, polysomnography provided maximal quality-adjusted life-years (QALYs). The incremental charges for polysomnography over in-home monitoring or no testing (in USD) were approximately \$13,400 and \$9,200, respectively, per QALY gained during this period. The results of that study suggest that the most precise and expensive test (polysomnography) not only provides better outcomes for patients but also represents, from a societal perspective, the most cost-effective option relative to in-home monitoring and no testing. However, those authors also suggested that future studies should be aimed at making a more precise determination of certain key variables in this model.

One study⁽⁵⁹⁾ used a decision-tree model that incorporated typical clinical algorithms to evaluate split-night polysomnography and in-home

monitoring in comparison with a conventional approach using full-night polysomnography, considering the cost-effectiveness, from a third-party payer perspective, over a five-year period. Probabilities and test characteristics were derived from data in the published literature. Cost estimates were based on the 2004 Medicare Fee Schedule, and survival rates were taken from the National Center for Health Statistics data and published studies. Effectiveness was measured in QALYs, and trade-offs of overall costs versus effectiveness were identified. The in-home monitoring strategy was less costly and less effective than was split-night polysomnography and full-night polysomnography, as was split-night polysomnography when compared with full-night polysomnography. Costs to gain additional QALYs were below commonly accepted thresholds. A probabilistic analysis suggested that the in-home monitoring approach was the most cost-effective at the lowest levels of third-party willingness to pay, whereas split-night polysomnography and full-night polysomnography were the most cost-effective at higher levels of such willingness. Therefore, in-home monitoring and split-night polysomnography are cost-effective alternatives to full-night polysomnography.

One group of authors⁽⁶⁰⁾ assessed the reliability and cost-effectiveness of one PMD by comparing it to polysomnography in the diagnosis of OSAS. The authors concluded that this PMD was a reliable device for such a purpose. For the cost analysis, and to make use of a diagnostic algorithm that included all of the facets of the in-home monitoring, the authors took into account not only the costs of the necessary disposable accessories but also the salaries of the medical personnel and sleep center staff. They found that the use of in-home monitoring represented a savings of only 18% when compared with the traditional practice of in-laboratory polysomnography.

Most studies evaluating the cost-effectiveness of in-home monitoring do not state the specific type of device, a factor that should be taken into account, since there can be significant differences in costs among PMD types. Future studies should also highlight the importance of the complexities within the overall evaluation of OSAS when comparing the costs of different procedures.

Final considerations

The current guidelines concerning PMDs allow for the use of these devices by patients who have no comorbidities and have a high pre-test probability of OSAS. Based on the CMS recommendations allowing PMDs to be used for the diagnosis of OSAS, it is believed that the use of in-home monitoring will become more widespread. Although various models have been introduced to meet this increased demand, each device will need to be validated individually. In addition, randomized clinical trials examining PMDs should be carried out in specific cohorts (children, the elderly, females, etc.) and in individuals with various comorbidities (such as severe lung disease, heart diseases, and neuropathy), as well as in patients who are asymptomatic or present with only mild OSAS. The conclusions and the recommended course of action will therefore hinge on the data as viewed in relation to the cost-effectiveness of in-home monitoring versus in-laboratory polysomnography.

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