Practice Parameters for the Use of Portable Monitoring Devices in the Investigation of Suspected Obstructive Sleep Apnea in Adults

A joint project sponsored by the American Academy of Sleep Medicine, the American Thoracic Society, and the American College of Chest Physicians

Andrew L. Chesson, Jr, MD[1]; Richard B. Berry, MD[2]; Allan Pack, MD, PhD[3]

[1]Louisiana State University Health Sciences Center – Shreveport, Shreveport, Louisiana; [2]Malcom Randall VAMC/University of Florida, Gainesville, Florida; [3]Center for Sleep and Respiratory Neurobiology, University of Pennsylvania, Philadelphia, Pennsylvania

Background: A variety of devices are used to evaluate patients with a potential diagnosis of obstructive sleep apnea (OSA). A committee comprised of members of the American Academy of Sleep Medicine, American Thoracic Society, and American College of Chest Physicians systematically evaluated data on the use of these devices and developed practice parameters.

Devices reviewed: Three categories of portable monitoring (PM) devices were reviewed with regard to assessing the probability of identifying an apnea-hypopnea index (AHI) of greater or less than 15 in attended and unattended settings. Type 2 (minimum of seven channels, including EEG, EOG, chin EMG, ECG or heart rate, airflow, respiratory effort, oxygen saturation), Type 3 (minimum of four channels, including ventilation or airflow (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG and oxygen saturation) and Type 4 (most monitors of this type measure a single parameter or two parameters) devices were evaluated, and in-laboratory, attended polysomnography was used as a reference.

Specific recommendations:

(1) Insufficient evidence is available to recommend the use of Type 2 PM devices in attended or unattended settings.

(2) Type 3 PM devices appear to be capable of being used in an attended setting to increase or to decrease the probability that a patient has an apnea-hypopnea index greater than 15.

(3) The use of Type 3 PM devices in an unattended setting is not recommended to rule in, rule out, or both rule in and rule out a diagnosis of OSA.

(4) There is some evidence that the use of Type 3 PM devices in an attended in-laboratory setting may be acceptable to both rule in and rule out a diagnosis of OSA if certain limitations are in place. These limitations include manually scoring the records, using the devices only in patients without significant comorbid conditions, having an awareness that symptomatic patients with a negative study should have a Type 1 study, and not using these devices for titrating positive airway pressure or conducting split-night studies.

(5) The use of Type 4 PM devices in attended or unattended settings is not recommended.

General Recommendations: Type 3 and 4 PM devices cannot score sleep and, therefore, do not meet some current Medicare guidelines. The use of PM devices is not recommended for general-population screening or in the absence of a pretest probability of the patient having a diagnosis of OSA, for complaints other than those associated with OSA, without review of raw data during interpretation, by physicians without familiarity with their use and limitations, and without trained personnel to perform technical scoring. Future research should address the use of PM devices in patients with comorbid conditions; non-White patients and women; larger, better-controlled studies; studies focused on the use of Type 2 and 3 devices; studies focusing on decision making and outcomes rather than simple classification using arbitrary cutoffs; and studies that seek to elucidate cost-effectiveness data on the use of PM devices.

Key Words: sleep apnea, obstructive; sleep disorders, diagnosis; polysomnography; practice guidelines; standards; consensus; quality assurance; sleep apnea syndromes; sleep-disordered breathing

Citation: Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. A joint project sponsored by the American Academy of Sleep Medicine, the American Thoracic Society, and the American College of Chest Physicians. *SLEEP* 2003;26(7):907-13.

INTRODUCTION

OBSTRUCTIVE SLEEP APNEA (OSA) IS A COMMON DISORDER THAT AFFECTS BOTH CHILDREN AND ADULTS. It is characterized by periods of breathing cessation (apnea) and periods of reduced breathing (hypopnea). Both types of events have similar pathophysiology and are generally considered equal with respect to their impact on patients. Accurately counting these events and assessing their impact on sleep, oxygen desaturation, and disruption of normal physiology form the basis of diagnostic polysomnography.

The standard approach to diagnosing OSA is in-laboratory, technician-attended, polysomnography. Portable monitoring (PM) has been proposed as a substitute for polysomnography in the diagnostic assessment of patients with suspected OSA. The proponents suggest that PM requires less technical expertise, is less labor intensive and time consuming, and is easier for patients to access. The term *portable monitoring* encompasses a wide range of devices that can record as many signals as does attended polysomnography or only 1 signal, such as oximetry. The use of PM to establish the diagnosis of OSA has been the subject of previous reviews of the literature.

In addition to these reviews, previous guidelines on the use of PM were issued between 1994 and 1999 by a number of authors, including the American Academy of Sleep Medicine, (AASM, formerly the American Sleep Disorders Association),[1-3] The Agency for Health Care Research and Quality (AHRQ—formerly the Agency for Health Care Policy and Research),[4] and ECRI (formerly the Emergency Care Research Institute).[5] Although differences in analysis techniques and classification of PM devices exists among these studies, a uniformity of recommendations resulted. Succinctly summarized, these reports indicate that at the present time there is insufficient evidence to recommend the widespread use of PM devices compared to traditional, technician-attended, laboratory-based polysomnography (Table 1). Nevertheless, PM devices are widely used in locations where patient access to attended laboratory polysomnography is limited or non-existent. There has also been a continuing development of new technology. Because policies guiding the development of AASM practice parameters indicate that all practice parameters are to be reviewed at least every 5 years, most of the AASM guidelines on the use of PM devices were approaching sunset review provisions. When the AASM was in the process of conduct-

ing a review of the literature that had been published since the 1994[1] and 1997 practice parameters[2,3] were developed, the American Thoracic Society (ATS) and the American College of Chest Physicians (ACCP) were also considering undertaking similar projects on this complex issue. After discussion at an ACCP-hosted conference on PM in September 2002, the 3 groups joined forces in this process. Additional groups that expressed a willingness to assist with input were the National Association for the Medical Directors of Respiratory Care and the Australasian Sleep Association.

The ATS, the AASM, and the ACCP identified members of a Steering Committee, Evidence Review Committee, and Guideline-Writing Committee. The final products are 3 coordinated publications: a review paper,[6] this practice-parameters paper, and an executive summary.[7] The procedures and methods used in this project are outlined briefly in this paper but are provided in much greater detail for the interested reader in the companion review paper. The detailed conflict of interest policy adopted is discussed in the review paper. [1.0] It is noted that all three members of the Guideline Writing Committee are directors of academic sleep disorders centers and are experienced in the use of both polysomnography and various portable monitoring devices in their clinical and/or research work, although none participate in industry sponsored research trials on PM devices for the diagnosis of apnea , or have financial interests outlined in the review paper in the conflict of interest exclusions.

This practice parameters paper is based entirely on the evidence presented in the review paper and is neither a consensus paper nor a statement of acceptable clinical practice based on expert opinion. The limitations on the strength of the recommendations are outlined in detail below.

METHODS

The compiling of evidence in the review paper[6] was collected by the Research Triangle Institute (University of North Carolina) under contract for this project and focused primarily on articles published since the 1997 AASM review.[2,3] A meta-analysis of results was not used because too much heterogeneity existed between studies with respect to types of signals measured, criteria used to define a breathing event, scoring of signals from PM devices, and study quality. Once collected, the articles were rated using the method of Sackett et al[8] to establish their levels of evidence. This method for rating the evidence of published studies regarding diagnostic tests was used because it closely aligns with accepted methods used for rating the quality of articles regarding therapeutics and prognosis. In addition this method focuses on the key aspects of the design of studies that are used to evaluate diagnostic tests: avoiding selection bias (by using a consecutively referred sample of patients), blinding interpreters, and avoiding verification bias (by performing the reference standard on all subjects). The Evidence Review Committee then compiled and analyzed these data and issued the companion report referred to as the *review paper*,[6] which will be frequently cited in this document through the use of numbers in square brackets, referring to a specific section or sections of the review paper.

Table 1—Portable Monitoring Devices

Type of Portable Monitoring Device	Parameters Measured
Type 2 Comprehensive Portable	Polysomnography Minimum of 7 channels, including electroencephalogram, electrooculogram, chin electromyogram, electrocardiogram or heart rate, airflow, respiratory effort, and oxygen saturation
Type 3 Modified Portable Sleep ApneaTesting	Minimum of 4 channels monitored, including ventilation or airflow (at least 2 channels of respiratory movement, or respiratory movement and airflow), heart rate or electrocardiogram, and oxygen saturation
Type 4 Continuous Single or Dual Bioparameters	One or 2 channels, typically including oxygen saturation or airflow

Based on data from the review paper, this paper identifies recommended practice parameters for using PM to study adult patients with suspected OSA. They define principles of practice that should meet the needs of most patients in most situations. These practice parameters should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results nor of those that consider the particular needs of the patient and available resources. The ultimate judgment, regarding the propriety of any specific care, must be made by the physician in light of the individual circumstances presented by the patient and the available diagnostic and treatment options and resources. The AASM, the ATS, and the ACCP expect these practice parameters to have a positive impact on professional behavior, patient outcomes, and possibly healthcare costs. These practice parameters reflect the state of knowledge at publication and will be reviewed, updated, and revised as new information becomes available. It is hoped that these practice parameters and the future research section will stimulate better studies to evaluate the role of PM devices in the evaluation of OSA patients.

BACKGROUND

The authors of the review paper[6] selected 3 endpoints to be used in their detailed review and analysis of published data. They evaluated the ability of PM devices to *reduce* the probability that a patient has an abnormal apnea-hypopnea index (AHI) (to rule out the disorder), *increase* the probability that a patient has an abnormal AHI (to rule in the disorder), and both *reduce and increase* the probability that a patient has an abnormal AHI (to both rule out and rule in the disorder).

The authors also reviewed secondary endpoints, including the reproducibility of PM results, the costs and benefits of using of PM devices, the failure rates of PM devices, patient populations studied, and the generalizability of findings.

Four types of sleep-study monitoring devices are referenced in the review paper and were defined as Type 1—standard, in-laboratory, technician-attended, overnight polysomnography—and 3 types of PM devices: Type 2—comprehensive portable polysomnography; Type 3—modified portable sleep-apnea testing; and Type 4—continuous single or dual bioparameter recording (Table 1). Using the review-paper data analysis (types of monitors, sensitivity, specificity, likelihood ratios, pretest and posttest probabilities, study biases, patients' comorbid conditions, nondiagnostic results, etc.), the authors of these practice parameters determined the utility of the devices to provide reliable diagnoses for patients with OSA. Making this determination was a much more complex task than simply evaluating a single endpoint; it required that the data be compiled in a comprehensive manner to provide answers to practical diagnostic and treatment questions that are generated when a patient is referred to a sleep laboratory. The authors developed the practice parameters after identifying the strengths, deficiencies, and reliability or reproducibility of the devices, as provided in the review paper.[6]

LIMITATIONS

In order to correctly apply these practice parameters in the appropriate clinical setting, the physician must be cognizant of both the limitations of the data and of applications related to patient care.

The assessment of the utility of PM devices is based on the AHI

The main method of comparison between PM devices and the gold standard (polysomnography) was based on the agreement in the AHIs and/or using thresholds of severity defining sleep apnea to assess the agreement of PMs with polysomnography in identifying patients with or without OSA. Other methods of comparison such as a decision to treat or observe may be more meaningful but was not generally possible from the evidence. The current approach has limitations since only minor dif-

ferences between the AHI from a PM device and polysomnography can degrade sensitivity and specificity if the difference crosses an arbitrary threshold. For example, an AHI of 12 on one test and 17 on another will lead to apparent disagreement if a threshold value of AHI of 15 episodes/hour is used even though the difference is not clinically meaningful. Patient outcomes may be a more meaningful endpoint but would need to be assessed in studies of complete pathways. Such studies would likely compare both the efficacy of diagnostic and treatment algorithms based on information from PM devices with similar algorithms based on polysomnography. The outcomes would likely depend on both the accuracy of information obtained from the PM devices and the utility of the associated algorithms.

The use of in laboratory polysomnography as the gold standard has limitations

The evidence-based analysis used the AHI determined in the laboratory by polysomnography as the gold standard. However, it is possible that some patients slept more poorly in the laboratory than at home (the polysomnography AHI could underestimate the typical severity) or spent more time in the supine position in the laboratory (the polysomnography AHI could overestimate the typical severity).

These recommendations are based on the premise that polysomnography is available for patients. Previous AASM guidelines addressed some examples of when portable monitoring might be an acceptable alternative in the absence of available polysomnography [1]. These included: (1) for patients with severe clinical symptoms that are indicative of OSA, and when initiation of treatment is urgent and standard polysomnography is not readily available; (2) for patients unable to be studied in the sleep laboratory; (3) for follow-up studies where diagnosis has been established by standard polysomnography and therapy has been initiated, and the intent is a comparison to evaluate response to therapy. Nothing in the current review paper has provided evidence-based assessment to formally change such recommendations. Clinical judgment made by the physician in light of individual circumstances has to be applied to individual patients.

The use of PM devices is limited to the evaluation of OSA

The review and the data address only the evaluation of OSA; therefore, the compiled data are insufficient to recommend the use of PM devices in evaluating patients with any disorders other than suspected OSA.

The use of PM devices does not meet some Medicare qualification criteria

The review and the data were primarily related to patients with an AHI of at least 15 because the studies that were analyzed often did not include patients with an AHI of less than 15, and the results may not be able to be extrapolated to lower AHI levels. This limitation may become progressively more relevant with the new Medicare guidelines, which suggest that an indication for treatment may be an AHI of greater than 5 plus symptoms. Because Type 3 and Type 4 PM devices do not include electroencephalography and, therefore, cannot reliably record or evaluate sleep, the use of these devices does not meet the Medicare guidelines that require at least 2 hours of documented sleep time.

Table 2—Levels of Recommendations

Term	Definition
Standard	This is a generally accepted patient-care strategy that reflects a high degree of clinical certainty. The term *standard* generally implies the use of Level I evidence, which directly addresses the clinical issue, or overwhelming Level II evidence.
Guideline	This is a patient-care strategy that reflects a moderate degree of clinical certainty. The term *guideline* implies the use of Level II evidence or a consensus of Level III evidence.
Option	This is a patient-care strategy that reflects uncertain clinical use. The term *option* implies either inconclusive or conflicting evidence or conflicting expert opinion.

Reprinted with permission from American College of Physicians. Eddy DM, ed. A manual for assessing health practices and designing practice policies: the explicit approach. Philadelphia: American College of Physicians; 1992.

Aspects of PM use may have limitations based on practical applications to clinical use

The usual clinical application of polysomnography in the sleep laboratory is to both rule in and rule out a diagnosis of OSA (by reporting the AHI). The authors of the review paper performed separate analyses of the PM devices with respect to their ability to rule out (low likelihood ratio) [Table 2], rule in (high likelihood ratio) [Table 3], and then to both rule out and rule in (both low and high likelihood ratio) [Table 4] a diagnosis of OSA. These practice parameters were developed using this process (rule out, rule in, or both) in order to follow the data analysis in the review paper. However, few sleep disorders centers would (or could under insurance parameters) use a test to rule out a diagnosis of OSA, and if the results of the first study did not provide an answer, subsequently perform another test on the same patient to rule in a diagnosis of OSA, or vice versa. In addition, the literature review and analysis identified an appreciable number of patients with neither a positive nor a negative result [Table 4], and inconsistencies were found in the results of data from various PM devices in the same class.

Research studies that have evaluated the diagnostic accuracy of PM devices have used multiple thresholds for defining positive and negative results and assessing sensitivity and specificity. Although these results, which supplied the data for the review-paper analysis, used a variety of definitions of OSA, they were "standardized" to an AHI of 15 in order to allow a between-studies comparison of the data. Unfortunately many studies have not suggested that the evaluated devices have a single cut-off with both high sensitivity and specificity, which is a practical limitation of significance when moving that research data to laboratory use. Analysis by best-reported sensitivity gives the benefit of the lowest false negatives and lowest likelihood ratio.

RECOMMENDATIONS

The following recommendations are categorized based on classification of evidence from the accompanying review paper as adapted from the suggestions of Sackett[8] and as outlined in greater detail in the review paper [2.3.1 –2.3.2] (Table 2). Recommendations are given as standards, guidelines, and options as adapted from Eddy (Table 2).[9]

Type 2 PM Devices: Comprehensive Portable Polysomnography

1. **The clinical use of Type 2 PM devices in the attended setting is not recommended to evaluate patients with suspected OSA. (Option)**
2. **The clinical use of Type 2 PM devices in the unattended setting is not recommended to evaluate patients with suspected OSA. (Option)**

Although Type 2 devices theoretically should most resemble in-laboratory polysomnography and be best for calculating an AHI because they

Table 3—Levels of Evidence

Level of Evidence	Study Design
I	Blinded comparison, consecutive patients, reference standard performed on all patients
II	Blinded comparison, nonconsecutive patients, reference standard performed on all patients
II	Blinded comparison, consecutive patients, reference standard not performed on all patients
IV	Reference standard not applied blindly or independently

Adapted with permission from Sackett D. Rules of evidence and clinical recommendations for the management of patients. Can J Cardiol 1993;9:487-9 and [2.3.1].

permit sleep scoring, relatively few published studies provide data and address this use. Based on the small number of published studies, the absence of sensitivity and specificity data, and the low level of evidence, inadequate data are available to recommend the clinical use of Type 2 PM devices in the attended or unattended setting. In addition, a high rate of data loss in the unattended setting is often reported. [4.1.1; 4.1.2; 4.1.3; 4.2.3; 4.3.2.1; Table 2]. The absence of support for such use and the "option" guideline are based on insufficient data.

Type 3 PM Devices: Modified Portable Sleep Apnea Testing

Recommendations concerning the use of Type 3 PM devices to reduce the probability that a patient has an AHI less than 15 (ie, rule out a diagnosis of OSA at a level selected by the review-paper authors for their statistical cutoff; this is also one of the levels set by Medicare to reflect a level of significance)

3. The use of some Type 3 PM devices in an attended setting can decrease the probability that the patient has an AHI greater than 15. (Standard)

Type 3 PM devices have potential utility and reasonable reliability in the attended setting among patients who have a low pretest probability of having OSA and in whom the study is being conducted to confirm that impression. Use in this setting requires careful patient selection by history and examination findings to first identify a reasonably low pretest probability that OSA is present. [4.3.2.2; 4.1.1]

4. The use of Type 3 PM devices in an unattended setting is not recommended to decrease the probability that the patient has an AHI greater than 15. (Guideline)

The clinical use of Type 3 PM devices is not recommended in the evaluation of OSA in the unattended setting. Although some higher-level evidence (up to a Level II) is beginning to accumulate, a relatively high percentage of false negative results makes the reliability of these devices for making patient-care decisions below accepted standards. [4.1.1; 4.3.2.2]

Recommendations concerning the use of Type 3 PM devices to increase the probability that a patient has an AHI greater than 15 (ie, rule in a diagnosis of OSA at a level selected by the review-paper authors for their statistical cutoff; this is also one of the levels set by Medicare to reflect a level of significance)

5. Some Type 3 PM devices can be used in an attended setting to increase the probability that a patient has an AHI greater than 15. (Standard)

Available studies were of a higher quality and high likelihood ratios. Some had a lower percentage of false positive results. [4.1.2; 4.3.2.3]

6. The use of Type 3 PM devices in an unattended setting is not recommended to increase the probability that a patient has an AHI greater than 15. (Guideline)

The data supporting the usefulness and utility of PM devices in the unattended setting to increase the probability of the patient having a diagnosis of OSA is too limited to support clinical utility and is associated with high false-negative and false-positive rates. [4.1.2; 4.3.2.3]

Recommendations concerning the use of Type 3 PM devices to both increase and decrease the likelihood that a patient has a diagnosis of OSA with a single threshold, which is the most practical clinical use.

For practical use in a sleep center, a device should be able to reliably identify whether an AHI is less than or greater than a specific cutoff point, not simply determine one or the other. That does not appear to be the case with the use of Type 3 PM devices in unattended studies [Table 4, column 14]. In most unattended studies, multiple cutoff levels and careful screening seem to be necessary for these devices to be used. The data from unattended studies suggest that one would have to accept high rates of patients with neither a positive nor a negative (having a nondiagnostic) result, if PM devices were to be used in this setting. In addition, different AHI levels would be needed to provide a reasonable sensitivity and specificity.

7. The use of Type 3 PM devices may be acceptable in an attended in-laboratory setting to both rule in and rule out a diagnosis of OSA. Such a use, however, would require limitations, as noted below. (Standard) [4.1.3; 4.3.2.4]

a) In nearly all of the studies providing evidence that Type 3 devices could be used in an attended in-laboratory setting, the results were analyzed either manually or using a combination of automatic and manual scoring. Thus, careful review of raw data appears to be necessary.

Scoring of results should comply with the presented evidence, which indicates the superiority of manual scoring over automatic computer-generated scoring. For most of these devices, software that is currently used clinically differs from the software used in the studies, a factor that may need additional consideration. The use of time in bed rather than accurately scored total sleep time already produces changes in sensitivity and specificity and should not be compounded by use of automated scoring at this point. [1.1.3; Table 5; Appendix 4 – Table 10]

b) Type 3 PM devices should be used only in a population similar to those that have been studied—patients may not have significant comorbidities such as chronic obstructive pulmonary disease, congestive heart failure, etc.—and should be used in a sleep-clinic population (not applied as generalized screening).

Patients should be carefully screened prior to undergoing testing with a Type 3 PM device to assess the pretest probability that they do or do not have OSA. Clinically, this screening should be performed in a reliable manner by the laboratory that is doing the testing and would typically include an examination, a history, and information from a partner questionnaire. Assessment of the patient's pretest probability of having OSA is an important component of use in order to match the evidence, as reported in the review paper.[6] .

The use of PM devices has been considered here only with regard to the assessment of OSA and not to the assessment of other possible conditions in which cortical arousals, or an assessment of actual disruptions of sleep, may be an important part of clinical evaluation. The significance of this likely relates to the type of event being evaluated, the type of PM used, and has to be considered within the limitation of the outcomes being assessed. [4.3.1]

c) Type 3 PM devices do not measure sleep. Additionally, the AHI provided by Type 3 PM devices tends to underestimate the polysomnogram-defined AHI because monitoring time rather than total sleep time is used in the denominator. [4.1.2.2; 4.3.1]

Under current Medicare guidelines, which require documentation of 2 hours of sleep, the use of type 3 PM devices does not fit accepted Medicare definitions, an important awareness for any physician using PM devices. Use of monitoring time rather than total sleep time may result in misclassification of patients with mild disease.[4.3] The importance of this consideration would depend on the sleep efficiency of the patient during the time studied and the severity of OSA.

d) Symptomatic patients with a nondiagnostic or negative Type 3 PM study should undergo a definitive evaluation to determine the cause of their symptoms. If a sleep disorder remains part of the

clinical consideration, a full attended polysomnogram (Type 1 study) should be conducted.

e) *Patients with a diagnosis of OSA based on the results of a Type 3 PM study need a subsequent polysomnogram (Type 1 study) if continuous positive airway pressure (CPAP) titration is needed.*

Data on the use of Type 3 PM devices for reliably titrating CPAP are not available. The use of traditional polysomnography as a split study has not been compared to the use of Type 3 PM devices followed by CPAP titration with a traditional polysomnogram, and, therefore, no data are available regarding potential time or cost savings.

f) *The use of Type 3 PM devices is not recommended for split-night studies because there is little or no evidence to support such an approach. There is no data on such use of PMs.*

g) *The ability of Type 3 PM devices to perform their identified function could be device specific, and capabilities and limitations of each device must be taken into account by the interpreter of the studies. [4.3]*

8. The use of Type 3 PM devices in an <u>unattended</u> setting is not recommended to rule in and rule out a diagnosis of OSA. (Guideline)

Studies of limited quality using different AHI levels, and a high rate of patients with nondiagnostic studies (neither positive nor negative results) limit support for the use of Type 3 PM devices. The studies that evaluated the use of Type 3 PM devices in the unattended setting had high numbers of patients without a positive or negative result.

Type 4 PM Devices: Continuous Single Or Dual Bioparameter Recording

Type 4 PM devices generally use oximetry and a second (airflow-assessment) parameter, which varies between studies; depending upon the type of airflow evaluation, results among patients may also vary. Due to the high variability between devices and methods-related results, many of the results are device specific, and data across this group as a whole are difficult to evaluate. [4.1.1; 4.1.2; 4.1.3; 4.3.2; Tables 2, 3, and 4]

Recommendations concerning the use of Type 4 PM devices in the attended setting to increase, decrease, or both increase and decrease the probability of the patient having an AHI greater than 15.

9. The routine use of Type 4 PM devices with oximetry and at least one other airflow parameter in an <u>attended</u> setting is not recommended to <u>increase</u> the probability that a patient has an AHI greater than 15 (Option)

Some studies suggest that there is some benefit to using Type 4 PM devices in an attended setting; however, the fact that these studies show a significantly higher percentage of false-positive results is of concern, as are conflicting data, especially when coupled with issues concerning utility. These studies used a variety of methods, including oximetry alone, oximetry with airflow or nasal transducers, and other combinations such as heart rate or snoring. Among the higher-level studies, likelihood ratios are variable, as are higher numbers of false positives, resulting in conflicting data. [4.1.2; 4.3.2.3]

10. The routine use of Type 4 PM devices with oximetry and at least one other airflow parameter in an <u>attended</u> setting is not recommended to <u>decrease</u> the probability that a patient has an AHI greater than 15. (Option)

Serious limitations, as noted in the review paper, suggest that the clinical use of Type 4 PM devices may not be satisfactory for providing reliable patient care and for making treatment decisions. These limitations include a high rate of false-negative results in Level 1 and Level 2 studies, plus conflicting results from Level 1 studies. In addition, a high percentage of patients with neither positive nor negative results was seen across studies that had multiple levels of evidence [Table 4]. Other cautions are also noted: the studies that evaluated the use of Type 4 PM devices measured a variety of channels (1-3 variables), used inconsistent criteria for determining desaturations and sampling rates, and employed a variety of scoring methods (manual, computer generated, or both) [4.1.1; 4.3.2.2]

11. The routine use of Type 4 PM devices with oximetry and at least one other airflow parameter is not recommended in an <u>attended</u> setting to <u>both increase and decrease</u> the probability that a patient has an AHI greater than 15. (Option)

The studies that used Type 4 PM devices in an attempt to both reduce and increase the probability of a patient having a diagnosis of OSA used multiple cutoffs to achieve better likelihood ratios and had a high rate of patients who did not have a diagnostic result. Both of these factors defeat the purpose of a screening test and result in a lack of adequate data to establish the use of Type 4PM devices. In some studies in an attended setting, oximetry alone seems to be able to reduce, but not reasonably eliminate, the probability of the patient having an AHI of less than 15 even when the patient obtains sufficient sleep, as confirmed by other measures. If cyclic desaturation is present, clear evidence of the fact may be helpful but is not specific.

Moreover, Type 4 PM devices neither identify apnea nor measure and confirm sleep. Because oximetry identifies only saturation changes and not apneas or hypopneas and does not document sleep, the use of Type 4 PM devices does not meet Medicaid or Medicare criteria, particularly when considering an exclusion of OSA. The absence of significant desaturation does not mean the absence of upper airway resistance, hypopneas, or even apneas. [4.1.3; 4.3.2.4]

Recommendations concerning the use of Type 4 PM devices in the unattended setting to increase, decrease, or both increase and decrease the probability of a patient having an AHI greater than 15.

12. The use of Type 4 PM devices in the <u>unattended</u> setting with oximetry and one other airflow parameter is not recommended for diagnosing OSA or confirming that a patient has an AHI greater than or less than 15. (Guideline)

Insufficient evidence is available to suggest such use, especially in light of 1 Level 1 study in which the diagnosis of OSA was not adequately classified in 50% of patients. A substantial number of the studies used different thresholds to try to achieve their classification. In addition, most of the studies had substantial numbers of patients who were not classified as being either positive or negative with respect to an AHI greater than or less than 15. [4.1.3; 4.3.2.4]

AREAS REQUIRING SPECIAL ATTENTION

13. The use of PM devices is not recommended for general screening or clinical use without available knowledge of the patient's sleep-related history and complaints.

High and low pretest probability are important in assessing the effectiveness of the devices. Few studies were conducted in the general population. Based upon available evidence, data from the high-probability group for OSA (referrals to sleep centers) would not necessarily be generalizable for screening purposes among the general population.

14. The use of PM devices is not recommended in patients with comorbid conditions or secondary sleep complaints because there is little evidence to support the use of PM devices in evaluating these conditions or to diagnose other sleep disorders.

Most of the studies that have been evaluated in determining the evidence for the use of PM devices excluded patients with comorbid conditions, resulting in a lack of data in these conditions [4.2.4.2]. Instead, these studies focused on patients with a high pretest probability of having OSA and little or no comorbidity [5.1]. In all of the recommendations, where the possible use of PM devices is appropriate, subjects with comorbid conditions such as chronic obstructive pulmonary disease, heart failure, stroke, or severe hypertension (which are comorbidities that are frequently seen among patients in sleep clinics) should be studied with Type 1, traditional polysomnography rather than with PM devices. The review paper also raises concerns about the lack of data regarding the use of PM devices in women and ethnic groups other than Whites.

15. Even when PM devices are noted as being possibly useful, the general use of all types of devices across that category is not necessarily recommended. The laboratory should confirm that the commercial device selected in a category has specific studies documenting its performance and that it conforms to the use characteristics of that category as a whole.

All devices in a given category are not the same. Many of the results are probably device-type dependent. Any laboratory that uses a PM device should confirm that quality scientific studies have been conducted for that device and that the interpreting physician is familiar with the limitations, exclusions, and weaknesses of the particular device and interface components.

16. The review of raw data and the use of manual scoring for interpreting data from PM devices is recommended.

The interpreting physician must be able to assess and review the raw data generated by a PM device and must consider that data when interpreting the sleep study. Based on available evidence, scoring should be performed manually. The use of processed and computer-scored data has more errors and diagnostic problems.

17. Physicians with sleep training and familiarity with the devices and their limitations should interpret studies generated by PM devices and should review the raw data, as noted above. Trained and qualified technicians should perform any technical scoring.

FUTURE RESEARCH

Developing a consensus on the best way to validate the use of PM devices is urgently needed. Based on the limitations defined earlier, we need to move beyond assessing validity based on sensitivity and specificity for whether the AHI is above or below a fixed threshold, particularly given the known night-to-night variability in AHI. The urgency recognizes the fact that many OSA patients currently do not have access to in-laboratory polysomnography.

The reviewers of the evidence on the use of PM devices outlined recommendations for future research [5.0-5.3.2]. They addressed the lack of studies concerning the use of PM devices in primary-care populations, in patients with comorbid conditions such as heart failure or chronic obstructive pulmonary disease, and in ethnic populations other than Whites, and they highlighted the need for studies with sufficient numbers of women [5.1]. The reviewers also proposed key and important features of future studies to ensure that data with a high evidence level would be obtained [5.2]. The reader is referred to the review for the complete discussion.[6] A few points that the guideline-writing committee felt were particularly important are mentioned further.

As is evident throughout this report, the major problem in this area is lack of evidence. In general, studies include small sample sizes and are not particularly well designed. Other significant barriers to progress exist. First, there is no universally accepted platform for generating simplified studies in the diagnosis of OSA. This means that results obtained for a particular device are applicable only to that device and cannot be extrapolated to other devices, even to those in the same class. Because devices have different performance characteristics, lumping together results from devices of the same class can result in misleading conclusions. Even within a given device class, (eg, oximetry) results may be affected by the data-processing method, including digital signal analysis, sampling rate, and averaging time. If the use of PM devices is to develop its full potential, consensus must be reached regarding the variables that need to be recorded for simplified, general, respiratory-only, studies.

Several specific points that were raised by the evidence review committee for future studies are as follows: Certainly patients involved in research projects that are attempting to validate PM devices should also have a reference study (usually attended polysomnography). The order of the PM study and the reference standard study should be randomly assigned. The interpreter of each study should be blind to the results of the corresponding study. Clear descriptions of how breathing events are defined and the oximeter sampling rate and averaging time should be specified. Criteria for a positive result and a negative result should be selected before the study is conducted. Ideally the same cutoff should be chosen to both diagnose and exclude a diagnosis of OSA, thereby avoiding having large numbers of patients with neither a positive nor a negative study. The review also addressed the confounding problem of night-to-night variability; obviating this problem would optimally entail conducting multiple nights of both the PM study and the reference study.

In addition to the above issues, the guideline-writing committee also felt that more data were definitely needed concerning Type 2 devices. As technology advances, the ease and practicality of using Type 2 devices should increase. Use of these devices would also assist with evaluating sleep quality as well as respiratory disturbances. Certainly the use of Type 2 PM devices should have the potential to provide equivalent data to that generated by traditional polysomnography if the problem of data handling, analysis, and loss can be solved.

As type 3 PM devices in the attended setting were the only class that could be recommended for routine use (with the limitations as listed in mind), standardization of this type of device seems particularly important. The unattended type 3 PM study is probably the most common use of these devices in clinical practice especially in locales where polysomnography is not available. Given the better evidence for use of the devices in the attended setting it is possible that different devices, different study designs, or different strategies for application of type 3 devices in the unattended setting could result in better evidence for their use in this setting. Clearly, more studies in the unattended setting are needed.

The use of PM devices to make a diagnosis of OSA will not necessarily be of benefit unless timely treatment is available. On the basis of the available evidence, type 3 PM devices could not be recommended for either attended or unattended positive pressure titration. However, auto-titrating positive pressure devices have been shown to be effective in the attended setting in some CPAP naive patients .[10, 11] As these devices usually monitor only airflow and snoring there is no obvious reason why type 3 PM devices could not be successful for attended pressure titration. More study of the use of these devices in this setting seems warranted. For patients with limited access to attended polysomnography, a method to provide adequate treatment as well as diagnosis is needed.

At present there are also no clear guidelines on the expertise physicians reading PM devices should have. Limitations on reimbursement of PM studies are undoubtedly driven in part by a reasonable concern that there may be widespread use of these devices by physicians who have little training in sleep medicine.

Finally, the utility of diagnostic testing should always be assessed in terms of treatment algorithms and final patient outcomes. For example, if a PM study is conducted that results in a positive diagnosis of OSA and is then followed by a traditional Type 1 study for the titration of positive airway pressure, the utility of PM devices will be reduced if most PM studies are positive. Cost comparisons to an alternative, split-night-study format are needed to validate the assumption, espoused by some,

that the use of PM devices will result in cost savings. However, before outcome studies are initiated, there is a need to more clearly define the goals of the studies and investigations, assessing the overall outcomes of diagnosis and therapy, and comparing results from Type 1 studies to the results from more simplified studies.

REFERENCES

1. American Sleep Disorders Association Report. Standards of Practice Committee. Practice parameters for the use of portable recording in the assessment of obstructive sleep apnea. Sleep 1994;17:372-7.
2. American Sleep Disorders Association Report. Standards of Practice Committee. Practice parameters for the indications for polysomnography and related procedures. Sleep 1997;20:406-22.
3. Chesson AL, Ferber R, Fry J, et al. The indications for polysomnography and related procedures. Sleep 1997;20:423-87.
4. Rose SD, Allen IE, Harrison KJ, et al. Systematic review of the literature regarding the diagnosis of sleep apnea. Evidence Report/Technology Assessment No. 1 (Prepared by MetaWorks Inc., under Contract No. 290-97-0016.) AHCPR Publication No. 99-E002. Rockville, MD: Agency for Health Care Policy and Research; February 1999.
5. ECRI. Health Technology Assessment Information Service. Polysomnography: an overview of testing for sleep disorders. Plymouth Meeting, PA: 1996. Contract No:308240. WGE
6. Flemons W, Hudgel D, Littner M, et al. A systematic review of portable monitoring for investigating adult patients with suspected sleep apnea. Chest. (In Press).
7. Collop N, Shepard J, Strollo P. Executive Summary on the Systematic Review and Practice Parameters for Portable Monitoring in the Investigation of Adults with Suspected Sleep Apnea. Am J Respir Crit Care Med. (In Press).
8. Sackett D. Rules of evidence and clinical recommendations for the management of patients. Can J Cardiol 1993;9:487-9.
9 . Reprinted with permission from American College of Physicians. Eddy DM, ed. A manual for assessing health practices and designing practice policies: the explicit approach. Philadelphia: American College of Physicians; 1992.
10. Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the use of auto- titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstuctive sleep apnea. Sleep 2002; 25 (2): 143-147
11. Berry, R, Parish, J, Hartse, K. The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. Sleep 2002; 25 (2): 148-173