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SPECIAL ARTICLE

Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients

Portable Monitoring Task Force of the American Academy of Sleep Medicine

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Based on a review of literature and consensus, the Portable Monitoring Task Force of the American Academy of Sleep Medicine (AASM) makes the following recommendations: unattended portable monitoring (PM) for the diagnosis of obstructive sleep apnea (OSA) should be performed only in conjunction with a comprehensive sleep evaluation. Clinical sleep evaluations using PM must be supervised by a practitioner with board certification in sleep medicine or an individual who fulfills the eligibility criteria for the sleep medicine certification examination. PM may be used as an alternative to polysomnography (PSG) for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA. PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of PM. PM is not appropriate for the diagnostic evaluation of patients suspected of having comorbid sleep disorders. PM is not appropriate for general screening of asymptomatic populations. PM may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness. PM may also be indicated to monitor the response to non-CPAP treatments for sleep apnea.

At a minimum, PM must record airflow, respiratory effort, and blood oxygenation. The airflow, effort, and oximetric biosensors conventionally used for in-laboratory PSG should be used in PM.

The Task Force recommends that PM testing be performed under the auspices of an AASM-accredited comprehensive sleep medicine program with written policies and procedures. An experienced sleep technologist/technician must apply the sensors or directly educate patients in sensor application. The PM device must allow for display of raw data with the capability of manual scoring or editing of automated scoring by a qualified sleep technician/technologist. A board certified sleep specialist, or an individual who fulfills the eligibility criteria for the sleep medicine certification examination, must review the raw data from PM using scoring criteria consistent with current published AASM standards.

Under the conditions specified above, PM may be used for unattended studies in the patient's home. A follow-up visit to review test results should be performed for all patients undergoing PM. Negative or technically inadequate PM tests in patients with a high pretest probability of moderate to severe OSA should prompt in-laboratory polysomnography.

Keywords: Clinical guidelines, portable monitoring, home study, obstructive sleep apnea, comprehensive evaluation

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The current standard for clinical practice, established through evidence-based reviews by the American Academy of Sleep Medicine (AASM), is to confirm the diagnosis of obstructive sleep apnea (OSA) with in-laboratory polysomnography (PSG).[1] This method has been proven to be accurate with a low failure rate because the study is attended by technical staff; PSG, however, is considered relatively expensive and technically complex. Portable monitoring (PM) has been utilized as an alternative diagnostic test for OSA based in part on the premise that it is less expensive and quicker to deploy compared to in-laboratory PSG. However, there is a paucity of evidence that shows PM is equivalent to PSG in regards to diagnosis, treatment, and outcomes. The available literature typically shows PM can be as accurate as PSG for diagnosis in selected populations; however, in practice it is often used without prior determination of whether the patient is an appropriate candidate for PM.

The first practice parameter on PM was published in 1994.[2] A subsequent paper on the indications for polysomnography was published in 1997.[3] The Agency for Healthcare Research and Quality (AHRQ) reviewed articles and performed a meta-analysis

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of the literature on the diagnosis of OSA.[4] An evidence review and practice parameter was written by a committee composed of representatives of the AASM, American College of Chest Physicians and the American Thoracic Society.[1, 5] None of these documents supported broad use of PM due to lack of sufficient evidence. In 2004, the Centers for Medicare and Medicaid Services (CMS) reviewed its national coverage determination (NCD) 240.4 regarding the use of PM as a basis for prescribing CPAP therapy. Their final decision was released in April, 2005 stating that the evidence was *not adequate* to conclude that "the use of unattended portable multi-channel sleep testing with a minimum of 4 or 7 monitored channels was reasonable and necessary in the diagnosis of OSA; therefore these tests remain uncovered."[6] In 2006, the AASM released an interim position statement[7] regarding the use of PM in the diagnosis of OSA in response to an Institute of Medicine report.[8] In this statement, the AASM recommended that physicians who choose to use PMs should use them in combination with a clinical assessment and interpret them within the context of a comprehensive evaluation of the patient; that such devices should be used only by AASM-accredited sleep centers or laboratories or by board certified sleep specialists; and that decisions regarding therapy should be based on a comprehensive evaluation of the study results and the patient's symptoms.

CMS NCD 240.4 states that inadequate evidence exists to support PM as a diagnostic tool for OSA, and it is not covered as a reasonable and necessary test.[6] In 2007 CMS initiated a review of NCD 240.4 at the request of the American Academy of Otolaryngology – Head and Neck Surgery. In its testimony, the AASM presented evidence dismissing the assertion that patients experience unacceptable delays in accessing PSG, discussed the lack of available data on the efficacy of PM in the Medicare population and the lack of economic data in support of PM, and reiterated the AASM position that if PM is accepted as a diagnostic tool, it must be performed under the construct of AASM-accredited facilities or by specialists certified in sleep medicine. A decision from CMS is expected in March 2008.

The AASM charged the Portable Monitoring Task Force with a reevaluation of the evidence on PM as an alternative to in-laboratory PSG. The Task Force performed a limited literature search to capture articles published since the last literature review[5] and used evidence review and a consensus process to develop clinical guidelines for the use of PM in the diagnosis and management of OSA.

METHODS

The Portable Monitoring Task Force was charged with answering the following questions:

1. What are appropriate indications for PM?
2. What types of PM should be used?
3. How should PM data acquisition, analysis, and interpretation be performed?
4. What is the proper application of PM results?

The 1994 review[2] divided PM into 4 types:

1. Type 1: full attended polysomnography (≥ 7 channels) in a laboratory setting
2. Type 2: full unattended polysomnography (≥ 7 channels)
3. Type 3: limited channel devices (usually using 4–7 channels)
4. Type 4: 1 or 2 channels usually using oximetry as 1 of the parameters

That review included approximately 70 studies from 1960 to 1994. Inclusion criteria for studies were: 1) comparison of the PM device to in-laboratory PSG in adults age 18 and over; 2) publication in English; and 3) inclusion of at least 10 subjects.

Since the charge of the Portable Monitoring Task Force was not limited to a review of the accuracy of PM compared to PSG, we sought to review a broader range of literature in which PMs were evaluated using patient outcomes, treatment variables, or other parameters. A MEDLINE search was conducted on articles published between 1997 and August 2006 using the following main terms in various combinations: "polysomnography," "oximetry," "physiologic monitoring," and "sleep apnea." These terms were then combined with "airway resistance," "upper airway resistance syndrome," "respiratory disturbance index," "autoset," "snoring," and "respiratory event related arousal." The combined search was then refined by combining with the following terms: "reproducibility of results," "predictive value of tests," "sensitivity," and "specificity." Additional searches were then conducted with "polysomnography" combined with the terms "home monitoring" and "home care services."

The search found 291 articles and the Task Force reviewed all abstracts to exclude studies that did not meet the following criteria: subjects ≥ 18 years of age; patient evaluated for OSA; patients had testing with a monitoring device that offered fewer channels (Type 3 devices) than polysomnography; and a minimum of 10 subjects. We restricted our review to Type 3 devices because these are used most frequently in the outpatient setting. The Task Force developed an extraction form to address the specific questions posed above. We also evaluated the monitors with respect to the physiologic signals monitored and devised a new technology classification system to assist us in assessing what leads are most valuable:

Technology Used in Portable Monitoring

1. Oximetry
2. Respiratory monitoring, including but not limited to:
   a. Effort
   b. Airflow
   c. Snoring
   d. End-tidal CO_2
   e. Esophageal pressure
3. Cardiac monitoring, including but not limited to:
   a. Heart rate or heart rate variability
   b. Arterial tonometry
4. Measures of sleep wake activity, including but not limited to:
   a. Electroencephalography
   b. Actigraphy
5. Body position
6. Other

Review of the 291 articles resulted in 36 meeting inclusion criteria[9-43]; abstraction data is summarized in the Evidence Table. A decision was made to review an additional paper published in 2007 as it had important outcome data.[44] Therefore, the Evidence Table (available online at www.aasmnet.org/jcsm) shows data from 37 papers. The data were abstracted by an independent reviewer and reviewed for accuracy by a member of the Task Force. The Task Force included this data as well as data from all previous reviews in developing recommendations for the use of PMs.

The Task Force held a face-to-face meeting to develop consensus-based guidelines. Each of the 4 questions posed were reviewed

in detail by Task Force members and, using a modified nominal group technique, statements were developed and approved by the group. The AASM Board of Directors approved this guideline.

RECOMMENDATIONS

1. Indications for Portable Monitoring

1.1. PM FOR THE DIAGNOSIS OF OSA SHOULD BE PERFORMED ONLY IN CONJUNCTION WITH A COMPREHENSIVE SLEEP EVALUATION. CLINICAL SLEEP EVALUATIONS USING PM MUST BE SUPERVISED BY A PRACTITIONER WITH BOARD CERTIFICATION IN SLEEP MEDICINE OR AN INDIVIDUAL WHO FULFILLS THE ELIGIBILITY CRITERIA FOR THE SLEEP MEDICINE CERTIFICATION EXAMINATION. IN THE ABSENCE OF A COMPREHENSIVE SLEEP EVALUATION, THERE IS NO INDICATION FOR THE USE OF PM.

The Task Force recommends that the comprehensive evaluation of patients follow the AASM Standards for Accreditation of Sleep Disorders Centers[45] specifically with regard to the role of a sleep specialist board certified in sleep medicine, patient acceptance criteria, and quality assurance. This recommendation is consistent with the 2003 practice parameter defining indications for PSG.[46] This recommendation emphasizes the role of a complete diagnostic evaluation to establish a differential diagnosis of sleep disorders. Any consideration of PM applicability must be taken in the context of this evaluation process. This recommendation is based on evidence as indicated in the Evidence Table. The majority of the study designs in the literature reviewed included a screening evaluation (stated in 32 articles). Seven studies specified physician involvement in pretest evaluation. Screening measures (stated in 34 studies) referenced snoring, suspected sleep related breathing disorders or sleepiness. Exclusion criteria were stated in 19 studies (4 "other sleep diagnoses," 3 "logistics," 6 "other cardiopulmonary diagnoses or supplemental oxygen," and 6 "general medical or technical limitations").

It is the consensus of the Task Force that the clinical evaluation should be performed by a board certified sleep specialist or an individual who fulfills the eligibility criteria for the sleep medicine certification examination, and that interpretation of the PM study, supervision, and quality assurance be the responsibility of a sleep specialist board certified in sleep medicine as is required for sleep center accreditation.[45] This is because the skill set required for board certification includes: an understanding of differential diagnosis of a broad array of symptoms; interpretation of PM results and sources of error; and the ability to use the PM results in the context of the individual patient's history and physical examination. There are currently 2 recognized sleep medicine certification pathways: the American Board of Sleep Medicine and the American Board of Medical Specialties. Either of these pathways meets the requirements for sleep medicine certification.

The PM study should be 1 tool in the complete evaluation of the sleep disorders patient. This recommendation is an extension of the prior practice parameter for PM (section 16)[1] emphasizing the specialty training of the interpreting physician. The consensus of the Task Force is that PM interpretation must be supervised by a trained sleep physician who must have access to the raw data. Although most of the studies reviewed were conducted at sleep centers, 26 of the 37 studies were performed outside the United States so that the effect of board certification and sleep center accreditation cannot be assessed.

A study by Parthasarathy and colleagues[47] reported that the absence of accreditation or provider certification was associated with higher rates of PAP discontinuation (odds ratio = 1.9). Improved patient education and treatment of nasal congestion by the certified physicians and accredited center personnel was associated with increased treatment utilization and patient satisfaction. It is critical to recognize that the utility of unattended portable monitoring in the diagnosis of OSA rests on more than the recording accuracy of a portable device. Historically, the field of sleep medicine has placed a high priority on the provision of comprehensive clinical care to patients with sleep disorders. Specifically, the standards for care emphasize that polysomnographic evaluation should only occur within the context of a full evaluation of the patient by a trained expert in sleep medicine. Comprehensive clinical assessment ensures several important facets of care:

1. *Appropriate health care utilization.* By providing skilled assessment prior to study, sleep medicine clinicians ensure that use of portable monitoring is appropriate for a given patient, thereby avoiding overutilization or application of PM when attended study or alternate diagnostic assessments should be performed.
2. *Comprehensive diagnostic assessment.* Patients undergoing PM for suspected OSA frequently present with comorbid medical and psychiatric conditions as well as other sleep disorders. Comprehensive evaluation is necessary to ensure that these comorbid conditions are reliably identified and addressed in a comprehensive therapeutic approach.
3. *Accurate data collection and scoring.* Comprehensive sleep programs, particularly those accredited by the AASM, are expected to demonstrate adequate training of technologists, effective patient education regarding application and use of PM, and ongoing quality assessment programs that will maximize data quality, patient safety and satisfaction, and outcome. Accurate scoring is an additional consideration, which is addressed in a later section.
4. *Effective patient management.* Positive outcomes for patients with OSA depend on adequate diagnosis as well as effective treatment planning and follow-up. Comprehensive sleep centers maintain the necessary organizational structure and the administrative, technical, and professional personnel to provide these services. Demonstration of effective therapy is often incorporated into patient management in sleep laboratories.

1.2. PROVIDED THAT THE RECOMMENDATIONS OF 1.1 HAVE BEEN SATISFIED, PM MAY BE USED AS AN ALTERNATIVE TO POLYSOMNOGRAPHY (PSG) FOR THE DIAGNOSIS OF OSA IN PATIENTS WITH A HIGH PRETEST PROBABILITY OF MODERATE TO SEVERE OSA. PM SHOULD NOT BE USED IN THE PATIENT GROUPS DESCRIBED IN 1.2.1, 1.2.2, AND 1.2.3 (THOSE WITH COMORBIDITIES, OTHER SLEEP DISORDERS, OR FOR SCREENING).

The evidence to date shows that PM studies have been predominantly performed in high risk populations for moderate to severe OSA. The Task Force recommends that PM use should be limited to these groups. Clinical judgment remains the best method for determining OSA risk. The clinician must take into account the essential features of OSA: demographics; predisposing and precipitating factors; clinical features; and familial patterns. Treatment decisions must also rely on the judgment of an experienced clinician. PM results should be combined with clinical evaluation in determining whether additional testing is required or treatment should be initi-

ated. The majority of studies reviewed included patients screened as "suspected OSA" as an entry criterion (see Evidence Table). The AASM practice parameter paper reviewed indications for polysomnography in the diagnosis of OSA.[46] Risk factors included snoring, sleepiness, obesity, and witnessed apneas. All of these factors were strongly associated with OSA, and the severity of the risk factors often correlated with the severity of OSA. However, the predictive value of individual and combined risk factors is only moderate. The authors also reviewed clinical predictive models and concluded that none were sufficient to predict severity of OSA.

No study has been specifically designed to distinguish mild from severe disease. The majority of studies evaluate patients with a high pretest probability for OSA, thereby eliminating those with mild disease. Therefore, no systematic research has been done to determine the discriminatory capacity of various PM devices to detect low levels of OSA vs. high levels of OSA.

The taskforce recommendations specifically apply to adult populations. In addition, there are little data on the use of PM in the pediatric and older (> 65 years of age) populations. Most studies have been done in middle-aged adults; PM use in older patients who are more likely to have both comorbid conditions and comorbid sleep disorders should be approached cautiously. Clearly, more research is needed in these populations.

1.2.1. PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of PM, including, but not limited to, moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure.

Only 2 of the studies reviewed did not exclude patients with comorbid medical disorders.[15, 43] The other 35 studies either excluded patients with comorbid medical disorders or did not state exclusion criteria. No new data has been published on this topic since the 2003 guidelines.[1] Use of PM devices should be restricted to populations with data supporting its diagnostic accuracy, and therefore in-laboratory PSG remains the standard for patients with co-morbid medical disorders.

1.2.2. PM is not appropriate for the diagnostic evaluation of OSA in patients suspected of having other sleep disorders, including central sleep apnea, periodic limb movement disorder (PLMD), insomnia, parasomnias, circadian rhythm disorders, or narcolepsy.

This recommendation is consistent with the previous recommendations[1]; no new data are available to evaluate PM in patients with central sleep apnea or OSA with comorbid sleep disorders. In-laboratory PSG should be used in patients suspected of central sleep apnea or hypoventilation syndromes because there are no data evaluating the accuracy of PM devices for the detection of central apneas or hypoventilation. Furthermore, PM does not include data necessary to reach diagnostic criteria for PLMD, parasomnias, circadian rhythm disorders or narcolepsy.[48] PM is not an appropriate methodology for the diagnosis of circadian rhythm disorders.

1.2.3. PM is not appropriate for general screening of asymptomatic populations.

It was the consensus of the Task Force that PM is not appropriate for general screening at this time. Even if screening may be appropriate for asymptomatic individuals in high risk populations (such as congestive heart failure,[49,50] hypertensives,[51,52] commercial truck drivers or patients undergoing bariatric surgery[53]) currently available PM devices are not acceptable tools. They have only been shown to have good specificity and sensitivity in populations evaluated by sleep specialists, considered to be at high risk for OSA based on clinical symptoms and without significant comorbid medical disorders or suspicion of comorbid sleep disorders. Although it was the consensus of the Task Force that there is not yet sufficient evidence to guide the use of PM in general screening even of high-risk populations, it is recommended that if such screening is performed, appropriate clinical assessment tools should be used to address potential false positives and false negatives.

1.3. PM MAY BE INDICATED FOR THE DIAGNOSIS OF OSA IN PATIENTS FOR WHOM IN-LABORATORY PSG IS NOT POSSIBLE BY VIRTUE OF IMMOBILITY, SAFETY, OR CRITICAL ILLNESS.

This recommendation is a modification of the previous practice parameter.[1] PM may be used when other forms of sleep evaluation are not possible, and, as stated in the previous paper, "clinical judgment made by the physician in light of individual circumstances has to be applied to individual patients."

1.4. PM MAY BE INDICATED TO MONITOR THE RESPONSE TO NON-CPAP TREATMENTS FOR OBSTRUCTIVE SLEEP APNEA, INCLUDING ORAL APPLIANCES, UPPER AIRWAY SURGERY, AND WEIGHT LOSS.

This recommendation is based on Task Force consensus. PM may be used to monitor the efficacy of therapies other than CPAP when the diagnosis of OSA has already been made, either through PM or in-laboratory PSG.

Summary of Indications for Portable Monitoring: Figure 1 summarizes a pathway for patients under consideration for PM. Patients appropriate for PM must be high risk for OSA and not have comorbid medical disorders or comorbid sleep disorders. Failure to meet these criteria in patients that are high risk for moderate to severe OSA should lead to an in-laboratory PSG. In laboratory PSG is also the standard in patients with other sleep disorders, such as narcolepsy and central sleep apnea.

2. Technology for Portable Monitors

2.1. AT A MINIMUM, THE PMS MUST RECORD AIRFLOW, RESPIRATORY EFFORT, AND BLOOD OXYGENATION. THE TYPE OF BIOSENSORS USED TO MONITOR THESE PARAMETERS FOR IN-LABORATORY PSG ARE RECOMMENDED FOR USE IN PMS.

The previous reviews and the work of this Task Force uncovered little data on the validity and reliability of Type 2 PM devices. Therefore, our assessment focused on Type 3 devices. With the proliferation of these devices, the validity of a scheme based on the number of channels is no longer clear. The Task Force chose instead to focus on the types of signals used rather than their number. Although some monitors have not been adequately tested in the home environment, the Task Force chose to apply AASM recommendations for in-laboratory sensors to PM. The AASM Task Force on Respiratory Scoring recently completed a

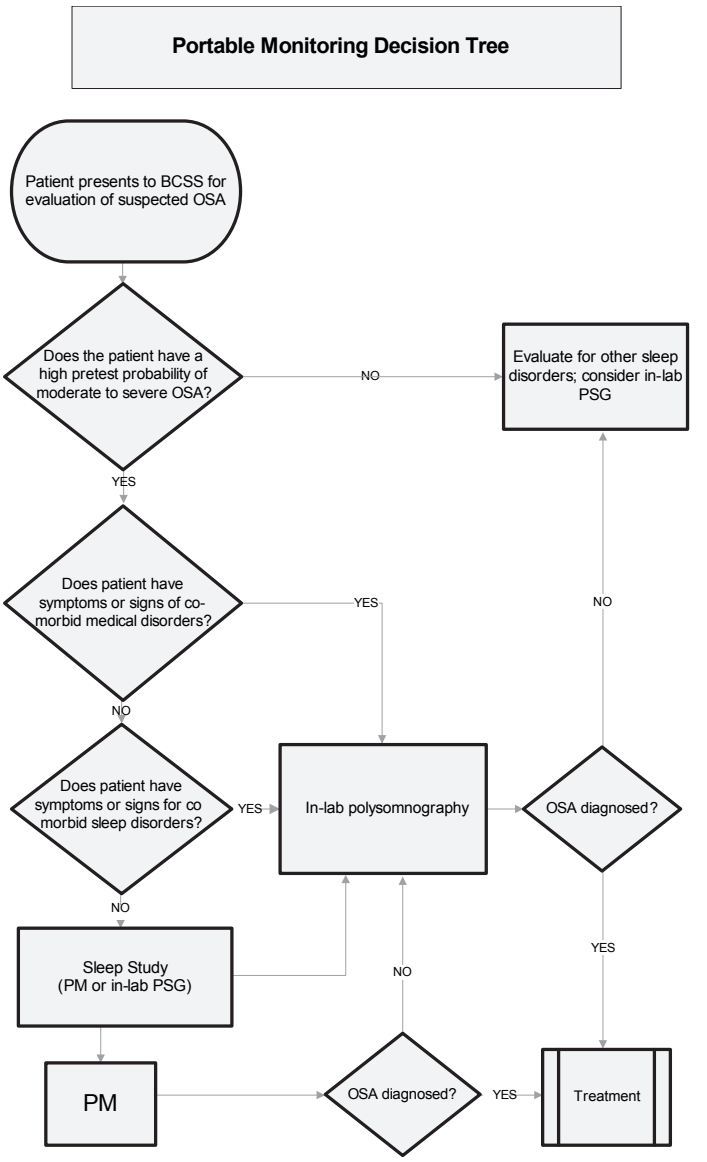

Figure 1—Flow chart depicting recommended pathway of patients considered for PM. Patients appropriate for PM should have moderate to high risk for OSA, have no comorbid medical conditions and no comorbid sleep disorders. Patients not considered appropriate for PM should have in-laboratory polysomnography. (BCSS = Board Certified Sleep Specialist or an individual who fulfills the eligibility criteria for the sleep medicine certification examination)

review of signals used in the detection of sleep related breathing disorders.[54] The review was used to determine criteria for scoring respiratory events in the *AASM Manual for the Scoring of Sleep and Associated Events*.[55] Technical considerations as well as the consensus of this Task Force support measurement of airflow, respiratory effort and blood oxygenation.

The Task Force evaluated other sensor types in great detail. Four studies in the current review[14,29,31,43] evaluated a PM that uses arterial tone, actigraphy, and oximetry. The evidence for their use has been rated level B or C in past reviews.[57] Bar and colleagues[14] reported good accuracy in 15 home unattended studies for respiratory disturbance indexes (RDIs) of 10 or 20 per hour with receiver operating characteristic areas under the curve of 0.82 and 0.87, respectively. In 30 patients studied both in-laboratory and at home[31] and in a larger study of 98 individuals studied at home,[43] similar degrees of accuracy were found in preselected populations of OSA and non-OSA subjects. However, Penzel and colleagues[29] found a significant technical failure rate (4 of 21 or 19%). None of the articles noted any issues of safety, discomfort, or patient application. Unlike most PM devices, the arterial tone device uses a proprietary algorithm for scoring; although review of the raw data is possible, manual scoring is not.

One article assessed the time of transmission of an arterial waveform from the ECG to oximeter-derived pulse sensation (pulse transit time) in 13 patients at home.[30] Automated scoring could not distinguish normal from mild to moderate OSA, or mild to moderate OSA from severe OSA accurately. Ectopic beats were clearly felt to affect the results.

End-tidal CO_2, considered a standard polysomnographic measure in pediatric patients, was evaluated in 1 study.[18] Stroke patients were screened for OSA in the ICU, where end-tidal CO_2 monitoring is commonly available. The study was limited by the use of another PM as the gold standard rather than in-laboratory PSG, and inclusion of central with obstructive events in the AHI.

Two investigations included the use of esophageal manometry[13,28] as part of a PM array of bioparameters. In this context the technique had relatively poor sensitivity (64%) and specificity (78%) in the detection of OSA and is not recommended for routine use.

Addition of biosensors that assist in determining sleep/wake state would clearly improve accuracy and provide a more accurate denominator for the apnea-hypopnea index. However a previous evidence review[6] described only 3 studies, 2 in-laboratory and 1 at home, that could be used to provide support that this improves accuracy. Despite its overwhelming face validity, the subsequent practice parameter requested further research be done before Type 2 monitors could be recommended. Although numerous studies using unattended home polysomnography to assess sleep disordered breathing have been published since the last evidence review, there is a lack of new information comparing type 2 monitors to laboratory PSG. Therefore, the current committee only evaluated a PM if it did not include a measure of sleep stage. Our review also found that actigraphy[28,29] was not a sufficiently accurate substitute measure of sleep time to recommend its routine use.

2.2. The sensor to detect apnea is an oronasal thermal sensor and to detect hypopnea is a nasal pressure transducer. Ideally, PMs should use both sensor types.

The recommendation for use of the thermal sensor is based on limited evidence and consensus of the Task Force on Respiratory Scoring.[55] The use of a nasal pressure transducer is supported by consistent Level 1 to 5 evidence and consensus agreement of the Task Force on Respiratory Scoring. Both of these recommendations are based on in-laboratory studies.

Previous literature review reveals that as a measure of airflow, nasal pressure is less accurate than pneumotachometer but more accurate than thermal sensors (thermocouples and thermistors).[56] In spite of this, the most common signal used in portable monitors has been airflow measured by thermistor.[5] These flow sensors have been shown to be nonlinearly related to actual airflow and may even overestimate ventilation. Although nasal pressure devices may be superior to thermistors for detection of flow, they are limited to only nasal flow assessment, leaving mouth flow undetected. The signals may be significantly dampened in mouth

breathers. The current recommendation for use of both sensor types reflects these considerations. At the time of the earlier evidence review, nasal pressure monitors had not been tested in the unattended home setting,[5] and the current literature review sheds no further light on the relative performance of PM devices using nasal pressure versus thermal sensors.

2.3. Ideally the sensor for identification of respiratory effort is either calibrated or uncalibrated inductance plethysmography.

This recommendation is based on consistent Level 1 to 5 evidence and consensus agreement of Task Force on Respiratory Scoring.[55] Recommendations for techniques for in-laboratory PSG used to measure chest and abdominal effort were reviewed in 1999.[56] These techniques are still current and include respiratory inductive plethysmography, piezo sensors, strain gauges, and thoracic impedance. None of these techniques have been thoroughly evaluated during PM. With the exception of respiratory inductive plethysmography, these signals provide a qualitative measure only. Therefore, previous guidelines for PSG have not recommended their routine use during in-laboratory PSG. In order to make the sensor more accurate in the detection of a hypopnea, they must be measured in conjunction with another event, e.g., oxygen desaturation.[5] Much less information is available for their use in PMs. Respiratory inductive plethysmography that is appropriately calibrated can use changes in excursion of the chest and abdomen during inspiration and expiration to measure actual tidal volume.[5] Although there is good to excellent reproducibility demonstrated for scoring hypopneas with calibrated in-laboratory inductive plethysmography and moderate agreement between observers when uncalibrated respiratory inductive plethysmography is used in the laboratory setting, similar data do not exist for PM.

2.4. The sensor for the detection of blood oxygen is pulse oximetry with the appropriate signal averaging time and accommodation for motion artifact.

The use of pulse oximetry and recommended sampling rates are based entirely on consensus by the Task Force on Respiratory Scoring.[55] The standards require an oximeter to have a maximum signal averaging time of ≤ 3 seconds at a heart rate of 80 beats per minute or more. The use of an averaging time of ≤ 3 seconds is based on Level 3 to 4 evidence and adjudication by the Steering Committee. A discussion of the rationale for these criteria is available in a recent review by the Task Force on Respiratory Scoring.[54] The task force did not address the location of the probe (ear vs. finger vs. other site); however, it is noted that most studies utilized finger probes.

3. Methodology for Portable Monitoring

3.1. PM testing should be performed under the auspices of an AASM accredited comprehensive sleep medicine program with policies and procedures for sensor application, scoring, and interpretation of PM. A quality/performance improvement program for PM including inter-scorer reliability must be in place to assure accuracy and reliability.

No studies were found that allowed the Task Force to directly evaluate the role of sleep center accreditation on the evaluation of OSA patients with PM. Therefore, this recommendation was based on consensus. Standards for patient evaluation and follow-up, requirements for policies and procedures, and recommendations for quality control are part of the AASM Standards for Accreditation of Sleep Centers.[45] Until specific standards for PM studies are developed, the center standards should be used as a model for the development of a comprehensive program using PM for the diagnosis and management of OSA. For programs that employ PM for clinical assessment, a monitoring program for data loss and quality is a recommended component in addition to inter-scorer reliability.

Large scale studies using PM, most notably the Sleep Heart Health Study (SHHS), have been cited as examples of successful application of PM technology. It is important to recognize, however, that research applications of PM entail careful training of technologists, detailed protocols for data acquisition and scoring and ongoing, systematic monitoring by senior scientists. In the case of the SHHS, technologists were specifically trained and certified for data acquisition and scoring. Technologists applied all of the sensors following carefully designed protocols. Studies were scored at a central facility using a detailed scoring manual. With such measures, there were no significant differences in quality scores between PM and in-laboratory PSG.[24] Inter - and intra-scorer reliability were assessed for all aspects of scoring and were found to show good agreement.

Data on quality obtained in the SHHS study cannot be extrapolated to the clinical arena. This does not mean that high quality PM data cannot be obtained in a clinical setting, but adequate training, well-designed policies and procedures, careful attention to sensor application, manual scoring, and systematic review of the raw data by a skilled sleep medicine practitioner are all important components in producing a positive outcome for the patient.

3.2. An experienced sleep technician, sleep technologist, or appropriately trained healthcare practitioner must perform the application of PM sensors or directly educate the patient in the correct application of sensors.

After review of the evidence, it was the consensus of the Task Force that an experienced sleep technologist/technician or trained health care provider must be involved in the application of PM. Proper functioning of the sensors and PM equipment is essential to obtain accurate physiologic information and thus a person thoroughly familiar with the equipment and its operation must perform the setup or provide detailed instruction to the patient. The evidence review of portable monitors reported data loss of 3%-18%[a] for Type 3 monitors and 7%-10%[b] for oxygen saturation measurements in Type 4 monitors.[5] The subsequent AHRQ review[57] noted inadequate or missing data precluding adequate interpretation reported in 13%-20%[c] of studies for Type 3 monitors.[17, 20, 58] Golpe and coworkers[20] reported data loss that prevented interpretation in 7% of studies in which a technologist applied the sensors as compared to 33% in which the patient applied the sensors independently at home. A more recent study found that 5.6% of patients had more than 20% of time in bed with absent or inadequate airflow.[40] For Type 4 devices used in the home, data loss was reported to be between 11% and 16%.[14] This study also reported on the use of the PM in the laboratory with technologist application of the sensors resulting in only 3% data loss. A new Type 4 device provides an audible alarm if the device comes off

or need adjustment. This approach resulted in only 2% of studies with insufficient data.[36]

3.3. PM devices must allow for the display of raw data for manual scoring or editing of automated scoring by a trained and qualified sleep technician/technologist. Evaluation of PM data must include review of the raw data by a board certified sleep specialist or an individual who fulfills the eligibility criteria for the sleep medicine certification examination.

This is consistent with the prior practice parameter. In our literature review, 18 studies indicated whether edited or manual scoring was performed. Of these, 6 studies included a physician role. When they have been compared, studies have found manual scoring to be superior to automated scoring.[11,15,17,28,40,41] Calleja and coworkers[59] used a Type 3 device in a laboratory setting and found that the mean difference between the AHI on PSG and that obtained from the PM was smaller when the PM data were scored manually (4 ± 14) than when they were scored using an automated algorithm (24 ± 30). Another home study using a type 3 device[17] noted that agreement between the AHI from PSG and that from the PM was better if the data were manually-scored (kappa = 0.54) than if automated scoring was used (kappa = 0.10). A Type 3 device when used in a laboratory setting also had a smaller mean difference between PSG AHI and PM when manual scoring was used (3.5 ± 5.3) than when automated scoring was used (10.7 ± 8.5).[28] Golpe and coworkers[20] used receiver operating characteristic analysis and reported a slightly better area under the curve with manual scoring of Type 4 PM data for identification of patients with an RDI of greater than 10 on in-laboratory PSG. Finally, Esnaola[60] reported an average difference of 2 events per hour between facility-based PSG and manual scoring of a Type 4 monitor. With automated scoring, the difference rose to 9 events per hour. One study[41] specifically compared manual and automated scoring, showing good correlation ($r = 0.949$; $p < 0.001$) for severe OSA, but poor correlation for mild and moderate OSA. Some PM devices do not permit manual scoring. Although lack of direct comparisons of different PM devices precludes a conclusion that those devices are inherently less accurate, the preceding conclusion raises this concern. It is also noted that automated analysis software is frequently modified as newer versions are released. Consequently, one should be cautious in interpretation of published data on the performance of any scoring software as the commercially updated software is often not the version in the literature.

3.4. Scoring criteria should be consistent with the current published AASM standards for scoring of apneas and hypopneas.

Although intended for in-laboratory PSG, these criteria provide standard and accepted definitions for apnea and hypopnea.[55] To maintain consistency, it is recommended that the same standards be used for PM.

3.5. Due to the known rate of false negative PM tests, in laboratory polysomnography should be performed in cases where PM is technically inadequate or fails to establish the diagnosis of OSA in patients with a high pretest probability.

False negative rates may be as high as 17% in unattended PM studies. In patients who are selected to have a high pretest probability for OSA, studying with PM is expected to result in a positive test. If the PM test is technically inadequate or does not provide the expected result, in-laboratory polysomnography should be performed.

3.6. A follow-up visit with a physician or other appropriately trained and supervised health care provider should be performed on all patients undergoing PM to discuss the results of the test.

No specific guidance on this is provided in the published practice parameters.[5] Few studies have included clinical outcomes in the evaluation of the effectiveness of the use PM in the diagnosis and management of OSA. However a study by Whitelaw and coworkers[37] compared the ability of experienced sleep physicians to predict the probability of an improvement of at least 1 unit in patients' Sleep Apnea Quality of Life Index (SAQLI) score after treatment with CPAP based on information from home oximetry or a PSG. Patients had been referred to the sleep center by family physicians and had to have somnolence or fatigue. Those with "important co-morbidity" were excluded. Although no significant difference between the predictive accuracy using PSG and that using home oximetry information was found, the overall accuracy was only 0.60. Mulgrew and coworkers[44] compared the symptoms and SAQLI score after 3 months of CPAP treatment for patients who had been managed using either a PSG or an ambulatory CPAP titration. All patients had had a pretest probability of OSA of 95% or greater. At 3 months 13% of patients managed using a PSG titration and 19% of patients managed with the ambulatory titration still had excessive sleepiness manifest by an ESS score greater than 10. Thus many patients with sleep complaints who are diagnosed with OSA based on information from a PM (or a PSG) may not respond to treatment as expected and need follow-up by a trained health care provider for adequate management.

3.7. Unattended PM can be used within the parameters specified above in the patient's home.

This is a change from the previous practice parameter[1] and is based in part on new data[44] suggesting that PM is an appropriate alternative to in-laboratory PSG in carefully-selected patients who have a moderate to high clinical likelihood of OSA and in the absence of significant comorbid conditions.

This new data, as well as the study of Whitelaw and coworkers,[37] suggests that a protocol involving PM and auto-PAP (APAP) could be used to diagnose and treat carefully selected patients without in-laboratory PSG. No significant outcome differences were found between the 2 groups. Home use of APAP following diagnosis by "an established method" is listed as an option in the forthcoming AASM practice parameter,[61] which states, "certain APAP devices may be initiated and used in the self-adjusting mode for unattended treatment of patients with moderate to severe OSA without significant comorbidities." The comorbidities match those specified in this paper for the use of PM. Further, the practice parameter includes as a second option that APAP, "may be used in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant comorbidities."

Summary of Methodology and Technology for Portable Monitoring: PM for OSA is defined as including recording of airflow, respiratory effort, and blood oxygenation. The Task Force recommends that sensors endorsed in the *AASM Manual for the Scoring of Sleep and Associated Events*[55] be used in PM studies. This includes an oronasal thermal sensor and nasal pressure transducer for airflow, respiratory inductance plethysmography for effort, and an oximeter with a high sampling rate and fast averaging time for blood oxygenation. Devices must allow review of raw data. PM should be performed under the auspices of an AASM accredited comprehensive sleep medicine program, including written policies and procedures with quality control including scoring reliability. Manual scoring or manual editing of automated scoring by skilled personnel with review of the raw data by a board certified sleep specialist or a person who fulfills the requirements to take the sleep medicine certification examination is recommended. Scoring criteria should be consistent with published criteria.[55] Under the circumstances as outlined, PM may be performed unattended in the home. If PM testing in the high-risk patient is negative or technically inadequate, in laboratory polysomnography is recommended.

CONCLUSIONS

The Portable Monitoring Task Force of the American Academy of Sleep Medicine reviewed available evidence and met to develop consensus recommendations on the use of PM in the diagnosis and management of patients with OSA. The AASM Board of Directors approved this clinical guideline. Previous reviews have concluded that PM should be used only on a limited basis. The Task Force identified additional appropriate indications and usage of PM within parameters guided by the following principles: **PM use should be integrated into a comprehensive program of patient evaluation and treatment under the direction of a sleep specialist board certified in sleep medicine.** Studies have shown that board certification improves outcomes in patients with OSA.[47] The determination of whether a patient meets criteria for PM is complex, requiring understanding of the risk factors for OSA and the diagnostic criteria for other sleep disorders. Evaluation of PM data requires experience and expertise that are part of the training and certification of sleep specialists. **PM should only be used in populations with substantive published data on specificity and sensitivity.** This restricts PM use to patients with a high probability of OSA based on clinical evaluation and without evidence of significant comorbidities (both medical and other sleep disorders). **PM should be regulated by policies and procedures that maximize the reliability and validity of the diagnostic process.** The stringent requirements for AASM sleep center accreditation[45] provide a guide for PM use. Data support a review of raw data rather than reliance on automated scoring. Written protocols, safety procedures, and ongoing quality assurance (including inter-scorer reliability at regular intervals) are methods to insure the highest quality of care for OSA patients.

It is expected that future studies will expand the populations appropriate for PM studies. The AASM will continue to monitor the literature and issue updates as necessary.

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APPENDIX I – CONSIDERATIONS FOR PM EQUIPMENT

Based on review of the literature and the personal experience of the Task Force members, the following recommendations were developed to aid sleep centers in the selection of a PM device and development of a program for their use:

a. Safety – The previously published evidence review and subsequent practice parameters did not specifically address this issue.[1,5] This is partially due to the lack of specific published information in this area, which is also lacking in the 37 articles in the current evidence table. Potential safety concerns that may be more relevant to PM than to laboratory based PSG include but are not limited to fall risk from loose wires, electrical risk in devices that use battery rather than AC power, patient abuse of or by a technologist in the home, burns from faulty oximeter probes, and accidents due to distraction by the monitor while driving home after application of the monitor in the lab.

b. Ease of use – No comparison studies exist either in the prior evidence review or the current review that address ease of use. The Task Force felt that reduced time to attach sensors would be beneficial. Complicated data collection and transfer procedures are to be avoided.

c. Reliability – Data loss is an important issue in evaluating PM devices. The prior evidence review of Type 3 studies reported a range of 3% to 18% data loss in unattended home studies.[5] Type 4 monitors had similar data loss of 7% to 10% unattended versus 2% to 16% in attended settings, where oxygen saturation was the main signal analyzed. Reliability may also depend on reproducibility in 3 areas: human scoring, night-to-night variability and independent validation by different groups. Of the 51 studies reviewed by Flemons et al[5] none reported interrater or intrarater reliability for human or computer/human scoring. Scoring variability is also of concern in laboratory PSG, and it is not clear that interrater or intrarater reliability is lower for PM than for PSG. Regarding night to night variability, 1 prior unattended home study reported no significant difference in mean RDI between 2 study nights.[17] This was extended to 7 nights in a more recent study by Fietze et al.[19] However, in that study, 28% of patients had severity of illness reclassification from normal to mild. Another study revealed a 23% difference in RDI > 10 between in-laboratory PSG compared to study in the home unattended. Although biologic night-to-night variability is also of concern in interpreting PSG results, technical causes of night-to-night variability may be greater for PM. Actual sleep apnea severity is known to vary with sleep position and the estimated severity will vary depending on the accuracy with which sleep time can be estimated. Neither sleep position nor sleep time is accurately recorded by most PMs. Fietze reported 17% (6/35) of studies were deleted because of sleep position errors. The prior practice parameters concluded that one reason sensitivity and specificity differ between PM and in-laboratory PSG is that the latter measures sleep time whereas the former measures only recording time. This translates into generally decreased AHI as recorded by PM compared to full PSG. Finally, one should consider independent validation between different groups of investigators using different protocols. Standardization of testing and scoring protocols is also a concern in PSG; however, this is of greater concern in PM given the greater differences among signals recorded across devices. There are insufficient data to assess reliability of PM between different centers, even those using the same equipment, due to differences in

testing and scoring protocols. Centers performing PM should also consider how much scoreable data is needed to reliably evaluate sleep related breathing disorders.

d. Durability – The committee felt that this was a significant and yet poorly described issue in the literature reviews. Although not addressed in the prior evidence review, equipment breakage, wire disconnections, water/sweat resistance, and battery life may become issues over extended periods of time as equipment is reused by multiple patients.[1] Furthermore, there is minimal information available concerning battery power needed to provide an adequate recording for prolonged periods.

e. Economy – Although the actual purchase cost of PM devices has decreased substantially over the past decade, the total health care costs of evaluating and treating suspected sleep apnea using PM have not been adequately compared to the costs using PSG. In the prior practice parameter, of 12 studies utilizing 3 or more recording channels (Type 3), only 2 actually reported costs of PM in the home.[1] Twenty-two percent to 33% cost savings were described when compared to in-lab PSG. In the 35 studies previously reviewed, 5 attended, 2 unattended and 1 mixed population in-home protocols were described. Cost savings were universally reported, but there was significant variability in study design, pretest probability for OSA and threshold level (i.e., RDI) for the diagnosis of sleep apnea. Among the more recent studies, Dingli and coworkers[17]reported a 42% savings including technician time, supplies, and equipment depreciation if patients went straight from PM to CPAP. However, they had 24% initial and 12% later PM failure rates which must be included in such analysis. Bachour and coworkers[13] evaluated an esophageal monitor with flow and oximetry compared to in-lab polysomnography, each followed by CPAP titration. Some savings were noted, but the analysis did not include costs incurred from reevaluation of the 40% of false negative studies. Regardless of the number of channels recorded, none of the studies previously or currently reviewed address costs relative to the popular use of split study protocols (an initial baseline evaluation in the laboratory followed by nasal CPAP titration in appropriately selected patients). Furthermore, costs of treatment are often not compared, such as those incurred when auto-adjusting positive airway pressure (APAP) or empiric CPAP home treatment protocols versus the standard 2 night baseline and CPAP in-laboratory titration studies are used.

f. Diagnostic accuracy – The diagnostic accuracy of the PM is clearly critical to its success. The previous evidence review found that on the basis of only 3 studies, the addition of measures of sleep (Type 2 PM) did not have sufficient sensitivity or specificity to reduce the probability of OSA in either in-laboratory attended or home-unattended PM studies. False-negative results in the latter group could be as high as 15%. In contrast, Type 3 PM attended in-laboratory studies demonstrated a significant number of patients with a negative result (range, 20% to 73%) with a small percentage of false negatives (4% to 8%). However, in 4 home unattended studies, the false negative rate was as high as 17%. Type 4 PM studies had similar success as Type 3 when used attended in the laboratory, however, had higher false negative results when unattended as the quality grade of the study design diminished. A high pretest probability for having OSA pointed to the importance of a pretest clinical examination in increasing the probability that a PM could significantly aid in increasing the diagnosis of OSA. Insufficient data were available at the time of the evidence review to recommend portable full polysomnography (Type 2 PM), either in the laboratory or less so, unattended in the home. In contrast, 9 high-quality studies using similar scoring definitions for AHI were shown to have high specificity (> 90%), sensitivity and likelihood ratios when attended in the laboratory. However, the clinical situation of most interest would be in the home and here there were only 2 high-quality studies. The number of patients found to have a positive result was high at 46% to 82% with a corresponding wide range of false positive results between 2% and 31%. When Type 4 PM attended studies were evaluated, higher quality studies with likelihood ratios of > 10 had low false positive rates (range, 0% to 12%) while lower quality studies with lower likelihood ratios had much higher false positive rates (range, 3% to 37%). Thus Type 4 home-unattended studies had wide variance of false positives (range, 41% to 73%). Based on this and other data, the prior practice parameter stated that there was insufficient evidence to support the use of a PM with full monitoring capability, attended or unattended to evaluate patients with suspected OSA (option).[5] In contrast, Type 3 monitors of > 3 signals in an attended setting could be used to decrease or increase the probability that a patient has an AHI greater than 15 as well as both rule in and rule out a diagnosis of OSA (Standard), however, there was insufficient evidence to support these devices in the home-unattended setting. Furthermore, there was insufficient evidence to support Type 4 PM to increase or decrease the probability of an AHI of > 15 or make a diagnosis of OSA. The task force could find no substantial evidence in the subsequent literature that would significantly alter these recommendations.

EVIDENCE TABLES

Evidence tables are available online at www.aasmnet.org/jcsm.

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