Executive Summary on the Systematic Review and Practice Parameters for Portable Monitoring in the Investigation of Suspected Sleep Apnea in Adults

This Executive Summary of the American Thoracic Society, the American College of Chest Physicians, and the American Association of Sleep Medicine was accepted by the Executive Committee of the ATS, October, 2003.

Obstructive sleep apnea (OSA) is a highly prevalent disorder with estimates that it afflicts up to 5% of the population of the Western world (1). This, along with increasing patient and health care provider awareness of the disease, has placed burdens on the health care system to provide prompt diagnosis and treatment. The "gold standard" diagnostic method of polysomnography in a sleep disorders laboratory is typically performed as an overnight study away from the patient's home with a technician in attendance utilizing sophisticated monitoring equipment. With the advance of computers and microchip technology, manufacturers and researchers alike have been working to develop screening devices that are both portable and simple, to screen for OSA without requiring the patient to come into a sleep disorders laboratory and be monitored by a technician.

Because of the growing body of literature on this subject, a number of efforts over the past decade have attempted to evaluate the utility of portable monitoring (PM). The first was published in 1994 (2). This was the first to partition portable monitoring into four different levels: Level I is attended polysomnography; Level II is full polysomnography outside the laboratory setting; Level III is limited channel polysomnography (four or more cardiopulmonary bioparameters); and Level IV is testing with only one or two cardiopulmonary bioparameters. This practice parameter did not recommend the use of portable monitoring except in specific situations when in-lab polysomnography was unavailable. A second look at the data in 1997 had essentially no change in the recommendations (3). In 1998, the Agency for Health Care Research and Quality performed a literature review and metaanalysis on studies of portable monitoring for OSA done through 1997. On the basis of this review, it was once again felt there was insufficient evidence to make firm recommendations for use of portable monitoring in the diagnosis of OSA in clinical practice because of diversity of study design and lack of methodologic rigor (4).

An international conference on this topic sponsored by the American College of Chest Physicians was held in Chicago in September 2000 (Use of Home Monitors for the Diagnosis of Sleep Apnea). As an outgrowth of this conference, the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), and the American Academy of Sleep Medicine (AASM) entered into a collaborative project to evaluate the current literature and develop a guideline on portable monitoring to diagnosis OSA. All three societies had been examining this issue in separate working groups. The development of a taskforce with representatives from each of the societies was a logical step. A united voice would obviously strengthen the message. A Steering Committee and working groups were selected (*see* Table 1). A memorandum of understanding (MOU) was drafted that included information about the scope of the guideline; administrative responsibility; levels of participation with the ACCP, ATS and AASM as sponsoring organizations (*see* Table 2); the process of approval and publication; and where documents would be published. Integral to the MOU was information regarding conflict of interest that each member of the committee was required to disclose. Each conflict of interest statement was reviewed by the Steering Committee and by an independent member of the sleep community to confirm that no conflict was present.

The first order of business, once the MOU was agreed on and signed by each of the sponsoring organizations, was development of a "Request for Proposals" for an evidence review by an Evidence-based Practice Center (EPC). The Research Triangle Institute, in cooperation with the Cecil G. Sheps Center for Health Services Research at the University of North Carolina, were chosen. An abstraction form was developed in conjunction with the Evidence Review Committee. Evidence tables were then abstracted from the literature and the Evidence Review Committee developed their review (5). Because the methodology was so important to this process, it was decided that a separate methodology article ("Measuring Agreement between Diagnostic Devices" [4]) would be written to explain how such a review is performed. This article accompanies the evidence review in *Chest* (6). The drafts of the evidence review and methodology article were submitted for review to the sponsoring agencies, in addition to the liaison and reviewing organizations, for comment. The Guideline Committee developed practice parameters, using the data from the evidence review.

METHODS

The principles of evidence-based medicine were utilized to conduct the systematic literature review (7, 8). For the analysis, the types of monitoring devices were classified similarly to the methodology utilized in the 1994 American Sleep Disorders Association Review (2). Type 1 monitoring (attended in-laboratory polysomnography) was the reference standard to which the other monitor types were compared. Type 2 monitors incorporated sleep staging in addition to respiratory measures. Type 3 monitors utilized at least three respiratory channels. Type 4 monitors utilized at least one respiratory channel that was usually either oxygen saturation or airflow.

Three primary and four secondary research questions were formulated (*see* Table 3). The inclusion criteria for the literature review were as follows: (*1*) male/female patients, ages 18 years and over, with any diagnosis of obstructive sleep apnea; (*2*) study published in English; (*3*) no race- or sex-based restrictions; (*4*) portable device used for diagnosis; (*5*) polysomnography or other acceptable objective test used for diagnosis of sleep apnea; and (*6*) after completion of the study, each analysis group consists of 10 or more subjects. Studies of children, studies in languages besides English, reviews, meta-analyses, case reports, abstracts, letters, and editorials were excluded from the data analysis.

Members of the ad hoc statement committee have disclosed any direct commercial associations (financial relationships or legal obligations) related to the preparation of this statement. This information is kept on file at the ATS headquarters.

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TABLE 1. ORGANIZATIONAL STRUCTURE AND COMMITTEE MEMBERS

Committee	Purpose	Members
Steering	Project oversight; develop scope of project; review and approve documents	Nancy A. Collop, M.D. (ACCP)*; John W. Shepard, Jr., M.D. (AASM); Patrick J. Strollo, Jr. (ATS)
Evidence Review	Develop evidence review working with EPC	Ward Flemons, MBBS (ATS)*; James Rowley, M.D. (ATS); Michael Littner, M.D. (AASM); William Anderson, M.D. (AASM); Daniel Loube, M.D. (ACCP); David Hudgel (ACCP)
Guideline	Develop practice parameter	Andrew Chesson, M.D. (AASM)*; Rich Berry (ACCP); Allan Pack (ATS)

Definition of abbreviations: AASM = American Academy of Sleep Medicine; ACCP = American College of Chest Physicians; ATS = American Thoracic Society; EPC = Evidence-based Practice Center.
* Chairperson.

Evidence tables were constructed from data abstraction forms that were generated by two independent Research Triangle Institute (University of North Carolina) reviewers. Disagreement was resolved by consensus. Agreement between the portable monitor and the reference standard (polysomnography unless otherwise stated) was reported as the sensitivity, specificity, and likelihood ratios (positive and negative). The finalized abstraction forms were forwarded to the Evidence Review Committee (ERC).

The data from the abstraction forms were compiled into tables to facilitate comparison of the data sets and to rate the level (I–IV) and quality of the studies (a–d) (5). A metaanalysis of the data was deemed inappropriate because of the heterogeneity of the data sets.

RESULTS

A total of 51 studies, from 1990 through December 31, 2001, met inclusion criteria and were included in the analysis. To facilitate comparison of the data, the analysis was "standardized" to an apnea–hypopnea index (AHI) of 15. The majority of the studies included in the results dealt with Type 4 monitors (n = 35) versus Type 3 monitors (n = 12) and Type 2 monitors (n = 4). The level of evidence and quality of these studies varied considerably (5).

RECOMMENDATIONS

The levels of evidence developed in the evidence review article (5) were used by the Guideline Committee to formulate the levels of recommendations made in the practice parameters article (9). The definitions of these levels of recommendation (standard, guideline, and option) are presented in Table 4 as adapted from Eddy (7). The levels of recommendations for the use of Type 2, 3, and 4 portable monitors for the diagnosis of sleep apnea are summarized below in both the attended and unattended settings.

Type 2 PMs: Comprehensive Portable Polysomnography

Attended setting. Type 2 PMs are not recommended for clinical use to evaluate patients with sleep apnea. (*Option*)

Unattended setting. Type 2 PMs are not recommended for clinical use to evaluate patients with sleep apnea. (*Option*)

Comment. At the time of this evidence-based review, Type 2 PMs did not have adequate available data to recommend their clinical use based on the small number of published studies, the absence of sensitivity/specificity data, and the low level of evidence.

TYPE 3 PMs: Modified Portable Sleep Apnea Testing

Attended Setting.

- Some Type 3 PMs appear capable of being used to *decrease* the probability that the patient has an AHI > 15. (*Standard*)
- Some Type 3 PMs appear capable of being used to *increase* the probability that a patient has an AHI > 15. (*Standard*)

Comment. There appears to be some evidence suggesting that the use of Type 3 PMs may be acceptable in an in-laboratory setting, both to rule in and rule out OSA. Such a use would require limitations noted below. (*Standard*)

Limitations.

1. In nearly all the studies providing evidence that Type 3 devices could be used for this purpose, analysis was either manual or a combination of automatic and manual. Thus, careful review of raw data appears necessary.
2. Application to a population similar to the ones studied—no significant comorbidity such as chronic obstructive pulmonary disease, congestive heart failure, etc.—and a sleep clinic population (not applied as generalized screening).
3. These devices do not measure sleep. In addition, the AHI provided by Type 3 devices tends to underestimate the polysomnogram-defined AHI, as monitoring time rather than total sleep time is used in the denominator.
4. Symptomatic patients with a nondiagnostic or negative Type 3 study should undergo definitive evaluation to determine the cause of symptoms. If a sleep disorder requiring a sleep study remains part of the clinical consideration, a full attended polysomnogram should be used.
5. Patients with a positive Type 3 study need a subsequent polysomnogram if continuous positive airway pressure titration is needed.
6. Type 3 PMs are not recommended for split-night studies

TABLE 2. ORGANIZATIONAL STRUCTURE

Level of Participation	Organization
Sponsoring	American College of Chest Physicians
	American Thoracic Societ
	American Academy of Sleep Medicine
Liaison	Australasian Sleep Association
	National Association of Medical Directors for Respiratory Care
	Canadian Thoracic Society

TABLE 3. PRIMARY AND SECONDARY RESEARCH QUESTIONS

Primary research questions
1. Can portable monitoring rule out obstructive sleep apnea?
2. Can portable monitoring rule in obstructive sleep apnea?
3. Can portable monitoring both rule out and rule in obstructive sleep apnea?

Secondary research questions
1. What is the reproducibility of portable monitor results?
2. What is the cost benefit of testing with portable monitors?
3. What are the failure rates of testing with portable monitors?
4. What patient populations were studied?

TABLE 4. 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

Adapted from Eddy (7).

because there is little or no evidence to support such an approach.

7. The ability of Type 3 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.

Unattended Setting.

- Type 3 PMs are not recommended for use to *decrease* the probability that the patient has an AHI < 15. (*Guideline*)
- Type 3 PMs are not recommended for clinical use to *increase* the probability that the patient has an AHI > 15. (*Guideline*)
- Type 3 PMs are not recommended for use to rule in and rule out OSA. (*Guideline*)

Type 4 PMs: Continuous Single or Dual Bioparameter Recording

Attended Setting.

- Type 4 PMs with oximetry and at least one other airflow parameter are not recommended for routine use to *increase* the probability that a patient has an AHI > 15. (*Option*)
- Type 4 PMs with oximetry and at least one other airflow parameter are not recommended to *decrease* the probability that that a patient has an AHI > 15. (*Option*)
- Type 4 PMs with oximetry and at least one other airflow parameter are not recommended for routine use *both to increase and reduce* the probability that a patient has an AHI > 15. (*Option*)

Unattended Setting.

- Type 4 PMs with the utilization of oximetry and at least one other airflow parameter are not recommended for use in diagnosing sleep apnea or confirming that a patient has an AHI > 15 or AHI < 15. (*Guideline*)

Caveats

A number of other comments were also offered in the guideline regarding the use of PM devices in certain situations. These include the following:

- 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.
- The use of PM devices is not recommended in patients with comorbid conditions or secondary sleep complaints because there is little evidence to support evaluation in these conditions by PMs or use of PMs to diagnosis other sleep disorders.
- Even where PMs are noted as possibly useful as described above, the general use of all types of devices across that category are not necessarily recommended; a laboratory should confirm that the commercial device selected in a category has specific studies on its use and conforms to the use characteristics of that category as a whole.
- Review of raw data and use of manual scoring for PM interpretation are recommended; physicians with sleep training and familiarity with the devices and their limitations should interpret these studies, and should do so with review of the raw data as noted above; technicians trained and qualified to do so should perform any technical scoring.

FUTURE DIRECTIONS

From their systematic review of the literature, the Evidence Review Committee has suggested a number of important goals for future research. Some of these goals are focused on areas that have not received sufficient attention. Others are focused on correcting deficiencies in prior research methods by making recommendations that would lead to improvements in study methodology.

Most studies on portable monitoring have been conducted with white men with few comorbidities and drawn from sleep clinic/laboratory populations with a high pretest probability of sleep apnea. Consequently, the results of these studies may not be generalizable to other groups or types of patients. Future studies should include more diverse populations including patients recruited from primary care settings both with and without important comorbidities such as chronic obstructive pulmonary disease and heart failure. Future studies should also address the use of clinical prediction algorithms in combination with PMs in the diagnosis of sleep apnea. The Evidence Review Committee made numerous specific recommendations that would improve study methodology (*see* Table 11 in Reference 5). Investigators should document any potential conflicts of interest and sources of funding for the study. Recruitment should be of consecutive subjects from an adequately sized and defined population that is not subject to selection bias. Study design should control for sources of bias and methodologic details on the scoring of the polysomnogram and the portable monitor should be reported to allow a reader to replicate the study. The portable monitor respiratory disturbance index (RDI) and polysomnographic AHI thresholds should be selected before the study as the primary outcome variable on which to base sensitivity and sensitivity.

In addition, the study design should address how to adjust unattended portable monitoring results that are compared with a separate night of polysomnography for the night-to-night variability that is observed with repeated sleep studies. The order in which a patient's polysomnography and portable monitoring studies are done should also be randomly assigned to avoid a possible order effect. It is recommended that studies use an accurate method to determine sleep position and report the total, supine, and nonsupine AHIs and RDIs. This would help to determine how much of the night-to-night variability was the result of differences in sleeping position.

Future research should also assess the cost-effectiveness and outcomes associated with various diagnostic and management strategies. In particular, unattended Type 3 and 4 portable monitors (in or out of the hospital) *may* prove useful in augmenting diagnostic decision making, in evaluating the adequacy of therapeutic intervention(s), as well as in triaging patients for priority care. With the substantial number of patients at risk for complications of sleep-disordered breathing increasing, access and "streamlining" initiation of treatment would clearly be advantageous. Portable monitoring could then be assessed not as a stand alone test but as a component of a broader patient management strategy. In selected patient populations, portable monitoring coupled with split-night polysomnography or unattended autotitra-

tion of positive pressure *might* prove to be a cost-effective management strategy.

From a clinical point of view it is important to recognize that evidence-based medicine will always be behind the curve of progress. New ideas generate new technologies and methods of health care delivery. These advances must await the collection and analysis of data before their role can be established with scientific certainty. Today's option or guideline may become tomorrow's standard or be rejected on the basis of accumulated evidence. We are fortunate that our pluralistic system of medical care allows room for innovation and simultaneously demands evidence to justify what we do. The clinical demand for tests that investigate possible sleep-disordered breathing is rising. It is apparent from the findings of this report that there is an urgent need for additional high-quality studies to clarify the performance and role of portable monitors in the diagnosis and management of sleep apnea.

This Executive Summary was prepared by the ATS/ACCP/AASM Taskforce Steering Committee. Representative Members of the Taskforce Steering Committee are:

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