Complete Summary

GUIDELINE TITLE

Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults.

BIBLIOGRAPHIC SOURCE(S)

Chesson AL Jr, Berry RB, Pack A. Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. Sleep 2003 Nov 1;26(7):907-13. [11 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Obstructive sleep apnea

GUIDELINE CATEGORY

Diagnosis
Technology Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology

Pulmonary Medicine
Sleep Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To present recommendations regarding the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults

TARGET POPULATION

Adults with suspected obstructive sleep apnea

INTERVENTIONS AND PRACTICES CONSIDERED

1. Type 2 portable monitoring (PM) devices: minimum of seven channels, including electroencephalogram (EEG), electrooculogram (EOG), chin electromyogram (EMG), electrocardiogram (ECG) or heart rate, airflow, respiratory effort, oxygen saturation
2. Type 3 PM devices: minimum of four channels, including ventilation or airflow (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or electrocardiogram and oxygen saturation
3. Type 4 PM devices: most monitors of this type measure a single parameter or two parameters

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of portable monitoring devices
- Percentage of patients with either positive or negative result
- Percentage of misclassified patients (false-negative results)
- Cost
- Failure rate and repeatability

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A systematic review of the literature on the use of portable monitoring (PM) had been compiled between 1994 and 1997 by the American Academy of Sleep Medicine (AASM, formerly the American Sleep Disorders Association), the Agency

for Healthcare Research and Quality (AHRQ, formerly the Agency for Healthcare Policy and Research) and ECRI (Emergency Care Research Institute).

The literature search for this guideline focused on articles published since 1997. The initial search was completed June 26, 2001. The bibliographies from two American Sleep Disorder Association reviews also were searched for relevant articles. Several search strategies were used, focusing on screening, diagnosis, and costs. The search strategy used the headings "Screening" (including the terms "Reproducibility of Results," or "Predictive Value of Tests," or "Sensitivity and Specificity"), "Diagnosis" for finding citations involving the terms "Sleep Apnea Syndromes," "Sleep Apnea (Obstructive)," "Oximetry," "Polysomnography," "Monitoring Physiologic," "Airway Resistance," "Upper Airway Resistance Syndrome," "Respiratory Disturbance Index," "Autoset," "Snoring," or "Respiratory Event-Related Arousals." The term "Home Care Services" also was used to identify citations. For the heading "Screening," the MEDLINE search identified 157 citations, and for "Diagnosis," the MEDLINE search identified 180 citations. The use of the terms "Home Care Services" and "Polysomnography" identified 14 additional citations.

For costs, the Medical Subject Heading (MeSH) heading "Costs and Cost Analysis" was exploded to include the terms "Cost Benefit Analysis," "Cost Allocation," Cost Control," "Cost Savings," "Cost Sharing," "Cost of Illness," "Health Care Costs," and "Health Expenditures." The MEDLINE search was conducted from 1997 to the present (June 26, 2001) and identified 35 citations.

The inclusion criteria were as follows:

- Male/female patients, ages $\geq$18 years, with ANY diagnosis of obstructive sleep apnea
- Study published in English, no race or gender restrictions
- Portable device used for diagnosis
- Polysomnography or other acceptable objective test used for the diagnosis of sleep apnea
- After completion of the study, each analysis group was $\geq$10 subjects

The exclusion criteria were as follows:

- Studies in children
- Studies in languages besides English
- Reviews, meta-analyses, case reports, abstracts, letters, and editorials

The titles of retrieved articles were reviewed, and the abstract of any article the title of which mentioned *diagnosis of sleep apnea* was reviewed for relevance to this review. If there was ambiguity about the study meeting the inclusion/exclusion criteria, the full article was reviewed. The reference lists of articles included in this review were scanned to determine other possible articles that should be included.

The guideline developer's Evidence Review Committee elected to have the search updated to include articles up to December 31, 2001; that identified two additional articles.

NUMBER OF SOURCE DOCUMENTS

51

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Adapted by the guideline developers from (1) Sackett D. Rules of evidence and clinical recommendations for the management of patients. Can J Cardiol 1993;9:487-489.

Level I: Blinded comparison, consecutive patients, reference standard performed on all patients

Level II: Blinded comparison, nonconsecutive patients, reference standard performed on all patients

Level III: Blinded comparison, consecutive patients, reference standard not performed on all patients

Level IV: Reference standard not applied blindly or independently

In addition, seven other aspects of a study's methodology were scored, and a quality rating was assigned based on the number of indicators for which the study met criteria. Refer to the evidence review cosponsored by the guideline developers (see the "Companion Documents" field).

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Research Triangle Institute-University of North Carolina (RTI-UNC) evidence-based practice center worked closely with the guideline developer's Evidence Review Committee (ERC) to identify the key questions, to develop an abstract review form, to identify the key extraction elements, and then to develop a data extraction elements form. Two evidence practice center reviewers then abstracted complete data independently from each study. The reviewers then compared their results for each element on the data extraction form for each study, and in situations in which there was disagreement a consensus was reached among the reviewers. The final data abstraction forms then were completed by the evidence practice center and were sent to members of the ERC. Members of the ERC abstracted two additional articles identified from the updated literature search.

A meta-analysis of results, generated by RTI-UNC, was not used by the guideline working group 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 portable monitoring (PM) devices, and study quality.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

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.

COST ANALYSIS

Cost-benefit analyses of portable monitors

There were a limited number of studies that included commentary and data on cost comparison between portable monitoring and polysomnography. Since the focus of these articles was on a diagnostic comparison with polysomnography, formal cost-benefit analysis methods were not used. Reports variably mentioned effectiveness, benefits, or costs of portable monitoring alone or examined the potential cost savings if polysomnography had been avoided. When conducting the latter analysis, most investigators assumed the necessity of a dual-night monitoring (i.e., diagnostic and therapeutic) format and did not consider the reduced cost for a single, split-night polysomnogram.

When performed, the analysis of costs was limited to the obvious direct costs of performing portable monitoring and polysomnography. The broader impact on society, such as access to sleep apnea diagnostic testing, the indirect costs of not diagnosing and treating patients (e.g., motor vehicle accidents, industrial accidents, and lost time from work) that could occur either by missing the diagnosis with a false-negative portable monitor test result or because the alternative polysomnogram was not accessible, was not considered.

Many of the studies make inferences about cost savings that would occur based on favorable conclusions regarding portable monitor sensitivity and specificity.

Refer to section 4.2.2 in the evidence review companion document for more information.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Board of Directors of the American Academy of Sleep Medicine (AASM) approved these recommendations.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Level of recommendation (Standard, Guideline, and Option) definitions are provided at the end of the "Major Recommendation" field.

Type 2 Portable Monitoring (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 obstructive sleep apnea (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**)

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 apnea-hypopnea index (AHI) less than 15 (i.e., 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**)
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**)

Recommendations concerning the use of Type 3 PM devices to increase the probability that a patient has an AHI greater than 15 (i.e., 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**)

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**)

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.

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 (see original guideline document). (Flemons et al., 2003; sections 4.1.3 and 4.3.2.4) (**Standard**)
8. The use of Type 3 PM devices in an unattended setting is not recommended to rule in and rule out a diagnosis of OSA. (**Guideline**)

Type 4 PM Devices: Continuous Single Or Dual Bioparameter Recording

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

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 unattended 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**)

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.
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.

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

Definitions:

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.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The use of diagnostic polysomnography may provide accurate counting of apnea and hypopnea and assess their impact on sleep, oxygen desaturation, and disruption of normal physiology.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Based on data from the review paper, this paper identifies recommended practice parameters for using portable monitoring (PM) to study adult patients with suspected obstructive sleep apnea (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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Chesson AL Jr, Berry RB, Pack A. Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. Sleep 2003 Nov 1;26(7):907-13. [11 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Nov 1

GUIDELINE DEVELOPER(S)

American Academy of Sleep Medicine - Professional Association
American College of Chest Physicians - Medical Specialty Society
American Thoracic Society - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

When the American Academy of Sleep Medicine (AASM) was in the process of conducting a review of the literature that had been published since the 1994 and 1997 practice parameters 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 portable monitoring (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.

SOURCE(S) OF FUNDING

American Academy of Sleep Medicine
American Thoracic Society
American College of Chest Physicians

GUIDELINE COMMITTEE

Representative appointed by the American Academy of Sleep Medicine (AASM), American College of Chest Physicians (ACCP), and American Thoracic Society (ATS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Authors: Andrew L. Chesson, Jr, MD (Louisiana State University Health Sciences Center – Shreveport, Shreveport, Louisiana); Richard B. Berry, MD (Malcom Randall VAMC/University of Florida, Gainesville, Florida); Allan Pack, MD, PhD (Center for Sleep and Respiratory Neurobiology, University of Pennsylvania, Philadelphia, Pennsylvania)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The detailed conflict of interest policy adopted is discussed in the review paper. 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 portable monitoring (PM) devices for the diagnosis of apnea, or have financial interests outlined in the review paper in the conflict of interest exclusions.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Sleep Medicine (AASM) Web site.

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: www.aasmnet.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Flemons WW, Littner MR, Rowley JA, Gay P, Anderson WM, Hudgel DW, McEvoy RD, Loube DI. Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. Chest 2003 Oct;124(4):1543-79.

Electronic copies available in HTML and Portable Document Format (PDF) at the American College of Chest Physicians Web site.

Also available in Portable Document Format (PDF) from the American Academy of Sleep Medicine (AASM) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 18, 2004. The information was verified by the guideline developer on April 22, 2004.

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