

Practice Parameters for the Use of Portable Recording in the Assessment of Obstructive Sleep Apnea

An American Sleep Disorders Association Report

Standards of Practice Committee of the American Sleep Disorders Association

Michael Thorpy, MD¹, Andrew Chesson, MD², Richard Ferber, MD³, Gihan Kader, MD⁴, Richard Millman, MD⁵, Martin Reite, MD⁶, Philip Smith, MD⁷, Virgil Wooten, MD⁸

¹*Sleep-Wake Disorders Center, Montefiore Medical Center, Bronx, NY*, ²*LSUMC Sleep Disorders Center, Shreveport, LA*, ³*Center for Pediatric Sleep Disorders, Children's Hospital, Boston, MA*, ⁴*HCA-Wesley Neurodiagnostics and Sleep Disorders Center, Wichita, KS*, ⁵*Sleep Disorders Center, Rhode Island Hospital, Providence, RI*, ⁶*National Jewish/University of Colorado Sleep Disorders Center, Denver, CO*, ⁷*The Johns Hopkins Sleep Disorders Center, Baltimore, MD*, ⁸*Sleep Disorders Center, Sentara Norfolk General Hospital, Norfolk, VA*.

Summary: The general public and the medical community have become increasingly aware of the prevalence of, and morbidity and mortality associated with, obstructive sleep apnea (OSA). This knowledge, recent technologic advances, and other issues have led to an increase in the use of portable recording devices intended to diagnose OSA. The American Sleep Disorders Association's Standards of Practice Committee has developed these practice parameters to guide the clinician in the appropriate use of these portable recording devices. This is a publication from the American Sleep Disorders Association. It has been reviewed and edited by the Board of the ASDA. It reflects their recommendations for the practice of sleep medicine in North America.

Key Words: Durable medical equipment; Equipment and supplies; Guidelines; Monitoring, physiologic; Outcome and process assessment; Practice guidelines; Sleep; Sleep apnea syndromes, diagnosis; Sleep apnea syndromes; Polysomnography; Sleep disorders; Sleep disorders, diagnosis; Technology; Technology assessment, biomedical.

[This position paper is referenced by the square-bracketed numbers to the numbered sections in the accompanying review.]

Obstructive sleep apnea (OSA), which affects the sleep of millions of individuals, is the most common sleep disorder for which a polysomnogram is conducted and is associated with considerable morbidity and probably with significant mortality [1.0,4.0,8.1]. Diagnostic assessment and treatment evaluation of this disorder have been based on the standard polysomnogram, which is an attended recording of sleep stage, respiratory and other parameters. The standard polysomnogram continues to be the accepted diagnostic method used in most clinical and research settings [4.0]. However, presumptions that accurate sleep apnea evaluations can be performed more quickly, more conveniently and at a lower cost by the unattended recording of fewer parameters than are recorded on standard polysomnography have led to a rapid increase in the use of portable equipment [1.0,10.0]. The specifics of the equipment used, the methods by which they are applied and the criteria by which individuals are selected for study have not

been standardized [5.3,6.4,7.3]. The use of portable recordings for the assessment of sleep apnea could lead to incorrect or missed diagnoses, improper therapy, lack of cost efficiency and increases in the cost of healthcare delivery because of equipment limitations, inadequate recording techniques and inappropriate clinical indications and interpretations [4.0,5.1,5.3,6.1,6.3,6.4,7.3,8.2,8.4-8.7].

I. METHODS

The Standards of Practice Committee of the American Sleep Disorders Association (ASDA) formed a task force to review the current role of portable recording in the diagnosis, assessment and management of OSA in adults ⁽¹⁾. Based on the accompanying review and on consultation with other specialists and interested parties, the subsequent recommendations were developed by the Standards of Practice Committee and approved by the Board of Directors of the ASDA. All authors and ASDA Board members completed detailed conflict of interest statements and were found to have no conflicts of interest with regard to this topic. Wherever possible, the conclusions are evidence

based; however, in those instances where the scientific data are absent, insufficient or inconclusive, recommendations are based on consensus opinion. These recommendations will be updated as new information becomes available.

This position paper is meant to apply to all types of portable recording, but the variability of recording systems and available techniques precludes the listing of specific recommendations for each system. Therefore, recommendations will focus on unattended portable recordings that are conducted in nonlaboratory settings because this is the type of portable sleep study currently viewed with the most interest and performed with the most frequency.

Clinical outcome studies, which ultimately will determine the usefulness and reliability of portable recordings, do not yet exist [11.0]. The possibility of false positives and false negatives appears to be a problem [5.2,6.2,7.2.1-7.2.3,8.6]. Whereas reasonable confidence exists that the results of most of these recordings are reliable when they are positive for significant OSA in highly symptomatic patients [8.6], it is not yet known how to interpret negative studies in symptomatic patients or how to interpret positive studies (or, for that matter negative ones) in nearly asymptomatic patients. We also do not know how often other sleep disorders go unrecognized when using unattended portable recording [8.6]. Because of the presence of these potential problems and the absence of sufficient validation studies, the limits, usefulness and appropriateness of these studies remain undefined.

In the absence of clear scientific evidence to support a major change in clinical practice, the ASDA has produced these guidelines that it regards as conservative and yet do not inhibit the development or application of new technologies. The Association also encourages the production of additional scientific data to evaluate the appropriate use of portable recording devices.

The ASDA expects the guidelines to have an impact on professional behavior, patient outcomes and, possibly, healthcare costs. Adherence to these guidelines is voluntary. These guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of the patient's individual circumstances.

II. BACKGROUND (CURRENT STATE OF PORTABLE RECORDING)

A. Equipment

Portable recording equipment has not yet been standardized in terms of the type and number of physiologic parameters measured or the techniques used for recording and interpreting the signals generated from the specific sensors. The task force, therefore, developed definitions and delin-

eated levels of equipment (Appendix). The complexity of the devices ranges from those that record a single channel (such as oxygen saturation) to those that replicate a full polysomnographic study [5.2,6.2,7.2.1-7.2.3]. Parameters may be recorded and displayed by a variety of methods that range from full data disclosure to limited data sampling, albeit at sampling rates that permit reasonable reproduction of original data [4.3,5.3]. Alternative methods utilize computer-processed data collection that do not permit raw data review [Appendix C 4.1.4,4.4]. Most methods convert analog data to digital form that are stored in solid-state or tape format [Appendix C 4.1.3].

Studies that compare portable recording with standard polysomnography are few and have not yet provided an accurate estimate of the technical proficiency of the portable recordings [5.3,6.4,7.3]. Furthermore, because such recording devices are evolving rapidly, published reports of efficacy often refer to devices that (at least in the form tested) are no longer available.

B. Personnel

In the absence of guidelines, portable recording studies have been conducted by individuals and facilities with highly variable degrees of training and experience, including accredited and unaccredited sleep centers and laboratories, home healthcare companies, durable medical equipment suppliers, physicians and technologists with variable expertise in sleep disorders medicine and others with no healthcare training [10.0]. The SPC's consensus opinion is, however, that the training and experience necessary to ensure high-quality and properly interpreted portable records is as great as, or greater than, that necessary for standard polysomnographic evaluations.

C. Advantages/limitations

The advantages and limitations of unattended portable recording in the evaluation of OSA are discussed in detail in the accompanying review article [8.0]. Potential or actual advantages of portable recordings include accessibility; convenience; patient acceptability; familiarity of the sleep environment; and labor, equipment and operating costs [8.1-8.3]. The main limitations of unattended portable recording arise because of the absence of a trained technologist who, when present, is able to correct and clarify artifacts and to make ongoing equipment adjustments that are based on on-line data display. Additional limitations of unattended monitoring and recording include the lack of ability to enlist patient cooperation; make continuous patient observations; intervene as needed to ensure a satisfactory study and the well-being of medically unstable patients; and provide provocative or therapeutic interventions such as supine positioning, continuous positive air-

way pressure (CPAP) adjustment, oxygen administration or resuscitation [8.4-8.6].

Other limitations are specific to the general type of study (level-II, -III or -IV), to the particular characteristics of the device chosen (sensors used and methods of data collection, storage, reproduction and analysis) and to the training of the personnel used for set-up and interpretation [3.2,5.1,5.2,5.6,6.3,10.5,10.6]. Level-III and -IV studies, in particular, are limited by their inability to document and stage sleep and hence to recognize sleep-stage loss, sleep fragmentation and nonrespiratory sleep disorders. They also do not, when indicated, allow for subsequent multiple sleep latency tests (MSLT) to be conducted according to standard protocol [6.3,7.3].

III. RECOMMENDATIONS

A. Standard polysomnography is the accepted test for the diagnosis and determination of the severity and treatment of OSA.

B. Unattended portable recording for the assessment of OSA is an acceptable alternative only in the following situations:

1. For patients with severe clinical symptoms that are indicative of a diagnosis of OSA and when initiation of treatment is urgent and standard polysomnography is not readily available.

The diagnosis of OSA should be well ensured clinically, but a baseline study to confirm the clinical impression and assess the severity of the disorder is required before initiating treatment. Specifically, the patient should have several of the following: loud snoring, observed apneas, nocturnal choking, daytime sleepiness, hypertension and moderate to severe obesity. Although it would be desirable to assess the degree of sleep disruption present and to rule out other disorders (such as periodic limb movements of sleep) on an initial study, this information may be difficult to obtain if severe OSA is present. In this case, sleep disruption may be presumed to exist and other disorders may be difficult to diagnose (even on standard studies). At least one follow-up standard polysomnographic study will be necessary to assess or determine treatment or to look for other diagnoses if apnea is minimal or absent [8.1,8.4-8.6].

Portable studies are *not* recommended for the routine assessment of OSA, for the assessment of isolated symptoms of excessive sleepiness (without loud snoring and respiratory pauses) or loud snoring (without sleepiness and respiratory pauses), or for convenience. Portable studies are *not* indicated for medically unstable outpatients (who may require medical intervention during the study) or as screening studies in "high-risk" but asymptomatic patients (obese, elderly). Portable studies are *not* recommended for mildly symptomatic patients (even if plans are to obtain a

full standard polysomnogram if the portable one is positive; if the portable study is "negative", then a standard polysomnogram is indicated anyway because insufficient data support the predictive value of a negative study in this setting). And, portable studies are *not* indicated for home (or other non-laboratory) CPAP calibration (sufficient information is not yet available to recommend automated CPAP calibration) [10.3,10.5,10.6].

2. For patients unable to be studied in the sleep laboratory.

Patients unable to be studied in the sleep laboratory include nonambulatory patients and medically unstable inpatients who cannot be readily or safely moved to another hospital location [10.0]. One should recognize, however, that such patients are likely to have disturbed sleep patterns. Therefore, false negative and otherwise inaccurate assessments of sleep quality and sleep-apnea severity might result.

3. For follow-up studies when a diagnosis has been established by standard polysomnography and therapy has been initiated. The intent most often is to evaluate response to therapy.

Such follow-up portable recordings may be used to assess treatment or changes (such as weight loss or gain, surgery, medication, concurrent illness, intraoral device, CPAP or nonsupine sleep), especially if multiple studies will be necessary, and for reassessment after a recurrence of snoring, observed apneas or sleepiness in a previously diagnosed and treated patient. Mild obstruction and sleep disruption may, however, be undetected by an unattended study. Clinical judgment should determine the necessity for standard polysomnography [10.0].

C. Technical recommendations:

1. If portable studies are indicated, only level-II and level-III studies are acceptable for the diagnosis and assessment of therapy for OSA.

Use of level-IV studies, even those including oxygen saturation measurements, are not acceptable for the evaluation of OSA [5.3,6.4,7.3].

2. Body position must be documented during recordings to assess the presence of OSA.

Body position must be documented by position sensor or trained observer to avoid underestimation of apnea severity in patients with positional findings [8.5].

3. Portable sleep-apnea devices must record raw (unprocessed) data, and stored data must be reproducible.

Raw data from all measured physiologic parameters must be recorded; both tape and solid-state storage are acceptable. Full disclosure of raw data is necessary for oxygen saturation, chest and abdominal respiratory movement and, if recorded, airflow, tracheal sounds, EEG, EOG and

chin EMG. Full disclosure of raw data is desirable and preferable for the ECG signal and should be considered mandatory once signal-processing and data-storage techniques make this economically feasible. Until then, processed heart-rate recording is only acceptable if it is known that arrhythmias are not present (through previous polysomnography or Holter monitoring). Computer analysis of data is acceptable only if used as an aid to interpretation in conjunction with visual inspection of the entire raw data record [4.1.3,4.1.4,4.2.2,4.4].

D. Personnel and operational recommendations:

1. **An order from a licensed physician is required to initiate a portable sleep-apnea recording.**

Physicians inexperienced in sleep disorders medicine should consult with a trained specialist to initiate an unattended portable study.

2. **Only an appropriately trained technologist, physician or other doctoral-level professional should conduct a portable sleep-apnea recording.**

Hook-up should, ideally, be performed by a technologist with experience in sleep disorders. The technologist scoring the sleep study should, preferably, have the same level of training as is required for registration by the board of the Association of Polysomnographic Technologists. These technologists should, by preference, be supervised by a physician, or other doctoral-level professional, knowledgeable in sleep medicine. Preferably, this professional should have the same level of training as is required for certification by the American Board of Sleep Medicine.

3. **A physician, or other doctoral-level professional, with satisfactory training in sleep medicine and significant experience in the interpretation of standard polysomnograms should interpret portable recordings.**

The same training as required to be eligible for the American Board of Sleep Medicine exam is highly recommended for a physician; eligibility is required for a doctoral-level professional without a medical degree. Board certification is desirable. Interpretation by a technician is not acceptable; a computer-interpreted study without physician or Ph.D. review of the raw unprocessed data is also not acceptable; and, it is unacceptable for a physician or Ph.D. to sign computer-processed reports after partial review. Clinical information must be available to the interpreting professional [4.4].

4. **An interpretation and a representative sample of the record must be provided to the referring clinician; the complete recording (with full disclosure) must be available upon request.**

Upon request from the referring clinician, the full record must be available for other parties to review and interpret. The person responsible for the initial interpretation must be available to review the record with the clinician and to

explain positive and negative findings, artifacts and impressions.

5. **Physicians should not order, and commercial testing companies should not conduct, portable sleep studies for OSA when conflicts of interest are present.**

Neither the ordering physician nor the company conducting the study should stand to profit from prescriptions based on the results of the study.

REFERENCES

1. Ferber R, Millman R, Coppola M, et al. Portable recording in the assessment of obstructive sleep apnea. *Sleep* 1994;17:378-392.

APPENDIX:

Definitions

A. **Recording:** Passive collection and storage of physiologic and behavior signals.

B. **Attended:** Trained personnel are physically present throughout recording session (data observation via modem link is not considered "attended").

C. **Unattended:** Trained personnel are not physically present throughout recording session (data observation via modem link is still considered "unattended").

D. **Monitoring:** Recording of physiologic and behavior events with continuous data observation by trained personnel present either at the recording site or at a remote location.

E. **Portable recording:** Recording that uses moveable equipment that is easily transported for use outside of the sleep laboratory.

F. **Home recording:** Portable recording in the patient's home setting. ("Home monitoring," although often used synonymously, technically requires supervision.)

G. **Ambulatory recording:** Recording conducted in a manner that allows a patient to walk around and engage in other usual daily activities during data collection. Although portable equipment is usually used, the patient may be connected to nonportable equipment by direct or radio linkage.

H. **Standard polysomnography:** Polysomnography for the evaluation of sleep apnea, performed under supervision in a laboratory setting, utilizing the measurement of sleep stages, airflow, respiratory effort, oxygen saturation, electrocardiogram and body position and the recording of optional parameters such as limb movement, vocalization and carbon dioxide level.

I. **Screening:** A study conducted on an individual who is asymptomatic for features of OSA (though possibly at high risk for this disorder). Most often such studies are reserved for epidemiologic and research protocols and are used clinically only when the cost/benefit ratio is low.

J. **Raw data:** Data that are collected and can be reproduced in a format identical to, and visually indistinguishable from, analog data as collected and displayed in a

standard polysomnogram. Analog data may be converted to digital form as long as sampling rates allow reproduction to analog signals with sufficient accuracy to allow the same visual interpretation as is possible with the pure analog signal in standard polysomnography.

K. Processed data: Sampled, averaged, filtered, staged or otherwise altered data that cannot be reproduced in a format identical to, and visually indistinguishable from, analog data as collected and displayed in a standard polysomnogram.

L. Unprocessed data: Raw data whose only processing is that considered to be routine on standard polysomnography (such as high- and low-frequency filtering appropriate to recorded individual parameters).

M. Full disclosure: Presentation of all raw data from a complete study for visual review.

Types of studies for sleep apnea evaluation

(6-hour overnight recording minimum)

A. Level I: Standard polysomnography

Minimal requirements include recording of electroencephalogram (EEG), electrooculogram (EOG), chin electromyogram (EMG), electrocardiogram (ECG), airflow, respiratory effort and oxygen saturation. Body position must be documented or objectively measured. Trained personnel must be in constant attendance and able to intervene. Leg movement recording (EMG or motion sensor) is desirable but optional.

B. Level II: Comprehensive portable polysomnography

Same as for level I except heart rate instead of ECG is acceptable, and having trained personnel present and able to intervene is not required for all studies.

C. Level III: Modified portable sleep-apnea testing

Minimum requirements include recording of ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), ECG or heart rate and oxygen saturation. Personnel are needed for preparation, but the ability to intervene is not required for all studies.

D. Level IV: Continuous (single or dual) bioparameter recording

Only one or two physiologic variables need be recorded. The ability to intervene is not required.

Reprinted from *SLEEP*

Thorpy M, et al. Practice Parameters for the Use of Portable Recording in the Assessment of Obstructive Sleep Apnea. *SLEEP* 1994;17:372-377.