Portable Recording in the Assessment of Obstructive Sleep Apnea

An American Sleep Disorders Association Review

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Summary: This review is part of the Standards of Practice recommendations. It has been commended and reviewed by the Board of the ASDA. It reflects recommendations of the Board for the practice of sleep medicine in North America. The subcommittee is responsible for the presented write-up. The objective assessment of patients with a presumptive diagnosis of obstructive sleep apnea (OSA) has primarily used attended polysomnographic study. Recent technologic advances and issues of availability, convenience and cost have led to a rapid increase in the use of portable recording devices. However, limited scientific information has been published regarding the evaluation of the efficacy, accuracy, validity, utility, cost effectiveness and limitations of this portable equipment. Attaining a clear assessment of the role of portable devices is complicated by the multiplicity of recording systems and the variability of clinical settings in which they have been analyzed. This paper reviews the current knowledge base regarding portable recording in the assessment of OSA, including technical considerations, validation studies, potential advantages and disadvantages, issues of safety, current clinical usage and areas most in need of further study.

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

1.0 INTRODUCTION

Laboratory-based polysomnography forms the framework upon which the field of sleep disorders medicine has been built over the last 30-40 years. When obstructive sleep apnea (OSA) became recognized as a common disorder, cardiorespiratory variables were added to polysomnography as a standard feature. Patients can now be evaluated outside of the laboratory by using portable devices that can record a single channel such as oximetry, two or more channels that measure only respiratory variables, or multiple channels that allow for sleep staging as well as measurement of respiratory variables.

Recently recognized adverse consequences of sleep apnea, along with ongoing therapeutic advances, have heightened the urgency for expeditious diagnosis and treatment. The high prevalence of sleep-related breathing disorders has highlighted limitations in patient accessibility to diagnostic and therapeutic services. In addition, as the need for studies has increased, less costly but comparable efficacious alternatives to laboratory-based polysomnography are being sought in response to current economic imperatives. Finally, home studies may provide a more realistic appraisal of nighttime pathology than can be obtained in the laboratory setting.

Because of these and other considerations, portable systems intended to assess sleep apnea have been developed for use in settings outside the sleep laboratory. These new developments in diagnostic methods may eventually prove to be advantageous; however, most of the validation data from these systems designed for home use have been generated during laboratory studies in the presence of a technologist. This review examines the published knowledge base concerning the validity, clinical utility, advantages and limitations of portable devices.

2.0 METHODS

The Standards of Practice Committee of the American Sleep Disorders Association appointed a task force to review the role of portable recording in the diagnosis of OSA in adults. All members of the task force completed detailed conflict of interest statements. A literature review was conducted based primarily on MEDLINE (1966-1994), medical library catalog searches, manual reviews of the bibliographic and abstract sections of *Sleep Research* and the *American Review of Respiratory Disease*, and reference lists of selected papers and book chapters.

In reviewing validation studies, the task force used the following inclusion criteria: the studies must have 1) been

Table 1—Sleep-apnea evaluation studies (6-hour overnight recording minimum)

	Level I Standard polysomnography	Level II Comprehensive portable polysomnography	Level III Modified portable sleep apnea testing	Level IV Continuous single- or dual-bioparameter recording
Parameters	Minimum of seven, including EEG (C4-A1 or C3-A2), EOG, chin EMG, ECG, airflow, respiratory effort, oxygen saturation	Minimum of seven, including EEG (C4-A1 or C3-A2), EOG, chin EMG, ECG or heart rate, airflow, respiratory effort, oxygen saturation	Minimum of four, including ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG, oxygen saturation	Minimum of one
Body position	Documented or objectively measured	May be objectively measured	May be objectively measured	Not measured
Leg movement	EMG or motion sensor desirable but optional	EMG or motion sensor desirable but optional	May be recorded	Not recorded
Personnel	In constant attendance	Not in attendance	Not in attendance	Not in attendance
Interventions	Possible	Not possible	Not possible	Not possible

Abbreviations used: EEG, electroencephalogram; EOG, electrooculogram; EMG, electromyogram; ECG, electrocardiogram.

published in a peer-reviewed journal, 2) used polysomnography as a control and 3) blinded the scorers of the polysomnographic tracings to the study results of the equipment under evaluation. Case reports and abstracts of papers were excluded from our review of validation studies.

This paper is limited to the topic of OSA and does not cover the broader subject of sleep-related breathing disorders, including upper-airway resistance syndrome, because no data are available for the use of portable recording in the assessment of sleep-related breathing disorders other than sleep apnea.

Uniform terminology regarding portable recording devices is nonexistent; therefore, the task force developed definitions (see Appendix A) to use in referring to the equipment, the conditions under which portable studies are performed and the test results from that equipment. The task force also determined levels of portable recording equipment and delineated specifications for each of those categories (Table 1).

3.0 OBSTRUCTIVE SLEEP APNEA

During sleep, OSA occurs with repetitive upper-airway collapse [1], which leads to measurable physiologic changes. The disorder's characteristic asphyxia and awakenings are responsible for many of the clinical manifestations [2], including excessive daytime sleepiness [3,4], hemodynamic changes and cardiovascular and cerebrovascular problems [5-7].

4.0 TECHNICAL CONSIDERATIONS

The proper use of standard in-laboratory polysomnography for the diagnosis of OSA has been established by consensus [8,9]. Similar agreement regarding the off-site use of equipment intended for the detection of OSA has not been achieved, and the clinical applications of such systems have not been objectively defined [10]. This lack of consensus regarding off-site technology partially reflects uncertainty about the ability of unattended portable technology to acquire and reproduce required physiologic data in a sufficiently consistent and unambiguous manner to permit accurate clinical assessments. Though recent developments in computer sampling, storage, information retrieval and display have made possible the virtual replication of conventional polysomnographic records in the field, concerns persist regarding potential data loss or distortion and regarding any reduction in the number of parameters measured.

Many different (and constantly upgraded) systems, using different technologies to obtain, store and analyze data, are currently marketed. Various sensors may be used in variable combinations in studies ranging from the simple to the complex. In a recent report, Zimmerman et al. [11] listed the technical features of 32 sleep data-acquisition and analysis systems manufactured by 17 different companies. Twenty-seven of these devices could be used in an off-site setting. Since this article was published, several additional devices have been marketed (J. Zimmerman, personal communication). (See Appendix B for a detailed description of data acquisition, storage, retrieval and analysis; device configuration; power requirements; and a discussion of artifacts and data loss.)

5.0 LEVEL-II STUDIES (COMPREHENSIVE PORTABLE POLYSOMNOGRAPHY)

5.1 Background

Level-II devices measure both respiratory and sleep variables. Respiratory variables are measured via induc-

Table 2—Validation studies of level-III devices

First author	Device	Parameters measured	No. of patients	% Data loss	OSA diagnosis		
					RDI	Sensitivity	Specificity[a]
Emsellem (25)	Edentrace 2700	Nasal/oral airflow, chest-wall movement, SaO_2, HR	67[b]	6	>5	95	96
Redline (26)	Edentrace 4700	Nasal/oral airflow, chest-wall movement, SaO_2, HR, body movement	25[c]	0	>10	95	100
Ancoli-Israel (27)	Medilog	Chestwall movement, leg movement, body movement	36[b] 36[d]	23 25	>30 per night >30 per night	100 78	97 92
Gyulay (28)	Vitalog PMS-8	Chestwall movement, respiratory paradox, SaO_2, HR, body movement	14[b]	15	>5	100	83
Svanborg (32)	SCSB and PO	Respiratory movement, SaO_2	77[b]	0	>5	100	67
Salmi (33)	SCSB, thermistor and PO	Body movement, airflow, SaO_2	55[b]	0	>5	100	86
Stoohs (38)	MESAM 4	SaO_2, HR, snoring, body position	56[b]	0	>10	92	97

Abbreviations used: OSA, obstructive sleep apnea; RDI, respiratory disturbance index; SaO_2, oxygen saturation; HR, heart rate; SCSB, static charge sensitive bed; PO, pulse oximetry.

[a] Sensitivity and specificity for the device's ability to diagnose OSA are determined by the following equations: Sensitivity = true negative/(true positive + false negative), Specificity = true positive/(true negative + false positive).

[b] In-lab attended.

[c] Twenty patients in-lab attended and five home unattended.

[d] Home unattended.

tance plethysmography or nasal or oral thermistors. Sleep variables [electroencephalogram (EEG), electrooculogram (EOG) and chin electromyogram (EMG)] are measured in basically the same way as they are in level-I studies (attended standard polysomnography) [17], except for the absence of both trained personnel to ensure continuous recording quality and of on-line paper or monitor display. Like level-I studies (but un-like level-III and -IV), level-II studies allow for the identification and quantification of sleep stages; calculation of total sleep time; recognition of arousals; and, if leg movements are monitored, tabulation of leg movements. These data, in turn, permit calculation of the respiratory disturbance index (RDI), which is the number of sleep-related breathing-disordered events per hour of sleep; determination of stage-specific OSA severity; and recognition of cause and effect relationships among respiratory abnormalities, leg movements and arousal. These data enable the clinician to exclude waking respiratory irregularities from summary calculations.

5.2 Validation studies

Orr et al. recorded simultaneous tracings from an 8-channel recorder (Sleep I/T, CNS, Inc.) and standard polysomnography in 40 patients suspected of having OSA [19]. This device records single channels of EEG, EOG, tibialis EMG, wrist activity, tracheal noise, pulse oximetry and chest and abdominal movement, with resultant data automatically scored by the equipment's preset default settings. Using an RDI of at least 15 events per hour, the authors found the device to have a sensitivity of 100% and a specificity of 93%. The RDIs from this portable device and standard polysomnography correlated extremely well (r = 0.93), but sleep efficiencies were poorly correlated (r = 0.28). Because the authors perceived that this poor correlation was a result of the device's inaccurate sleep-staging default settings, they made no attempts to try to correlate specific sleep stages. They felt that for screening purposes, an accurate determination of sleep parameters was unnecessary.

Grote et al. have worked extensively with a portable, 10-channel, level-II instrument, SIDAS 10. A recent paper [20] reported their comparisons between the respiratory but not sleep-staging capabilities of this device with simultaneous measurements of nasal airflow, esophageal pressure and oxygen saturation during 1 night in the sleep laboratory in 20 unselected patients. (Note that this study does not meet our inclusion criterion regarding the use of polysomnography as a control but will, nonetheless, be discussed here.) Apneas and hypopneas were detected by the SIDAS 10 using respiratory inductive plethysmography, ITP (a non-invasive recording of intrathoracic pressure variations), nasal airflow and pulse oximetry. Using a definition for OSA of greater than 10 apneas per hour, they found the device to have both a sensitivity and a specificity of 100%. The respiratory parameters of the SIDAS 10 classified the type of apneas and hypopneas with at least 90% accuracy.

5.3 Portable sleep staging

Though few validation studies of level-II devices have been published, the literature does include reports of studies that examine the validity of sleep staging without including the measurement of respiratory parameters. Some commercially available sleep-staging devices generate high-quality EEG, EOG and chin EMG recordings and reproductions; when these signals are subsequently interpreted by visual review, assessments of total sleep time are very accurate [21].

Reports also show that automated scoring of total sleep time from normal patients in studies measuring EEG, EOG and chin EMG, agrees well with results obtained by standard polysomnography. A preliminary report detailed a demonstration of a 96% accuracy in discriminating sleep and waking in laboratory-based studies; reports of studies conducted in the home reveal accuracy rates of 70-94% [22,23]. Automated calculation of sleep staging, however, has been shown to make significant errors in discriminating among waking, stage-1 and rapid eye movement (REM) sleep in normal subjects [22-24].

5.4 Summary

Orr et al.'s paper [19], the only published report that compares the sleep-stage correlation from level-II devices and standard polysomnography for patients with OSA, found that the sleep-staging settings installed by the manufacturer were not very accurate. However, the device's sensitivity and specificity for a diagnosis of OSA were 100% and 93%, respectively. Grote and his colleagues used a level-II device that has sleep-staging capabilities, but did not evaluate this aspect of the equipment [20]. The majority of the data from level-II devices, therefore, examine the utility of these devices in control subjects by studying patients with sleep disorders other than OSA or by assessing only sleep-staging capabilities.

6.0 LEVEL-III STUDIES (MODIFIED PORTABLE SLEEP APNEA TESTING)

6.1 Background

Level-III unattended recording devices allow for the assessment of cardiorespiratory variables. They do not record EEG, EOG or chin EMG and, therefore, do not allow for direct determination of wakefulness and the stages of sleep. Despite the growing clinical use of level-III unattended recording devices, the results of only a few studies evaluating their application have been published in peer-reviewed journals. The reported studies are difficult to compare as they use several different recording devices and require different severities of RDI to define OSA. Furthermore, most of the equipment has been tested in a laboratory setting with simultaneous attended full-polysomnographic monitoring rather than in the home setting, the venue in which the equipment is intended to be used.

6.2 Validations studies

Emsellem et al. compared data from a portable recording device (Edentrace 2700) with simultaneously recorded polysomnograms in 67 patients with a presumed diagnosis of OSA [25]. This device recorded nasal/oral airflow (thermistor), chestwall movement (impedance plethysmography), heart rate and pulse oximetry. The results of their study and subsequent level-III studies are shown in Table 2. The authors found that all diagnostic errors occurred in patients with RDIs < 5.8. Emsellem noted that the portable recording device was not consistently reliable in distinguishing between obstructive and central apneas.

Redline et al. compared polysomnograms and portable recordings using an upgraded device from the same manufacturer as that of the above-discussed equipment (Edentrace 4700) [26]. In addition to the four channels used by Emsellem et al., this unit detected body movement by comparing electrical signals from the electrocardiogram (ECG) and pulse oximetry channels. The authors found that both the number of respiratory disturbances and the degree of oxygen desaturation detected on the polysomnogram correlated very well with the values obtained on portable recording. However, the duration of the respiratory events recorded on the portable device averaged 10 seconds longer than the same events recorded by standard polysomnography.

Ancoli-Israel et al. compared recordings from a polysomnogram and a portable recording device (Medilog) in 36 elderly adults with presumed diagnoses of OSA or periodic limb movement disorder [27]. This setup was not strictly a level-III device because oxygen saturation and heart rate or ECG were not recorded. The portable recording was performed in the laboratory simultaneously with the polysomnogram on 1 night and, additionally, as an unattended study in the subject's home on the night either preceding or following the polysomnogram. For the group as a whole, a level of agreement noted between the RDIs measured on the 2 nights was $r = 0.94$ and, at least in terms of RDI, there was no suggestion of a 1st night effect. The discrepancy between the sensitivities and specificities for the two portable recordings (in the laboratory and in the home) was probably a result of the laboratory study being performed as an attended study and the home study as an unattended study. The technologist who performed the standard polysomnogram in the laboratory-based recordings monitored the respiratory signal from the impedance plethysmograph; however, this was the same signal that, via a parallel output, went to the unattended recording device.

Gyulay et al. obtained simultaneous standard

polysomnographic and portable recordings in a small sample of selected patients. The study population consisted of 14 patients who had been evaluated previously for OSA [28]. Two tests were lost due to operator error with the portable device. The parameters measured on the portable recording were chestwall movement (inductance plethysmography), respiratory paradox (determined from the phase angle of rib cage and abdominal movement), pulse oximetry, heart rate and wrist activity. OSA was diagnosed by the portable device in all 12 patients even though two patients, as determined by polysomnography, did not have OSA. The portable device's sensitivity to detect episodes of disturbed breathing among the 12 subjects ranged from 40 to 94%. Positive predictive values ranged from 12 to 84%.

The static charge sensitive bed (SCSB) is used in Europe to establish the diagnosis of OSA [29-33]. The SCSB is a light flexible plate weighing approximately 2 kg and measuring 1.5 cm x 0.9 m x 1.9 m [29]. This device consists of electrically active layers that generate static charge when deformed, thus inducing voltage changes across two volated metal plates. The active layers and the metal plates are shielded and grounded by a metal foil, which helps avoid electrical environmental noise. The SCSB, placed under an airfoam plastic mattress, detects movements and respiration. Filtering and amplification divide the primary signal into three signals: ballistocardiogram, respiratory effort and body movement. In its initial application, only the latter two signals were used to detect sleep-related apnea [30,31] and, thus, the SCSB could be classified as a level-IV device. More recently, the SCSB has been combined with either oximetry alone [32] or oximetry and airflow (thermistor) recordings [33]. The two studies employing this device in its level-III configuration will be discussed.

Svanborg et al. [32] performed simultaneous measurements using standard polysomnography and the SCSB with oximetry in 77 snorers suspected of having OSA. These researchers established the following thresholds to determine an abnormal study consistent with a diagnosis of OSA: periodic, diamond-shaped respiration movements during more than 45% of total sleep time and an oxygen-desaturation index greater than six 4% falls in oxygen saturation per hour. These thresholds were 67% sensitive with a specificity of 100%. Using a broader classification of OSA, consisting of periodic respiratory movements present less than 18% of total sleep time and an oxygen-desaturation index of less than 2 per hour, the authors detected all cases of OSA with an apnea index of 5 or more (sensitivity 100%) but had seven false positives (specificity 67%).

Salmi and his colleagues [33] added airflow measured by thermistor, oximetry and body position to SCSB and compared 90-120 minutes of daytime polysomnography to their system. The polysomnographic records were manually scored; the five test signals were recorded on tape and automatically scored. The attachment of a thermistor improved the specificity of the system. Though the mean values for the RDI were very similar between the two methods, the automated method failed to detect an RDI of greater than 5 in three patients.

The MESAM system, which monitors heart rate and breathing sounds [34, 35], has recently been combined with oximetry [36, 37] and with oximetry and body position [38]. The MESAM system does not measure respiratory effort and is, thus, not a classic level-III device, but will be reviewed in this section because it does involve monitoring several channels of breathing variables. Data from MESAM 4 can be automatically scored and provide three indices. These indices include an oxygen-desaturation index, expressing the number of oxygen desaturations of at least 3% per hour of analyzed time; a heart-rate-variation index; and a snoring index. Using standard polysomnography, Stoohs and Guilleminault [38] identified 26 patients with OSA; using MESAM 4, they identified 25. The authors found the oxygen-saturation index, with a sensitivity of 92% and a specificity of 97%, to be the most helpful parameter measured. Heart-rate variation (58% sensitivity, 30% specificity) was much less accurate, as was the snoring index (96% sensitivity, 29% specificity). According to the authors, the combination of the three indices prevented any false-positive results. However, not all authors have found automatic scoring using the MESAM 4 software to be this accurate and, instead, have relied on manual scoring methods [39].

6.3 Difficulties

Most of these articles comment that, given the absence of parameters for direct determination of sleep staging in level-III unattended recording devices, calculation of the RDI is a potential problem. The RDI may be underestimated if the subject is awake for a significant part of the study. Inclusion of wrist movement in the recording may help determine if the subject is awake or asleep, although studies validating this ability have been performed on patient groups other than those with OSA [40-44]. Even studies that do not use these indirect methods to detect periods of wakefulness report a surprisingly close correlation between the RDI determinations on the polysomnogram and the unattended recording for the subjects as a group [26, 28]. Large individual discrepancies are also present, however, and are not necessarily less common in patients with severe OSA [26, 28].

Many of the above articles also comment on the difficulty of accurately distinguishing the type of apnea (central, obstructive, mixed) when using the unattended portable recording devices. This difficulty may reflect the facts that portable recording requires a greater degree of subjectivity to classify respiratory events and that the amount of physiologic data available to aid this classification is usually more limited in portable recordings than in

standard polysomnography [26]. However, continuing technologic advances in the design of chestwall-movement sensors and microprocessing systems may ultimately obviate this problem. Portable recordings are more subject to data loss than are standard polysomnograms (with losses of 4-24% usually reported) [25,27,28,45].

6.4 Summary

The above studies indicate that, when applied to a patient population with the presumed diagnosis of OSA, certain, but not all, level-III recording devices appear to be highly sensitive and specific in establishing the diagnosis of this sleep-related breathing disorder. Most validation studies were actually performed in an attended setting with simultaneous polysomnographic recording. When studies were unattended, the sensitivity and specificity decreased and the percentage of data loss increased. One should recognize that the majority of commercially available level-III devices have not been subjected to vigorous peer-reviewed validation studies. Surmising that if one four-channel recorder is shown to be reasonably accurate, another recorder presumably recording the same variables would have the same degree of accuracy, would be inappropriate.

Table 3—Validation studies of pulse oximetry

First author	No. of patients	OSA diagnosis		
		RDI[a]	Sensitivity[b]	Specificity[b]
Farney (55)	54	>5[c]	80	71
Williams (56)	40	>10	58[d]	100[d]
Bonsignore (57)	83	>20	74	100
Douglas (58)	200	>5	92	67
		>10	97	53
		>15	97	46
		>20	99	36
Cooper (59)	41	>5	60	95
		>15	75	86
		>25	100	80
Sériès (60)	240	>10	98	48
		>20	100	39
Rauscher (61)	116	>10	94	45
		>20	95	41
Gyulay (62)	98	>15	40	98
			72[d]	88[d]

[a] RDI, respiratory disturbance index, as evidenced by >4% decline in oxygen saturation.
[b] Sensitivity and specificity for the device's ability to diagnose obstructive sleep apnea are determined by the following equations: Sensitivity = true negative/(true positive + false negative), Specificity = true positive/(true negative + false positive).
[c] Presumed level of RDI, no mention made in text of a specific number.
[d] Oximetry plus a clinical score.

7.0 LEVEL-IV STUDIES (CONTINUOUS SINGLE-OR DUAL-BIOPARAMETER RECORDING)

7.1 Background

Continuous recording of one or two cardiorespiratory parameters has been proposed as adequate for case finding, but few critically reviewed studies have examined this hypothesis. The signals that have been studied most often are airflow, respiratory movements, oximetry, heart rate, blood pressure and body movement. As with level-III devices, level-IV studies do not allow for the determination of sleep stage.

7.2 Validation studies

7.2.1 Airflow and tracheal-sound recordings

Mössinger et al. developed a method by which a thermistor was placed on a mask to record nasal and oral air flow [46]. They found that the thermistor accurately identified patients with an apnea frequency of more than 50 per night. Another study that the mask may be uncomfortable and interfere with sleep and, therefore, may not be suitable for home use [48].

Tracheal-sound recordings, derived from a stethoscope and microphone, may be used as an individual measure of airflow [49,50], but reports indicate that these recordings overestimate the number of apneas and underestimate total apneic time [49]. Hypopneas, in particular, are difficult to recognize and may go undetected. Mesliér reported that such tracheal-sound recordings could recognize OSA with a sensitivity of 74% [50]. This sensitivity can be improved somewhat by including registration of cardiac frequency [51]. Most recently, Issa et al. tested a new portable digital recorder that uses snoring sounds and oxygen saturation [52]. Their analysis program identifies a respiratory event when a quiet period of 10-120 seconds separates two snores and is associated with a fall in oxygen saturation of greater than 3%. They studied 120 patients using this device concurrently with standard polysomnography. The sensitivity and specificity of the device in detecting OSA ranged from 84 to 90% and 95 to 98%, respectively, depending on whether the authors' definition of OSA was based on an RDI of more than seven or more than 20 events per hour.

Finke et al. measured oral and nasal airflow using a device called the Apnoe-Check System [53]. This device combines thermistors to measure these airflows and pulse oximetry to determine the number, maximal duration and mean duration of apneas. The authors studied 28 patients during 1 night in the sleep laboratory on their system and on a 2nd night using standard polysomnography. This device overestimated the number of disturbed respiratory events and, therefore, overdiagnosed the presence of disease.

7.2.2 Oximetry

All oximeters do not have the same response characteristics. The manufacturer, software and probe placement (i.e. the patient's finger or ear) all determine the device's

accuracy level [54] (Table 3).

Farney et al. analyzed ear-oximetry tracings from 54 patients at an altitude of 1,400 m and diagnosed apnea with a sensitivity of 80% and a specificity of 71% [55]. Studies such as this that examine the value of visual analysis of oximetry tracings often find the tracings to be relatively specific, though somewhat insensitive. Williams et al.'s study of 40 patients with suspected sleep apnea correctly identified 15 of the 26 patients with sleep apnea (sensitivity 58%); there were no false positives [56]. Bonsignore et al. were able to identify 35 of 47 patients with sleep apnea (sensitivity 74%) [57].

Douglas et al. compared polysomnography and oximetry tracings in a prospective study of 200 patients [56]. In addition to the information in Table 3, they found visual scoring of oximeter results to be 67% sensitive and 100% specific. Cooper et al. compared ear oximetry and polysomnography in 41 patients [59] and established that the predictive accuracy of oximetry depended on the definition that they used for OSA. Their diagnostic criteria of an RDI > 5, > 15 and > 25 events per hour corresponded with sensitivities of 60%, 75% and 100% and specificities of 95%, 86% and 80%, respectively. More recently, Sériès and his colleagues compared nocturnal home oximetry followed by in-lab polysomnography in 240 patients suspected of having OSA [60]. They diagnosed OSA in 110 patients by polysomnography; their home oximetry testing had a sensitivity of 98%, but a specificity of only 48%.

As with any screening tool, the value of oximetry has been found to be positively influenced by pretest clinical suspicion [55,61,62]. In addition to the information in Table 3, Rauscher et al. found that oximetry plus their clinical model had a sensitivity of 100% for predicting an RDI of greater than 10 [61]. They also discovered that all patients with negative results from oximetry and with low probabilities (<0.50) on their clinical models had an RDI of less than 10. Gyulay et al. determined that if their patients spent less than 1% of time sleeping with an oxygen saturation below 80%, clinically significant OSA could essentially be excluded as a diagnosis [62]. Conversely, they found that more than 15 4% desaturations per hour of oximetry made a diagnosis of OSA likely. When the pretest probability of OSA was 30%, the positive predictive value of oximetry for OSA was 83%; with a pretest probability of 50%, the positive predictive value of oximetry increased to 90%.

7.2.3 Other variables

Many patients with OSA have cyclically varying heart rates. In an early study of patients with OSA, Guilleminault et al. reported that the pattern of R—R-interval variability determined from overnight Holter-monitor recordings was both highly sensitive (100%) and specific (100%) for diagnosing OSA [63]. However, another study using heart-rate variability in combination with breath sounds in an attempt to diagnose sleep apnea showed a sensitivity of 92% and a specificity of 72% [63]. Heart-rate changes may be even more difficult to correlate with respiratory events when the respiratory findings are not severe. Responses of the cardiovascular system, being dependent on intact functioning of the autonomic system, may also be blunted or eliminated in cases where an autonomic neuropathy exists, such as in association with diabetes, and when the autonomic response is altered by medications such as a beta blockade for hypertension or angina.

Blood-pressure fluctuation is another cardiovascular consequence of OSA. Using continuous invasive blood-pressure recordings, Shepard found a characteristic pattern that was periodically associated with apneas [6]. Preliminary studies using noninvasive continuous blood-pressure recording by finger plethysmography suggest that this method has some potential in identifying obstructive hypopneas and apneas [64] and is deserving of further study.

Finally, Aubert-Tulkens et al. have shown that increased body movements associated with sleep apnea produce a characteristic actigraphy tracing [65]. By defining a fragmentation and movement index, they reported a sensitivity of 89% and a specificity of 95% with actigraphy.

7.3 Summary

The studies described above indicate that unattended, continuous, single- or dual-bioparameter recordings for the diagnosis of sleep apnea vary greatly in their degree of precision. Data, which exist primarily for oximetry studies, indicate that level-IV recordings have inadequate sensitivity for routine diagnostic use. However, oximetry combined with a pretest clinical score can increase the sensitivity and, thus, may be a useful screening technique to select patients for standard polysomnography. Information on other signals remains too limited for proper assessment at this time.

8.0 ADVANTAGES AND DISADVANTAGES

Most of the advantages and disadvantages of unattended portable recording for the diagnosis and continued assessment of OSA remain theoretical.

8.1 Accessibility

Improved access to diagnosis has been a major goal behind the development of unattended sleep-apnea recording systems. Standard polysomnography is less accessible in Europe than in the United States, and this factor may account for an increased demand in Europe for the development of simplified, portable, sleep-apnea recording systems [66,67]. Regional availability of, and demand for, standard polysomnographic studies within the United States have not been documented; however, accessibility to these studies here appears to vary [68,69].

Factors that must be considered when examining lack of access to standard polysomnography are the number of sleep laboratories, the space requirements of laboratories, the availability of appropriately trained technologists and disease prevalence. A recent study by Young and her colleagues has ascertained a high presence of OSA in the general population [70]. Using standard polysomnography, they found that 9% of women and 24% of men ranging from 50 to 60 years of age were found to have an RDI greater than 5. When these researchers combined the RDI and the symptom of subjective daytime sleepiness, they found that the prevalence decreased to 2% of women and 4% of men, which still represents a substantial number of affected individuals.

The untested and theoretical assumption has been that accessibility to OSA assessment will be enhanced if portable recording devices allow for evaluation in the patient's home or other nonlaboratory facility. Except for pilot programs using portable recording in intensive-care units [71] and nursing homes [45,72,73], no published studies address the effect of portable recording on the general population's access to diagnosis.

8.2 Cost

No published cost-per-test data are available for portable recording devices. Potential savings with portable recorders appear to reflect decreased labor and storage costs but, for nonlaboratory studies, labor costs may have to include significant technologist travel time. The full financial effect of portable recording systems on society, however, remains unknown. An increase in studies, as a result of decreased costs and increased access, could lead to an increase in total sleep-apnea-related expenditures. If an increased number of studies reflect a greater number of patients appropriately diagnosed, these extra studies will allow for improved diagnosis, earlier treatment, decreased morbidity and increased productivity; long-range health-care savings and other economic benefits may, therefore, result. To the extent that the increased number of studies reflects multiple and repetitive studies needed to diagnose one patient, portable recording may not be cost effective.

8.3 Convenience and acceptability

Some patients may find themselves anxious and uncomfortable sleeping alone in a laboratory bed, under observation and in unpreferred postures [74]. Other patients may worry more if they are studied without perceived medical supervision. Home recording allows for improved comfort and familiarity during studies conducted at appropriate sleep-wake cycle times with 1st night effects minimized [25,74-76]. The full effect of these environmental factors on respiratory and sleep variables, however, is not known.

8.4 Reliability

Portable unattended recording devices are potentially subject to data loss or distortion because of equipment malfunction, sensor disconnections, technologist error, patient or family error or interference, power surges or loss, in-transit damage, phone-line interference during modem transfer and error during playback. The frequency with which subsequent standard polysomnography is required because the results of portable studies are inconclusive remains to be seen.

8.5 Diagnostic limitations

Serious consequences could result if unattended portable recordings fail to recognize other diseases in need of treatment. The results of a high-quality level-II study conducted with appropriately validated equipment that includes a measurement of body position should be similar to results from standard polysomnography; however, this supposition remains to be determined in unselected patients. Level-III studies, by failing to identify sleep stages and (perhaps) to record ECG, have a greater potential for errors of omission than does standard polysomnography.

The more severe the underlying apnea condition, the less important becomes the failure to recognize associated sleep abnormalities (except for cardiac arrhythmias) on an initial sleep study. In the presence of severe sleep apnea, certain coexisting disorders are often difficult to diagnose, even using standard polysomnography. Severe sleep disruption, which is easy to recognize on standard polysomnography, can probably be presumed present when a level-III study shows the existence of severe sleep apnea. Even if this presumption were not always true, the effect on initial treatment decisions would likely be minimal.

Body position often affects the severity of obstruction that some patients with OSA experience. Failure to identify this positional component in a patient diagnosed with OSA may lead a practitioner away from considering certain therapeutic approaches such as intraoral devices or body-position controls. Conversely, failure to diagnose the true severity of OSA in patients who have positional components to their disorder and who slept in mainly nonsupine positions during testing may lead practitioners away from needed treatments such as nasal continuous positive airway pressure (CPAP) or surgery. Formal outcome studies addressing a failure to monitor or record body position have not been reported in the literature. Based on current knowledge, however, most sleep laboratories would consider a study with findings of mild or absent OSA to be inconclusive if the patient did not spend some time sleeping in the supine position.

Level-III studies may be most inaccurate in patients who do not have sleep apnea or whose findings on polysomnog-

raphy are only mild. No data are available on false-negative or false-positive rates in patients for whom a low clinical suspicion of OSA exists. Excessively sleepy patients, with level-III studies that are either negative for sleep apnea or only equivocally positive, may well have a different disorder that is primarily responsible for their symptoms. Standard polysomnography would likely be required as a second study, and, in retrospect, the preliminary portable study would be considered an unnecessary expense. If one were able to predict, by history and associated clinical findings, those situations in which the clinical findings are most likely to reveal a diagnosis of OSA, then level-III studies could become more justified and cost effective.

Few data are available about the false-negative rate of level-III studies in patients with clinical symptoms that indicate a strong likelihood of an OSA diagnosis. It is not known whether a negative home recording in this setting is a true negative. Meyer et al. recently demonstrated that standard polysomnography may fail to detect OSA on an initial night of testing [77]. Six of 11 patients who had clinical symptoms that were highly indicative of OSA were found to have OSA only on their 2nd night of polysomnography and not on the 1st night. No such studies have been performed using level-III devices.

8.6 Study interpretation

No guidelines exist for scoring and interpreting level-III sleep apnea recordings, and experience in interpretation of these recordings is limited. Normative data on large numbers of patients sleeping at home are not available. Computer-assisted scoring may improve the speed and decrease the cost of scoring respiratory events [78] but, possibly, at the expense of accuracy.

9.0 SAFETY

Numerous reports of ventricular fibrillation attributed to medical recording equipment and other electrical devices have been published over the last several decades [79-82]; to our knowledge, however, no reports have been published regarding the morbidity or mortality associated with unattended recording devices designed for diagnosing sleep-disordered breathing.

A review of the technical criteria for electrical safety is beyond the scope of this communication, and the reader is advised to consult the Association for the Advancement of Medical Instrumentation (AAMI) Standards and Recommended Practices [83] for more detailed and definitive information. Briefly, however, certain established guidelines for the manufacture and operation of unattended recording equipment are set forth in the AAMI document. Comprehensive documentation should be provided by the manufacturer to facilitate the purchaser's thorough understanding of the device's operation, limitations, maintenance and service requirements and specific safety practices. The technical information should include the device's electrical requirements and power consumption, electrical input and output characteristics, and performance specifications. All specific environmental requirements should also be enumerated. The manufacturer should provide an algorithm for preventing the spread of infectious agents from patient to patient and should describe recommended techniques for maintaining the cleanliness of the equipment. All precautions regarding electrical safety, including but not limited to the need to maintain dry conditions, should be clearly marked on the device and visible to the patient.

10.0 CLINICAL APPLICATIONS

Very little literature describes the actual, ongoing, routine use of portable recording devices in the day-to-day assessment of patients with OSA in a clinical setting. In Germany, a system that records snoring and heart rate has been used to distinguish between OSA and simple snoring [84]. A portable system used by Ancoli-Israel for research purposes has also been routinely used clinically to diagnose sleep apnea [85]. Sixty-one percent of her patients from 1981 to 1984, and 97% of her patients since 1984, have been assessed using portable recordings. Only five of the patients reportedly required follow-up standard laboratory polysomnography. Three of these patients had polysomnograms because their treating physicians requested continuous ECG and oximetry values before initiating therapy. In the remaining two patients, the home recordings were judged to be of poor quality.

Richards described the preliminary use of portable recording equipment in intensive-care units [71]. In addition, Hill et al. used a four-channel system that measures continuous oximetry, pulse, chestwall impedance and airflow to diagnose OSA in patients with Duchenne's muscular dystrophy in chronic respiratory-care facilities [86]. Although these studies were conducted as research projects, they do demonstrate that portable recording equipment may be useful in diagnosing OSA in patients who are physically unable to go to a sleep-disorders center. Recent abstracts have also suggested that inpatients can be successfully studied using portable recording devices [87,88].

The use of portable recordings to evaluate nursing-home populations has been described by several authors [45,72,73]. Elderly subjects have also been studied in community dwellings by different groups as part of other research protocols [89,90]. These studies, using a variety of equipment, showed that, at least in this population, patients can be classified as normal or abnormal regarding the presence of sleep apnea.

Many clinicians use portable equipment to titrate nasal CPAP at home and to follow patients over the course of CPAP therapy. Recent papers have suggested that this use may be feasible [69,91], although one of these studies [91]

required a technologist to be present throughout the night to titrate the pressure and monitor a four-channel recorder in a fashion analogous to that of laboratory-based studies. A solid-state pressure sensor attached to the side port of a nasal CPAP mask has also been shown to be effective in the home setting in demonstrating whether the pressures established during laboratory testing remain effective in the home environment [69]. Wrist-activity recording has also been used in an attempt to assess the efficacy of nasal CPAP in the home environment [65].

11.0 SUMMARY AND FUTURE CONSIDERATIONS

The proper management of OSA, a common illness associated with significant morbidity and mortality, requires accurate assessment. Laboratory study is costly and requires highly trained personnel for its implementation and interpretation. The ability to obtain the necessary information more quickly, easily, conveniently, accurately and inexpensively than is currently possible with standard in-laboratory polysomnography is certainly desirable. Portable recording offers the promise of at least some of these realities, but these potential advantages remain to be documented and balanced against a number of equally important potential disadvantages, including those of missed or inaccurate diagnoses.

An accurate diagnosis of OSA appears to be best in those patients with severe OSA and poorest in those patients with only mild respiratory abnormalities. The importance of unrecognized and possibly coexistent (nonapnea) sleep-disorders diagnoses increases inversely with decreasing OSA severity.

Outcome studies are necessary to determine the usefulness of portable recording systems in the assessment of patients with OSA. Ideally, such studies would compare the long-range morbidity and mortality of patients studied with standard polysomnography to that of patients studied using only portable devices. If patients studied with portable equipment fare as well as, or better than, those studied in the laboratory, then it makes little difference how the devices compare on individual recordings. If patients do well with both systems, then cost and accessibility considerations become primary. Unfortunately, no such information is available and is unlikely to be available for several years.

Of the more than 30 level-II and level-III portable recording systems now being marketed for the assessment of OSA, we found reports of validation studies published in peer-reviewed journals for nine of the devices. These validation studies assessed a total of 330 patients; 30 of these recordings were performed as unattended studies in the patients' homes. In addition, this existing literature includes data that have been largely collected from selected and not general populations, and the resulting information must be interpreted in that light. Until additional information becomes available, full assessment of the utility of particular recording systems for the detection of OSA is not possible, and one must be conservative when making decisions regarding the clinical indications for portable recordings.

Apart from these issues are the surprisingly complex considerations of cost, availability, convenience, training and safety, all of which need careful study to enable the formation of rational and precise parameters to guide the use of these devices. The American Sleep Disorders Association's practice parameters guide the clinician regarding the appropriate use of portable recording equipment for the assessment of OSA.

APPENDIX A: DEFINITIONS

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

B. Attended: 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 in a synonymous fashion, 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 obstructive sleep apnea (though possibly at high risk for this disorder). Such studies are most often reserved for epidemiologic and research protocols and are only used clinically 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.

APPENDIX B: TECHNICAL CONSIDERATIONS

4.1 Data acquisition

All portable polysomnographic recording equipment requires sensors and amplifiers, methods of storage and the ability to retrieve data for display and analysis.

4.1.1 Sensors

Sensors used in unattended portable recordings must function properly for extended periods of time without technologist intervention and must provide unambiguous information of conditions such as body position, snoring and waking without relying on direct observation. Airflow and respiratory-effort signals, although difficult to quantitate, are relatively easy to monitor and record with sensors that can be easily applied. However, these respiratory measurements are affected by body movement and sensor position and, therefore, the signals put out by these sensors can vary independently from the pathophysiologic changes they are supposed to reflect. Pulse oximetric measurements, on the other hand, are more likely to provide calibrated quantitative data, and usually provide the ability to distinguish artifact from physiologically relevant changes in the sensed signal [12-14].

4.1.2 Amplifiers

Small, portable, physiologic amplifiers used for data acquisition are set at the start of a study and cannot be readjusted for subsequent changes in signal strength or sensor placement. The capability of 60-cycle notch filtering is particularly important because of the high levels of electrical interference frequently encountered in nonlaboratory settings.

4.1.3 Sampling rate

Data collection may rely on analog or digital techniques. The choice of sampling frequency, intersample intervals and sample lengths affects the device's ability to detect and properly diagnose OSA [15,16]. EEG and ECG signals can be faithfully reproduced when sampled and stored at 200 Hz and at 125 Hz respectively. Ventilatory signals usually do not require sample rates above 25 Hz, and oxygen-saturation data can be sampled at rates as low as 5 Hz.

4.1.4 Preprocessing

When data are preprocessed prior to storage, the methods used are often peculiar to the individual devices. In systems with significant preprocessing (such as spectral analysis of EEG), raw data are not always available for visual review.

4.2 Storage

4.2.1 Storage requirements

Storage requirements may vary depending on the number of channels recorded, the rate at which they are sampled and the length of time the recording continues. Respiratory signals can be satisfactorily digitized and stored without large memory requirements. Digitization of an 8-hour polysomnographic recording consisting of seven high-frequency channels (EEG, EMG, ECG) sampled at 200 Hz and four low-frequency channels (airflow, respiratory excursion, oximetry) sampled at 25 Hz requires about 50 megabytes of storage. Storage of simplified processed signals can reduce the memory demand but with loss of information.

4.2.2 Storage devices

Acquired data must be temporarily stored for later analysis or review in devices resistant to static shocks and movement. Storage media in portable recorders are usually solid-state memory or streaming tape. Analog tape recorders can store large amounts of data, but retrieval is slow. Continuous digital recording onto tape or chip has primarily replaced analog recording. On-line transfer of data via modem, for storage on magnetic or optical disk, tape or memory chip, is also possible. Technologic advances in this area have been rapid; optimal storage and retrieval systems for the recorded signals remain to be determined.

4.3 Device configuration and size

Although portable devices may be full-sized polysomnographs on wheels or paperless systems on computer cards, most portable systems vary in size between that of a small tape recorder and a suitcase. Size and weight

considerations must take into account the requirements of transportability; space limitations; the ability to collect, store and transfer the necessary data in the manner desired; and the need for ambulatory use.

4.4 Retrieval and analysis

Data must usually be transferred to a separate computer system for analysis where the data may be then permanently stored on magnetic or optical disks or transferred to tape. Some devices process certain data during transfer without any storage of raw data. Analysis may be automatic, semiautomatic or manual, and the choice is sometimes user selectable. The algorithms for analyzing sleep and respiration are usually proprietary and developed specifically by the device's manufacturer; no current standards are in force. Sleep staging comes closest to following an accepted standard [17]; however, the algorithms in use vary widely because the rules for scoring were developed for visual analysis without the specificity usually required for computer processing. Algorithms for assessment of the presence, type, duration and consequences of sleep-disordered breathing also vary. In some systems, automatic or semiautomatic analyses can be checked against the raw data to verify scoring accuracy.

Display of raw data can be on either paper or computer monitor. However, the ability to visually review data on a screen can be affected by the digitizing rate; the length of epochs displayed; and the type, size and resolution of the monitor. High-resolution computer monitors (at least 1,024 x 768 pixels) are able to display usual polysomnographic parameters in 30-second epochs with minimal loss of information, but display of longer epochs, to clarify the sleep and behavioral context within which respiratory events arise, will limit the resolution. Maximal resolution may not be necessary simply to identify sleep stages, but it becomes increasingly important when one needs to closely examine the specific physiologic rhythms for subtler variations or abnormalities. Stored raw data may be redisplayed with high resolution on a polygraph or laser printer but at considerably slower speeds.

4.5 Power

Devices connected directly to wall sockets must be protected from power surges and spikes to avoid equipment damage and data loss. Battery-powered devices should have power sufficient for a full-night's study with a reasonable margin for error. Loss of battery power, or removal of battery prior to transfer of data for processing and analysis, can result in complete loss of data in some units.

4.6 Artifacts and data loss

One recent preliminary report found that interventions to maintain oximetry probes and continuous positive airway pressure (CPAP) masks were necessary in 14-20% of standard in-laboratory polysomnographic studies [18]. Reports of failure rates in unattended studies range from 0 to 24%. Artifacts and data loss may occur as a result of sensor failure; patient-related problems (movement, sweating, tampering or non-compliance); incorrect or broken connections; improper study setup, initiation or termination; power outages; software errors; and hardware malfunctions. Most errors are not detected until the data are scanned or reviewed during the analysis process. Some devices have error-checking systems to recognize artifacts or data loss and signal the need for adjustment. Other devices allow for on-line review of modem-transmitted data by personnel at a remote site. Some of the simpler problems possibly can be fixed by the patient or other persons if they are alerted properly by interactive technology at the recording site or by remotely located monitoring personnel. Systems monitored via modem sometimes allow the technician a limited ability to make modifications to the incoming physiologic signals, and even to the off-site portable equipment, directly from the remote monitoring site.

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