

PORTABLE DEVICES USED IN HOME TESTING FOR OBSTRUCTIVE SLEEP APNEA

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum (CTAF) has been asked to update its review of the scientific literature on the safety and efficacy of portable devices used in the home to diagnose patients with obstructive sleep apnea. Home diagnostic devices for sleep apnea were last reviewed by the Forum in June 2005. At that time, the recommendation of the systematic review was that portable devices did not meet CTAF criteria. Since that time, several new studies and reviews have been published and the Centers for Medicare and Medicaid Services (CMS) issued a national coverage decision supporting the coverage of continuous positive airway pressure (CPAP) based on home diagnosis of sleep apnea using portable devices.

BACKGROUND

Obstructive Sleep Apnea (OSA)

Untreated, obstructive sleep apnea is associated with significant morbidity and mortality including excessive sleepiness, poor memory, poor quality of life, hypertension, sudden death, stroke, congestive heart failure, myocardial infarction, and automobile and work-related accidents.¹⁻⁹ Apnea is usually defined as a cessation of airflow for >10 seconds, and hypopnea, as a reduction of >50% in thoracoabdominal movements for >10 seconds or as a discernable reduction in respiratory airflow for >10 seconds and accompanied by a decrease of >4% in SaO₂ and/or an arousal¹⁰. The apnea-hypopnea index (AHI) is calculated as the average number of apneas plus hypopneas per hour of sleep. The cut-off for the diagnosis of OSA for the AHI has varied from study to study. Recent studies using a “liberal” definition of OSA—an AHI of greater than five events per hour—have found that up to 24% of men and 9% of women have OSA. Using a more “conservative” diagnostic criterion—an AHI of at least 15 events per hour plus a history of daytime somnolence—up to 2% to 4% of adults have obstructive sleep apnea syndrome.^{11, 12} Treatment of OSA syndrome with nasal continuous positive airway pressure (nasal CPAP), dental devices, surgery, and weight loss improves patient daytime somnolence, cognitive dysfunction, and overall survival^{2, 13-18} Although there have been few comparative studies, the consensus is that CPAP should be the first line therapy for OSA.

The diagnosis of OSA cannot be made accurately by clinical history or physical examination alone. The “gold standard” for diagnosis of OSA is polysomnography (PSG), a recording of at least seven parameters—electroencephalography (EEG, brain waves), electro-oculography (EOG, eye movements), chin electromyography (muscle activity), electrocardiography (ECG), respiratory effort, airflow, and blood oxygen saturation—that is performed by a trained technologist using dedicated equipment with the patient sleeping overnight in a sleep laboratory. Full PSG also allows calculation of the respiratory disturbance index (RDI), which is the number of sleep-disordered events per hour of sleep including respiratory effort related arousals that don’t qualify as hypopneas or apneas. Consensus standards exist for the proper use of the in-laboratory PSG in the diagnosis of OSA.¹⁹⁻²¹ In-laboratory PSG is labor-intensive and long waiting lists are common in sleep laboratories²². Furthermore, single-night PSG is not perfect, and false-negative results have been reported²³. In addition, night-to-night variability of respiratory abnormalities has been well documented^{22, 24} and may give rise to divergent RDIs, causing reclassification of the diagnosis in up to 43% of patients with lower RDIs (5-15 respiratory events/hour)²⁵. Some do not consider standard PSG to be the “gold standard” for the diagnosis of OSA²⁶; instead, they suggest that therapeutic response to treatment (e.g., with nasal CPAP) might be a better “gold standard”²⁷.

The American Academy of Sleep Medicine recommends using the following definition for the diagnosis of sleep apnea.²¹ A patient must meet either criterion A or B plus criterion C:

- A. Excessive daytime sleepiness that is not better explained by other factors
- B. Two or more of the following that are not better explained by other factors:
 - a. Choking or gasping during sleep
 - b. Recurrent awakenings from sleep
 - c. Unrefreshing sleep
 - d. Daytime fatigue
 - e. Impaired concentration
- C. Overnight monitoring demonstrates five or more obstructed breathing events per hour during sleep

The report also recommends the following terminology for disease severity: mild = 5-15 events per hour; moderate = 15-30 events per hour, severe = more than 30 events per hour.²¹

Portable Devices for Home Diagnosis of Obstructive Sleep Apnea

Over the past twenty years, numerous portable devices have been developed that can record sleep, nocturnal breathing and oxygenation at home. A large number of portable sleep monitors are now available²⁸⁻³¹ with different diagnostic goals. Simple, inexpensive devices have been developed to screen or to case-select patients with sleep-disordered breathing. More complex equipment has been developed to allow the performance of a study equivalent to full PSG in the home setting²⁸. Screening refers to use of a device in an unselected population of subjects who may or may not have symptoms, or in a high-risk population such as first-degree relatives of patients with sleep-disordered breathing. Case selection is the usual clinical application for portable sleep monitors and refers to the use of a device in a patient for whom there is a clinical suspicion of sleep-disordered breathing. Another possible clinical application for portable devices is to assess the efficacy of treatments for sleep apnea, such as nasal CPAP, oromandibular devices, or upper airway surgery.

The portable devices offer some advantages^{32, 33}. Home studies might provide a more realistic appraisal of sleep-disordered breathing than can be obtained in the laboratory setting³⁴. The use of home devices could allow for wider access to sleep studies, as there are not enough sleep centers in the United States to perform full PSG on at risk patients. In the past, waiting lists at some centers have been six months or longer³⁵, but recent increases in the numbers of sleep centers has decreased wait times in most areas of the United States.³⁶ The data from these portable devices are relatively easy to interpret and data analysis is less time-consuming³⁷.

Potential disadvantages include lack of feasibility due to patient disability or transportation problems; possible unsatisfactory results obtained because of faulty placing of sensors or poor quality signals^{37, 38}; inability to diagnose position dependent OSA; and inaccurate diagnoses. Most portable devices are not able to diagnose other sleep disorders such as narcolepsy and restless leg syndrome. In addition, many portable home monitoring devices do not actually monitor sleep itself, making it impossible to determine the frequency of apneas and hypopneas per hour of sleep (AHI)³⁷.

In 1994 and 1999, a Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine reviewed the role of portable recording devices in the diagnosis of OSA in adults. Ferber et al³⁴ subsequently published a comprehensive review of published literature concerning the validity, clinical utility, advantages, and limitations of portable sleep monitoring devices. In 1996, an updated summary was published by Broughton et al²⁸. More recently both the Agency for Health Care Research and Quality and a

joint task force of the American Academy of Sleep Medicine, The American College of Chest Physicians, and the American Thoracic Society updated systematic reviews on home diagnosis of sleep apnea and were unable to identify any clearly effective portable home devices.^{30, 39} Many different (and constantly upgraded) systems employing different technologies to obtain, store, and analyze data have been marketed. These devices use various sensors in a variety of combinations; they measure different physiological parameters depending on the model. As far back as 1992, there were already at least 32 different sleep data monitoring systems manufactured by 17 different companies.²⁹

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

There are many portable devices approved by the FDA through the 510K program as substantially equivalent to predicate devices. Two devices are specifically noted in this assessment::

The Remmers Sleep Recorder (formerly SnoreSat) (SageTech Electronics Inc., Calgary, Alberta) received FDA 510(k) clearance in June 2002.

The Apnea Risk Evaluation System (ARES, Advanced Brain Monitoring, Carlsbad, CA) received FDA 510(k) clearance in October 2004.

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database, and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words sleep apnea, sleep study, polysomnography, home sleep study, home polysomnography, portable sleep study, portable polysomnography and sleep disorder breathing. These were cross-referenced with the keywords “sensitivity and specificity,” “screening,” “reproducibility of tests,” and human. The search was updated for the period from April 2005 through September 2008. The bibliographies of systematic reviews and key articles were manually searched for additional references. Further references were also solicited from the manufacturer,

local experts and sleep societies. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full.

The best studies would randomize patients to either full PSG in the laboratory or home testing with a portable device and evaluate differences in the rates of motor vehicle accidents, sudden death, strokes, myocardial infarctions, and total mortality. No such studies were identified. A much more feasible design would be to randomize patients as above and assess the short-term relative effects of the diagnostic approach on daytime somnolence, domains of cognitive function known to be associated with sleep apnea, quality of life, blood pressure, and measures of CPAP use. All patients should be evaluated, regardless of whether they were diagnosed with sleep apnea or received therapy with CPAP. Only one study was identified that approximated this design.⁴⁰ No comparative studies evaluating clinical outcomes using either concurrent controls or historical controls were identified.

Experts have noted a number of inherent difficulties in trying to compare one sleep diagnostic system to another. The most important problems are: (1) the lack of a true “gold standard” in assessing respiration during sleep and thus difficulties in detecting apneas and hypopneas; (2) the absence of a well-accepted cutoff for apnea-hypopnea frequency to make the diagnosis of obstructive sleep apnea; and (3) the night-to-night variability in measures of sleep and respiration that makes comparisons of home assessment versus in-laboratory evaluation difficult ^{24, 37, 41, 42}.

Many, if not most, studies of portable monitors have had serious methodological flaws ⁴³. First, often the validation data for these portable devices designed for unattended home use have been generated with the patient sleeping in the sleep laboratory in the presence of a technologist.^{34, 44, 45} The best validation studies compare data from portable devices used at home with data from full PSG as a “control” and have blinded the scoring of the full polysomnographic tracing to this study results of the home device under evaluation. Second, confounding some research studies are the long intervals between the full PSG and the home monitoring by portable devices. Third, studies have generally not included patients with few symptoms of OSA (and thus low pre-test probability of disease), so the utility of the devices as a screening tool in such cases cannot be determined.

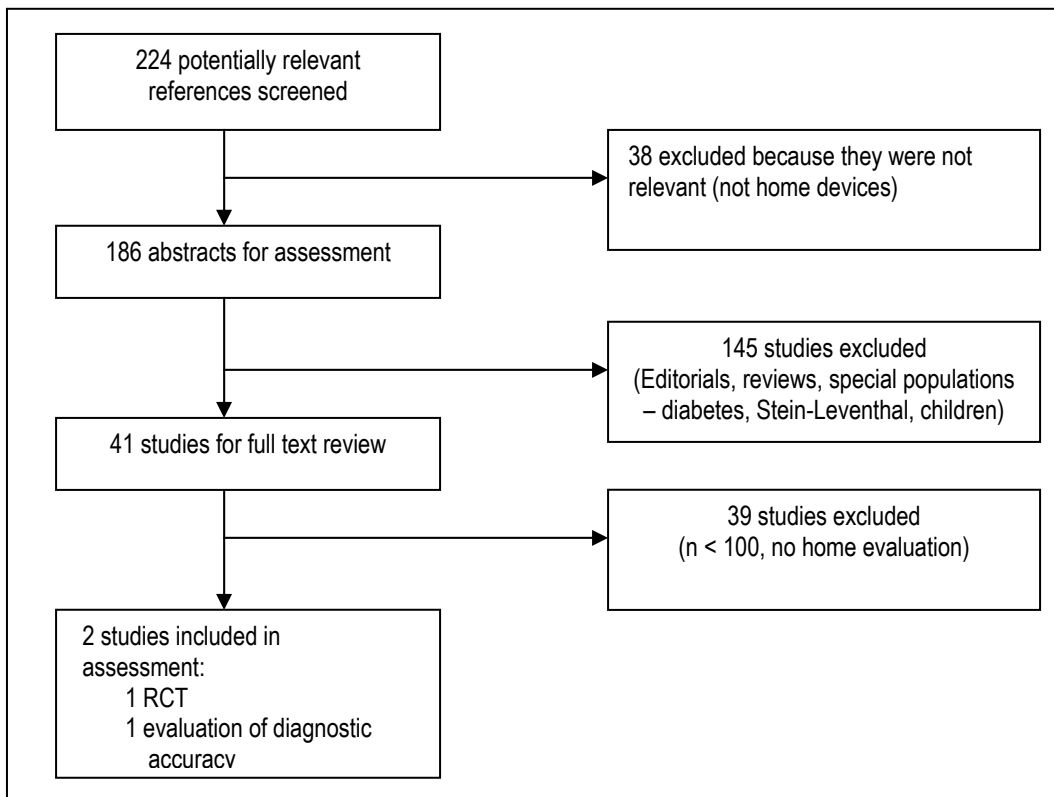
In 1994, the American Sleep Disorders Association published standards ²⁷ for the conduct of research studies investigating new diagnostic systems. These included: an independent, blind comparison with a reference standard; an appropriate spectrum of patients; avoidance of work-up bias; adequate detail regarding methods for performing the test; an adequate description of the study population; adequate

sample size (estimated to be >200 patients); avoidance of selection bias; and an adequate description of the study setting. No new studies were identified comparing in laboratory PSG to home testing with at least 200 patients and the majority of studies evaluated in the prior study failed to meet this standard. One study met criteria when the cut point was lowered to a minimum of 100 patients studied at home and in the sleep laboratory.⁴⁶

Level of evidence: 2 – 5 including studies from the prior reviews.

TA Criterion 2 is met.

Figure 1: Study Selection



TA Criterion 3: The technology must improve net health outcomes.

Randomized clinical trials

Mulgrew et al reported the results of a randomized trial that compared the results of a diagnostic strategy based on home monitoring to laboratory PSG in patients at high risk for obstructive sleep apnea.⁴⁰ Consecutive patients referred to a tertiary sleep center were screened for inclusion in the study. The primary inclusion criteria were a score on the Epworth Sleepiness Scale (ESS) ≥ 10 and a Sleep Apnea Clinical Score ≥ 15 . Exclusion criteria included prior treatment for OSA, unwillingness to use CPAP, pregnancy, unstable angina, abnormal spirometry, unwillingness to sign the informed consent and significant psychiatric illness. All 81 of the potentially eligible patients were then evaluated with an awake CPAP trial: two were unable to tolerate the trial and were excluded from the study. The remaining 79 were screened overnight with the Remmers Sleep Recorder (formerly SnoreSat). Sixty-eight of these patients had an RDA ≥ 15 per hour and were willing to be randomized. The study randomized 35 patients to PSG for diagnosis and titration of CPAP and 33 patients to the ambulatory arm with autotitrating CPAP at home. The investigators used the same model of CPAP machine for patients in both arms of the study. After three months, 30 patients in the PSG arm and 31 patients in the ambulatory arm complete in lab PSG while receiving CPAP at their usual level. The primary outcome was the AHI on CPAP after three months of treatment. Secondary outcomes included changes in the scores on the ESS (higher is sleepier; 3 point change is clinically meaningful) and the Sleep Apnea Quality of Life Index (SAQLI; higher is better; 1 point change is clinically meaningful). The study was powered to demonstrate equivalence for final AHI with a minimum between group difference of less than five events per hour. The investigators postulated that this would also give a minimum between group difference of less than one point on the SAQLI.

Among the patients eligible for randomization at baseline, 34 out of 36 (94%, 95% CI 81-99%) had an AHI > 15 per hour on PSG and thus met criteria for moderate to severe sleep apnea. After three months there was no difference in residual AHI on CPAP (polysomnography 3.2/hour; ambulatory 2.5/hour, $p=0.31$). The median decrease in sleepiness according to the ESS was clinically significant in both arms (PSG -10 points versus ambulatory -8 points, $p=0.26$). Quality of life using the SAQLI improved to a similar degree in both arms (2.2 versus 1.9, $p=0.69$). Compliance with CPAP was slightly worse in the PSG group (5.4 versus 6.0 hours per night, $p=0.021$), although the pressures required were nearly identical. All patients reported being satisfied with their treatment although 62% of patients in the PSG group would have preferred home management compared to only six percent of the ambulatory group expressing a preference for management in the sleep laboratory.

Based on these results, the authors concluded that in the initial management of patients with a high probability of sleep apnea PSG offers no advantage over the ambulatory approach and may be inferior in terms of compliance with CPAP. They recommend that patients meeting criteria for this study (ESS \geq 10; SACS \geq 15; RDI by home monitoring \geq 15/hour) be treated with autotitrating CPAP adjusted at weekly intervals. Patients not meeting the above criteria or who don't improve with CPAP at two weeks would require PSG.

The primary concern with this study is generalizing it to the clinic. As pointed out by Dr. Bloch and colleagues in a letter to the editor, only three percent of patients referred to the sleep clinic met the criteria for randomization.⁴⁷ Thus, use of this algorithm would have little impact on resource use as almost all patients would still require PSG. The authors replied that 15% of all patients would have met the eligibility requirements, but many declined participation in the study because of time and distance constraints. Thus, they argue that the results are applicable to an important percentage of patients referred to sleep centers and likely represent those with the most significant disease who are thus at greatest need for early intervention with CPAP. The study was not blinded, but allocation concealment was maintained until all baseline measurements were completed. Their primary outcome, three month AHI by PSG on CPAP, was objective and thus less likely to be affected by the lack of blinding. There were some dropouts after randomization, but the authors attempted to assess the potential impact by sensitivity analyses and the conclusions remained unchanged. The trial was also relatively small and thus may have been underpowered to detect clinically important differences between the groups. For example, the upper bound of the 95% confidence interval for the change in the ESS was 4, a potentially clinically meaningful decrease in sleepiness in favor of PSG-guided therapy. However, to the investigators credit, the 95% confidence interval for their primary outcome was less than their pre-specified cutoff for equivalence of five events per hour (between group difference 0.8, 95% CI -0.9 to 2.3) and the difference in the median SAQLI was less than 1 (between group difference -0.19, 95% CI -0.7 to 0.3).

Test characteristics of portable monitors compared with polysomnography

Since the last review, one new study has been published comparing portable device used in the home setting to PSG in the sleep laboratory. The investigators studied the Apnea Risk Evaluation System (ARES, Advanced Brain Monitoring, Carlsbad, CA). The device measures oxygen saturation, pulse rate, snoring level, and head position and movement. The study recruited 299 subjects: 210 consecutive patients referred to sleep centers, 36 general medicine patients recruited from local physicians' offices, and 53 "presumably healthy" subjects recruited from the community by advertisements. A total of 284 of the subjects

successfully underwent PSG in the sleep lab with concurrent readings by the portable monitor and 187 of these also had home monitoring performed with the portable device. PSG records were scored by a sleep specialist blinded to the results of the ARES monitor. The ARES scores were computed using an automated algorithm. Appropriate statistics were calculated evaluating the concordance of the portable device with PSG (kappa, Bland-Altman plots, sensitivity and specificity at standard AHI cutpoints). When used in the laboratory at the same time as PSG, the ARES device was in good agreement with PSG. The kappa was 0.85 (95% CI 0.77-0.89), which corresponds to excellent agreement beyond that expected by chance. Using an AHI cutpoint of ten per hour to diagnose sleep apnea, the ARES device had a sensitivity of 97.4% (95% CI 95.0-98.8) and a specificity of 85.6% (95% CI 80.4-88.5). As expected, the results from use of the device in the home where less accurate although specificity remained high. The corresponding results were 0.77 (0.66-0.85) for kappa, 91.5% (87.3-94.4) for sensitivity, and 85.7% (78.8-90.6) for specificity. The devices functioned acceptably for patients as only 2% (4/191 attempts) had unusable data because of insufficient recording time. In the discussion, the authors note that less than ten percent of the subjects evaluated at home called for technical support (full data not presented in paper), primarily to clarify the directions for use of the device. The “majority” of subjects reported that the device was comfortable and did not disrupt their sleep significantly.

This study presents data from one of the larger studies comparing PSG results to in-home use of a portable device. The results suggest that the ARES device has reasonable sensitivity and specificity at the cutpoint of ten for the AHI. However, the study suffers from several important flaws. There is clear spectrum bias – otherwise healthy volunteers should not be included in the spectrum of patients evaluated with the device and given the artificial nature of the sample, data on the positive and negative predictive value of the test should not be presented. Finally, it is not clear whether or not the AHI cutpoint of ten emphasized by the authors, was established *a priori* in the study. The authors also report the sensitivity and specificity at cutpoints of 5, 15, 20 and 30 with a broad range of point estimates for the statistics at each of the cutpoints. The authors offer no justification for primarily presenting the results at a cutpoint of 10. The device also does not incorporate measures of airflow or respiratory effort into its scoring algorithm: the AASM guideline on the use of portable monitors (PM) states that “at a minimum, PM must record airflow, respiratory effort, and blood oxygenation.”⁴⁸ Finally, as in all such studies, there are no clinical outcomes reported in such studies. It is unclear how these test characteristics will translate into benefits for patients with or without obstructive sleep apnea.

Summary

Since the last review of the topic, our literature search identified one study comparing the diagnostic test characteristics of a portable device to PSG that had a sample size larger than 100.⁴⁶ The study was of moderate quality due to the presence of spectrum bias. Furthermore, it is unclear how to incorporate the device into the diagnosis and management of sleep apnea. The authors suggest that in combination with automated or self-titrated CPAP, it could be a low cost option for detection and management of OSA, but it remains unclear which populations should be offered this option, the recommended ARES score for initiating CPAP, how to manage patients not meeting this threshold, and what benefits patients evaluated with this approach would accrue when compared with PSG.

On the other hand, the randomized trial published by Mulgrew et al⁴⁰ defines a clear population of patients to assess at home with the PM (those with $ESS \geq 10$ and $SACS \geq 15$, no other cause of somnolence). Those patients with an $RDI \geq 15$ measured using the Remmers Sleep Recorder at home would then be offered autotitrating CPAP. All patients not meeting these criteria and those failing auto-CPAP would be referred for full PSG. In the randomized trial, patients randomized to this ambulatory approach had similar quality of life and sleepiness outcomes at three months and were slightly more compliant with use of CPAP when compared with treatment based on PSG. This trial adds to the findings of the randomized trial described in the prior review, which found that the results of home monitoring with the SnoreSat (earlier version of Remmers Sleep Recorder) was as useful as PSG in predicting which patients would respond to CPAP.

TA Criterion 3 is met for the Remmers Sleep Recorder when used in conjunction with the ESS and SABCS to identify and institute treatment in patients at very high risk for obstructive sleep apnea.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

The major established alternative to home studies is full PSG. The published data summarized in this and the prior review suggest that Level II, Level III, and Level IV portable devices used unattended at home do not achieve results comparable to full in-laboratory PSG in the diagnosis of OSA. However, it is widely acknowledged that PSG is an imperfect gold standard. The results are not highly correlated with symptoms or response to CPAP.⁴⁹⁻⁵² There is often significant variability from night to night using the same PSG equipment^{25, 53-55} and significant variability in trained readers' interpretation of the PSG data.⁵⁶⁻⁵⁸

However, the goal of both PSG and the portable home devices is to identify patients who will benefit from treatment for OSA. As described above, one new clinical trial⁴⁰ randomized patients referred to a sleep center to have either PSG or home monitoring. They found no difference in sleepiness and quality of life measures three months after randomization. The primary problem with the trial was the wide confidence intervals around estimates of effectiveness due to the small sample size. Some clinically important differences in outcome could not be ruled out. Furthermore, the results only apply to a limited portion of the patients referred to sleep centers (3% in trial; 15% of all patients according to the investigators) and it was performed at one tertiary care center. Larger, more definitive studies will be needed to confirm that this ambulatory approach is comparable to management based on PSG and to evaluate whether it can be extended to patients at lower risk for sleep apnea. Some investigators have even argued for and evaluated a strategy of instituting auto-titrated CPAP in high risk patients without any diagnostic strategy other than being a sleepy person (ESS \geq 8) who snores and has been referred for a sleep study.⁵⁹ Comparative studies need to be performed to identify the optimal approach for patients.

Decision Analysis

In the absence of large, randomized clinical trial evidence, decision analysis is often performed to model the relative risks and benefits for alternative diagnostic or therapeutic pathways. Several studies were evaluated for the last review and that consistently found PSG to be the preferred approach, even with unrealistically high estimates for the sensitivity and specificity of portable monitoring in the home.^{33, 60, 61} However the trials in patients at high risk for OSA suggest that similar proportions of patients will be adequately treated with CPAP, irregardless of the diagnostic approach. Thus, some of the assumptions underlying these models may be flawed. Further work is needed to better define the role of both portable devices and PSG in the management of patients suspected of suffering from OSA.

TA Criterion 4 is not met.

TA Criterion 5: **The improvement must be attainable outside of the investigational setting.**

Studies have not yet demonstrated the equivalence of portable home monitoring devices and polysomnography in leading to therapeutic interventions to improve symptoms and other outcomes of OSA in the investigational setting. Whether portable home monitoring devices will be effective in improving health outcomes when used to diagnose individuals with OSA when in the community under conditions of usual medical practice still remains to be demonstrated.

DRAFT



DRAFT

TA Criterion 5 is not met.

CONCLUSION

The validation trials of home portable monitoring devices are difficult because of known night to night variability in the AHI measured by full PSG, known first night effects when patients are monitored, probable differences between sleep patterns in the laboratory and at home, and the limited correlation of AHI with health outcomes. In fact, portable home testing may be better at predicting which patients will respond to treatment with CPAP or other interventions for OSA. Published reports are difficult to compare as they use many different recording devices and different definitions of RDI to define OSA. Many of the studies present analyses using multiple cutpoints for AHI to define sleep apnea and determine optimal cutpoints for the portable device based on data obtained in the study. Such results almost always provide overly optimistic estimates for sensitivity and specificity when the cutpoint is validated in an independent study.

Only one study compared outcomes of therapeutic interventions (e.g., nasal CPAP) based on home studies to those based on full in-laboratory PSG. The study was small (n=68), from a single center, and did not evaluate the most important outcomes associated with OSA (motor vehicle accidents, strokes, sudden death, myocardial infarctions). The study demonstrated equivalence of an ambulatory strategy incorporating portable home monitoring to PSG for the following outcomes: AHI on CPAP, sleepiness, and quality of life at three months. However, the confidence intervals for some outcomes were wide, reflecting the need for greater power to convincingly demonstrate equivalence.

The primary benefit of portable devices is greater availability of diagnostic testing, thus reducing wait times and reducing the burden for patients who live at great distances from a sleep center. They are also marketed as being more economical. However, symptomatic patients with negative or uninterpretable results on a home study may still need to undergo second home studies or full PSG. Finally, decision analyses suggest that even if portable home monitoring is assumed to have unrealistically high sensitivity (95%) and specificity (96%) for sleep apnea, the quality adjusted life years gained will still be greater with PSG than with portable home monitoring.

It is likely that many of the portable monitors have a role in the efficient diagnosis of OSA. Further trials comparing the sensitivity and specificity of these devices to the imperfect gold standard, PSG, will never be sufficient to demonstrate their clinical utility. Rather, studies should focus on identifying those patients in whom treatment guided by home monitoring gives results that are equivalent to PSG. Ideally randomized

DRAFT



DRAFT

clinical trials will demonstrate that these techniques can rival or exceed the outcomes achieved by laboratory-based PSG.

TA criteria 3-5 are not met.

RECOMMENDATION

It is recommended that the use of Level III portable home devices to diagnose OSA does not meet technology assessment criteria 3, 4, or 5 for safety, effectiveness, and improvement in health outcomes

October 15, 2008

DRAFT



DRAFT

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center Medical Advisory Panel has not conducted a formal review of this topic.

Centers for Medicare and Medicaid Services (CMS)

The CMS issued a National Coverage Determination on March 13, 2008 which allows for coverage of CPAP when OSA is diagnosed using polysomnography performed in a sleep laboratory, or Unattended home sleep monitoring using Type II, Type III or Type IV devices.

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=240.4&ncd_version=3&basket=ncd%3A240%2E4%3A3%3AContinuous+Positive+Airway+Pressure+%28CPAP%29+Therapy+For+Obstructive+Sleep+Apnea+%28OSA%29

American Academy of Sleep Medicine (AASM)

From the AASM web site: <http://www.aasmnet.org/PortableMonitoring.aspx>

Using evidence review and a consensus process, the AASM task force developed clinical guidelines that were approved by the AASM board of directors and published in the December 15, 2007, issue of the *Journal of Clinical Sleep Medicine*. The guidelines recommend the use of PM by AASM-accredited sleep disorders centers and labs under the direction of a board-certified sleep specialist for the diagnosis of OSA in select adults.

The AASM will be providing representatives to attend the meeting.

California Thoracic Society (CTS)

The CTS has been invited to attend the meeting and provide an opinion regarding this technology.

American College of Cardiology, California Chapter (CA ACC)

The CA ACC has been invited to provide an opinion regarding the use of this technology. A representative will attend the meeting.

DRAFT



DRAFT

Agency for Healthcare Research and Quality (AHRQ)

An AHRQ Technology Assessment: Obstructive Sleep Apnea-Hypopnea Syndrome: Modeling different diagnostic strategies dated December 4, 2007 is available at:

<http://www.cms.hhs.gov/determinationprocess/downloads/id50TA.pdf>

DRAFT



DRAFT

ABBREVIATIONS USED IN THIS REVIEW

CTAF	California Technology Assessment Forum
CMS	Centers for Medicare and Medicaid Services
CPAP	Continuous positive airway pressure
OSA	Obstructive sleep apnea
AHI	Apnea-hypopnea index
PSG	Polysomnography
EEG	Electroencephalography
EOG	Electro-oculography
ECG	Electrocardiography
RDI	Respiratory disturbance index
DARE	Database of Abstracts of Reviews of Effects
ESS	Epworth Sleepiness Scale
SAQLI	Sleep Apnea Quality of Life Index
ARES	Apnea Risk Evaluation System
PM	Portable monitors

REFERENCES

1. He J, Kryger MH, Zorick FJ, Conway W, Roth T. Mortality and apnea index in obstructive sleep apnea. Experience in 385 male patients. *Chest*. Jul 1988;94(1):9-14.
2. Medicine AAoS. Position paper: Life insurance risk assessment in patients with obstructive sleep-disordered breathing. *AASM Bulletin*. 2000;7(2):7-12.
3. George CF, Smiley A. Sleep apnea & automobile crashes. *Sleep*. Sep 15 1999;22(6):790-795.
4. Jenkinson C, Stradling J, Petersen S. Comparison of three measures of quality of life outcome in the evaluation of continuous positive airways pressure therapy for sleep apnoea. *J Sleep Res*. Sep 1997;6(3):199-204.
5. Marin JM, Carrizo SJ, Vicente E, Agusti AG. Long-term cardiovascular outcomes in men with obstructive sleep apnoea-hypopnoea with or without treatment with continuous positive airway pressure: an observational study. *Lancet*. Mar 19-25 2005;365(9464):1046-1053.
6. Shahar E, Whitney CW, Redline S, et al. Sleep-disordered breathing and cardiovascular disease: cross-sectional results of the Sleep Heart Health Study. *Am J Respir Crit Care Med*. Jan 2001;163(1):19-25.
7. Teran-Santos J, Jimenez-Gomez A, Cordero-Guevara J. The association between sleep apnea and the risk of traffic accidents. Cooperative Group Burgos-Santander. *N Engl J Med*. Mar 18 1999;340(11):847-851.
8. Thomas RJ, Rosen BR, Stern CE, Weiss JW, Kwong KK. Functional imaging of working memory in obstructive sleep-disordered breathing. *J Appl Physiol*. Jun 2005;98(6):2226-2234.
9. Gami AS, Howard DE, Olson EJ, Somers VK. Day-night pattern of sudden death in obstructive sleep apnea. *N Engl J Med*. Mar 24 2005;352(12):1206-1214.
10. Golpe R, Jimenez A, Carpizo R, Cifrian JM. Utility of home oximetry as a screening test for patients with moderate to severe symptoms of obstructive sleep apnea. *Sleep*. Nov 1 1999;22(7):932-937.
11. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. *N Engl J Med*. Apr 29 1993;328(17):1230-1235.
12. Bearpark H, Elliott L, Grunstein R, et al. Snoring and sleep apnea. A population study in Australian men. *Am J Respir Crit Care Med*. May 1995;151(5):1459-1465.
13. Practice parameters for the indications for polysomnography and related procedures. Polysomnography Task Force, American Sleep Disorders Association Standards of Practice Committee. *Sleep*. Jun 1997;20(6):406-422.
14. Engleman HM, Martin SE, Deary IJ, Douglas NJ. Effect of continuous positive airway pressure treatment on daytime function in sleep apnoea/hypopnoea syndrome. *Lancet*. Mar 5 1994;343(8897):572-575.

15. Kribbs NB, Pack AI, Kline LR, et al. Effects of one night without nasal CPAP treatment on sleep and sleepiness in patients with obstructive sleep apnea. *Am Rev Respir Dis*. May 1993;147(5):1162-1168.
16. Loredó JS, Ancoli-Israel S, Kim EJ, Lim WJ, Dimsdale JE. Effect of continuous positive airway pressure versus supplemental oxygen on sleep quality in obstructive sleep apnea: a placebo-CPAP-controlled study. *Sleep*. Apr 1 2006;29(4):564-571.
17. Campos-Rodriguez F, Pena-Grinan N, Reyes-Nunez N, et al. Mortality in obstructive sleep apnea-hypopnea patients treated with positive airway pressure. *Chest*. Aug 2005;128(2):624-633.
18. Marti S, Sampol G, Munoz X, et al. Mortality in severe sleep apnoea/hypopnoea syndrome patients: impact of treatment. *Eur Respir J*. Dec 2002;20(6):1511-1518.
19. Indications and standards for cardiopulmonary sleep studies. American Thoracic Society. Medical Section of the American Lung Association. *Am Rev Respir Dis*. Feb 1989;139(2):559-568.
20. Block AJ, Cohn MA, Conway WA, et al. Indications and standards for cardiopulmonary sleep studies. *Sleep*. Dec 1985;8(4):371-379.
21. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. *Sleep*. Aug 1 1999;22(5):667-689.
22. Portier F, Portmann A, Czernichow P, et al. Evaluation of home versus laboratory polysomnography in the diagnosis of sleep apnea syndrome. *Am J Respir Crit Care Med*. Sep 2000;162(3 Pt 1):814-818.
23. Meyer TJ, Eveloff SE, Kline LR, Millman RP. One negative polysomnogram does not exclude obstructive sleep apnea. *Chest*. Mar 1993;103(3):756-760.
24. Le Bon O, Hoffmann G, Tecco J, et al. Mild to moderate sleep respiratory events: one negative night may not be enough. *Chest*. Aug 2000;118(2):353-359.
25. Mosko SS, Dickel MJ, Ashurst J. Night-to-night variability in sleep apnea and sleep-related periodic leg movements in the elderly. *Sleep*. Aug 1988;11(4):340-348.
26. Teschler H, Berthon-Jones M. Full polysomnography versus home sleep study: searching for the optimal procedure. *Eur Respir J*. Aug 1997;10(8):1699-1700.
27. Indications and standards for use of nasal continuous positive airway pressure (CPAP) in sleep apnea syndromes. American Thoracic Society. Official statement adopted March 1944. *Am J Respir Crit Care Med*. Dec 1994;150(6 Pt 1):1738-1745.
28. Broughton R, Fleming J, Fleetham J. Home assessment of sleep disorders by portable monitoring. *J Clin Neurophysiol*. Jul 1996;13(4):272-284.
29. Zimmerman JT, Rorch WC, Reichert JA. A comparison of sleep-data acquisition and analysis systems. *Journal of Polysomnographic Technology*. 1992:30-44.

30. Executive summary on the systematic review and practice parameters for portable monitoring in the investigation of suspected sleep apnea in adults. *Am J Respir Crit Care Med.* May 15 2004;169(10):1160-1163.
31. Ghegan MD, Angelos PC, Stonebraker AC, Gillespie MB. Laboratory versus portable sleep studies: a meta-analysis. *Laryngoscope.* Jun 2006;116(6):859-864.
32. Boyer S, Kapur V. Role of portable sleep studies for diagnosis of obstructive sleep apnea. *Curr Opin Pulm Med.* Nov 2003;9(6):465-470.
33. Chervin RD, Murman DL, Malow BA, Totten V. Cost-utility of three approaches to the diagnosis of sleep apnea: polysomnography, home testing, and empirical therapy. *Ann Intern Med.* Mar 16 1999;130(6):496-505.
34. Ferber R, Millman R, Coppola M, et al. Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. *Sleep.* Jun 1994;17(4):378-392.
35. Flemons WW, Douglas NJ, Kuna ST, Rodenstein DO, Wheatley J. Access to diagnosis and treatment of patients with suspected sleep apnea. *Am J Respir Crit Care Med.* Mar 15 2004;169(6):668-672.
36. Shariq K. Sleep centers in the U.S. reach 2515 in 2004. *Sleep.* Jan 1 2005;28(1):145-146.
37. White DP, Gibb TJ, Wall JM, Westbrook PR. Assessment of accuracy and analysis time of a novel device to monitor sleep and breathing in the home. *Sleep.* Feb 1995;18(2):115-126.
38. Parra O, Garcia-Escasans N, Montserrat JM, et al. Should patients with sleep apnoea/hypopnoea syndrome be diagnosed and managed on the basis of home sleep studies? *Eur Respir J.* Aug 1997;10(8):1720-1724.
39. Flemons WW, Littner MR, Rowley JA, et al. 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.* Oct 2003;124(4):1543-1579.
40. Mulgrew AT, Fox N, Ayas NT, Ryan CF. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med.* Feb 6 2007;146(3):157-166.
41. Stoohs R, Guilleminault C. MESAM 4: an ambulatory device for the detection of patients at risk for obstructive sleep apnea syndrome (OSAS). *Chest.* May 1992;101(5):1221-1227.
42. Wittig RM, Romaker A, Zorick FJ, Roehrs TA, Conway WA, Roth T. Night-to-night consistency of apneas during sleep. *Am Rev Respir Dis.* Feb 1984;129(2):244-246.
43. Flemons WW, Remmers JE. The diagnosis of sleep apnea: questionnaires and home studies. *Sleep.* Dec 1996;19(10 Suppl):S243-247.
44. Emsellem HA, Corson WA, Rappaport BA, Hackett S, Smith LG, Hausfeld JN. Verification of sleep apnea using a portable sleep apnea screening device. *South Med J.* Jul 1990;83(7):748-752.

45. Man GC, Kang BV. Validation of a portable sleep apnea monitoring device. *Chest*. Aug 1995;108(2):388-393.
46. Westbrook PR, Levendowski DJ, Cvetinovic M, et al. Description and validation of the apnea risk evaluation system: a novel method to diagnose sleep apnea-hypopnea in the home. *Chest*. Oct 2005;128(4):2166-2175.
47. Bloch KE, Senn O, Brack T, Russi EW. Ambulatory management of obstructive sleep apnea without polysomnography. *Ann Intern Med*. Sep 4 2007;147(5):350; author reply 350-351.
48. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med*. Dec 15 2007;3(7):737-747.
49. Bennett LS, Langford BA, Stradling JR, Davies RJ. Sleep fragmentation indices as predictors of daytime sleepiness and nCPAP response in obstructive sleep apnea. *Am J Respir Crit Care Med*. Sep 1998;158(3):778-786.
50. Kingshott RN, Engleman HM, Deary IJ, Douglas NJ. Does arousal frequency predict daytime function? *Eur Respir J*. Dec 1998;12(6):1264-1270.
51. Lloberes P, Marti S, Sampol G, et al. Predictive factors of quality-of-life improvement and continuous positive airway pressure use in patients with sleep apnea-hypopnea syndrome: study at 1 year. *Chest*. Oct 2004;126(4):1241-1247.
52. Nosedá A, Jann E, Hoffmann G, Linkowski P, Kerkhofs M. Compliance with nasal continuous positive airway pressure assessed with a pressure monitor: pattern of use and influence of sleep habits. *Respir Med*. Jan 2000;94(1):76-81.
53. Aber WR, Block AJ, Hellard DW, Webb WB. Consistency of respiratory measurements from night to night during the sleep of elderly men. *Chest*. Oct 1989;96(4):747-751.
54. Chediak AD, Acevedo-Crespo JC, Seiden DJ, Kim HH, Kiel MH. Nightly variability in the indices of sleep-disordered breathing in men being evaluated for impotence with consecutive night polysomnograms. *Sleep*. Sep 1996;19(7):589-592.
55. Stepnowsky CJ, Jr., Orr WC, Davidson TM. Nightly variability of sleep-disordered breathing measured over 3 nights. *Otolaryngol Head Neck Surg*. Dec 2004;131(6):837-843.
56. Collop NA. Scoring variability between polysomnography technologists in different sleep laboratories. *Sleep Med*. Jan 2002;3(1):43-47.
57. Michaelson PG, Allan P, Chaney J, Mair EA. Validations of a portable home sleep study with twelve-lead polysomnography: comparisons and insights into a variable gold standard. *Ann Otol Rhinol Laryngol*. Nov 2006;115(11):802-809.
58. Su S, Baroody FM, Kohrman M, Suskind D. A comparison of polysomnography and a portable home sleep study in the diagnosis of obstructive sleep apnea syndrome. *Otolaryngol Head Neck Surg*. Dec 2004;131(6):844-850.
59. Senn O, Brack T, Russi EW, Bloch KE. A continuous positive airway pressure trial as a novel approach to the diagnosis of the obstructive sleep apnea syndrome. *Chest*. Jan 2006;129(1):67-75.

DRAFT



DRAFT

CALIFORNIA TECHNOLOGY ASSESSMENT FORUMSM

60. Reuven H, Schweitzer E, Tarasiuk A. A cost-effectiveness analysis of alternative at-home or in-laboratory technologies for the diagnosis of obstructive sleep apnea syndrome. *Med Decis Making*. Nov-Dec 2001;21(6):451-458.
61. Tarasiuk A, Reuveni H. Obstructive sleep apnea syndrome: the diagnostic strategy dilemma. *Isr Med Assoc J*. Nov 2004;6(11):686-690.