

Are Sleep Studies Appropriately Done in the Home?

Peter C Gay MD and Paul A Selecky MD FAARC

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For many years the greatest barrier to the diagnosis and treatment of obstructive sleep apnea (OSA) was recognizing the disease. That obstacle is now fading as more physicians of all types are aware of the high prevalence of OSA and the consequences of untreated OSA. Sleep-laboratory polysomnography has long been considered the accepted standard for OSA diagnosis and has become a lucrative practice. This, unfortunately, has led to a concentration on diagnosis rather than on management of OSA. Although several brands of portable polysomnograph have been approved for home polysomnography, obstacles to reimbursement (primarily from government, but also from private payers) have prevented widespread home polysomnography. Over the last 2 decades many scientific studies have supported a strong correlation between the findings from home polysomnography and sleep-laboratory polysomnography. However, limited data are available from good outcomes-oriented studies, so controversy surrounds home polysomnography in the diagnosis of OSA. We review the evidence and debate whether sleep studies are appropriately done in the home.

Key words: polysomnography, home; polysomnograph; obstructive sleep apnea; OSA. [Respir Care 2010;55(1):66–73. © 2010 Daedalus Enterprises]

Introduction

Obstructive sleep apnea (OSA) is present in 2–4% of middle-age adults,¹ and is associated with symptoms such as daytime somnolence and serious comorbidities and risks,

Peter C Gay MD is affiliated with the Department of Pulmonary, Critical Care, and Sleep Medicine, Mayo Clinic, Rochester, Minnesota. Paul A Selecky MD FAARC is affiliated with the Pulmonary Department, Hoag Hospital, Newport Beach, California.

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such as hypertension,² heart failure,³ stroke,⁴ diabetes and metabolic abnormalities,^{5,6} motor-vehicle accidents,⁷ and mood disorders.⁸ Continuous positive airway pressure (CPAP) is the most commonly prescribed treatment and successfully treats OSA in the majority of patients.⁹ As with any disease process, the sooner the diagnosis is made and treatment begins, the better the outcome and the less the likelihood of complications and adverse outcomes.

The present accepted standard for OSA diagnosis is a polysomnography in the sleep laboratory, largely because of the precedent set by the historically established clinical

Correspondence: Peter C Gay MD, Department of Pulmonary, Critical Care, and Sleep Medicine, Mayo Clinic, 200 1st Street SW, Rochester MN 55905. E-mail: pgay@mayo.edu.

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Table 1. American Academy of Sleep Medicine Classification of Levels of Portable Polysomnography (> 6 h)

	Type of Portable Polysomnography			
	Type I (attended)	Type II (unattended)	Type III (modified, for diagnosing OSA)	Type IV (1 or 2 channels)
Measurement channels (<i>n</i>)	≥ 7	≥ 7	≥ 4	≤ 2
Measurements	Electro-encephalogram Electro-oculogram Chin electro-myogram Electro-cardiogram Air flow Respiratory effort Pulse oximetry	Electro-encephalogram Electro-oculogram Chin electro-myogram Electro-cardiogram Air flow Respiratory effort Pulse oximetry	Electro-cardiogram Air flow 2 respiratory-effort channels Pulse oximetry Peripheral arterial tonometry*	Pulse oximetry Air flow or chest movement
Body position	Documented or objective	Possible	Possible	No
Leg movement	Electro-myogram or motion sensor	Optional	Optional	No
Personnel	Yes	No	No	No
Intervention	Possible	No	No	No

* Became available after 1994.

preference for sleep-laboratory polysomnography. Perhaps an even greater pressure to use sleep-laboratory polysomnography was that, initially, the Centers for Medicare and Medicaid Services (CMS) demanded it by way of a very restrictive reimbursement policy. The private sector was not so constrained, and technological advances led to the commercial availability of portable polysomnographs that produce credible home polysomnograms.

Types of Portable Polysomnograph

As portable polysomnography proliferated, there emerged a need to differentiate the various polysomnography technologies and bring order to the practice. The first practice standards paper from the American Academy of Sleep Medicine (AASM) emerged in 1994.¹⁰ It defined the different types of sleep studies and polysomnographs based on the technology available at that time (Table 1). Type I is a conventional, attended sleep-laboratory polysomnography that includes cardiorespiratory and sleep-stage/neurophysiologic measurements. All the other types of polysomnography are unattended and conducted with portable polysomnographs, and, of these types, only Type II includes sleep-stage/neurophysiologic assessment. Type III has at least 4 recorded parameters, including air flow and 2 respiratory-effort channels. Virtually all the polysomnographs include pulse oximetry and heart rate. Type IV requires only 2 parameters, one of which must be air flow or chest wall movement measurement, so presumably the other is oximetry.

A unique portable polysomnograph (Watch-PAT 100, Itamar Medical, Framingham, Massachusetts) now available (discussed below) utilizes pulsatile arterial tonometry and does not easily fit into any of the original categories,

since there is no direct measurement of air flow or chest wall movement. Presently, none of the types II–IV portable polysomnograph permit an intervention such as CPAP during the polysomnography. Auto-titrating CPAP polysomnography has to be done with a separate portable polysomnograph hookup, or the physician can exclusively use the software available in the chosen auto-titrating CPAP device, without any portable polysomnograph information.

Some of the rules change with respect to diagnostic criteria, but like sleep-laboratory polysomnographs, portable polysomnographs do allow quantification of the severity of breathing disturbances. Instead of the classic apnea-hypopnea index provided by polysomnography as events per sleep hour, a respiratory-disturbance index is reported as events per hour of recording time. The portable-polysomnography protocol assumes that the patient's sleep is the same as or better than usual under the study conditions, but there is no confirmation of this beyond subjective comments by the patient.

History of Portable Polysomnography Approval by Medicare/Medicaid

Portable polysomnographs were developed because of several recognized advantages over sleep-laboratory polysomnography, including sleep in a more familiar and flexible environment (home, mobile in-patient, hotel); fewer monitor leads; more convenience for patients with transportation problems; probably less disrupted sleep; less technical complexity; and lower cost. The ultimate conclusion of the 1994 AASM practice standards was that there was limited scientific information available on the efficacy, accuracy, validity, utility, cost-effectiveness, and limitations of portable polysomnography for OSA assessment.

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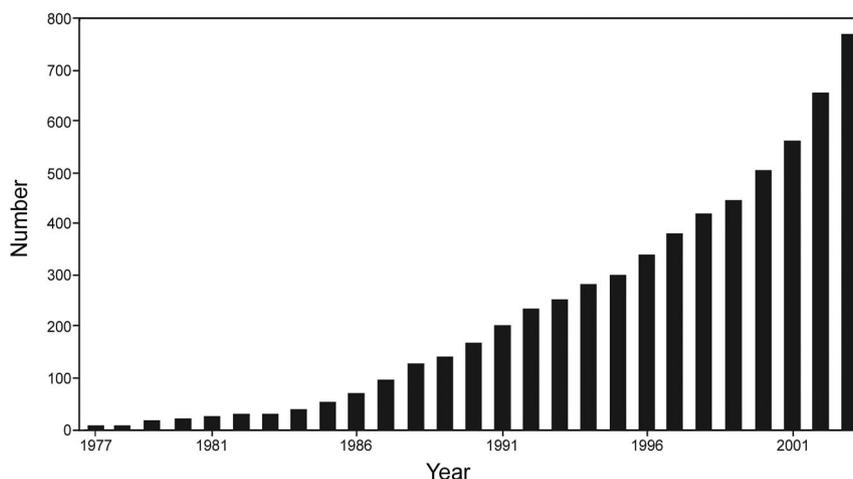


Fig. 1. Number of sleep laboratories accredited by the American Academy of Sleep Medicine from 1977 to 2003. Note the asymptotic rise. The number laboratories in 2006 was near 2,800. (Data from Reference 14.)

Investigations continued, and an international workshop, “Sleep Diagnostics in the Home,” was convened by the American College of Chest Physicians in September 2000, in Chicago. Although some at that conference urged more use of home polysomnography for OSA diagnosis, the convention recommended creating guidelines for home polysomnography for patients with suspected OSA, and that developing the guidelines should be a joint venture of multiple academic societies and be based on an updated formal literature review. The request for proposals for evidence review was made by the American College of Chest Physicians, AASM, American Thoracic Society, National Association for Medical Direction of Respiratory Care, and the European Respiratory Society. This led to the next workshop and a sentinel evidence review¹¹ and the practice standard.¹²

The evidence review¹¹ reviewed 51 studies and found that there was insufficient evidence to recommend type II portable polysomnography, whether attended or unattended. Although attended type III portable polysomnography appeared to increase or decrease the probability that a patient had an apnea-hypopnea index > 15 events/hour, unattended type III portable polysomnography was not recommended to rule in or out an OSA diagnosis. Some limitations were noted, including the need for manual scoring, using portable polysomnography only in patients with straightforward OSA, and that portable polysomnographs are not easily adapted to titrating CPAP or conducting split-night studies. Neither attended nor unattended type IV portable polysomnography was recommended. In essence, this reaffirmed the findings from 1994, and it was urged that future research focus on types II and III portable polysomnography, with a focus on outcomes (rather than just classification of disease severity with arbitrary cutoff values) and on determining the cost-effectiveness of portable

polysomnography. It was not surprising that CMS concluded in National Coverage Decision 240.4, in April 2005, that the evidence was not adequate to conclude that unattended type II, III, or IV portable polysomnography is reasonable and necessary in the diagnosis of OSA, and it therefore remained non-covered for OSA diagnosis.¹³

Pro: Home Polysomnography is Appropriate

What was most surprising was the fact that CMS initiated a review of National Coverage Decision 240.4 at the formal request of the American Academy of Otolaryngology–Head and Neck Surgery in 2007. The AASM dismissed arguments that there were unacceptable delays in accessing polysomnography, as they pointed to an asymptotic rise in the number of sleep laboratories up to 2003 (Fig. 1).¹⁴ The AASM also noted lack of data on the efficacy of home polysomnography in the Medicare population and lack of economic data in support of home polysomnography, as previously noted. Another factor was that the United States Office of Inspector General announced a plan to investigate the factors that contributed to the rapid rise in Medicare reimbursements for sleep studies, from \$62 million in 2001 to \$215 million in 2005.

With the report from the Office of Inspector General, and pressure from industry, caregivers, and the National Coverage Decision review request noted above, the AASM re-reviewed their position and conducted another evidence review,¹⁵ which considered 291 articles, 36 of which met the inclusion criteria. They also added an additional paper, published in 2007, that had important outcome data, so the evidence table included 37 articles: one on type II, 22 on type III, and 14 on type IV portable polysomnography. The evidence table has never been available online, but

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Table 2. Indications for Home Polysomnography Approved by the American Academy of Sleep Medicine

<p>Patient with a high pre-test probability of moderate to severe OSA When sleep-laboratory polysomnography is not feasible because of immobility, safety, or critical illness</p> <p>To monitor response to non-CPAP treatments for OSA, including oral appliances, upper-airway surgery, and weight loss</p> <p>OSA = obstructive sleep apnea CPAP = continuous positive airway pressure</p>
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Table 3. Home Polysomnography Measurement Parameters Approved by the American Academy of Sleep Medicine

<p>Air flow, respiratory efforts, and blood oxygenation, with the same sensors as in sleep-laboratory polysomnography</p> <p>Apnea, with nasal-oral thermal sensor</p> <p>Hypopnea, with nasal-pressure sensor (ideally both air-flow sensors)</p> <p>Respiratory effort, via inductance plethysmography</p> <p>Pulse oximetry: signal average time (≤ 3 s) and motion-artifact compensation</p>
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was sent to us after our request to the AASM central office in Chicago.

The AASM restricted review to type III portable polysomnographs, “because these are used most frequently in the out-patient setting.” Among the studies of type II home polysomnography (of which there were only three, all of which had low evidence levels [IV]), the false negative rate was as high as 15%, and the false positive rate range was 2–31%. Among the studies of type III home polysomnography, the false negative rate was as high as 17%, and the false positive rate depended on the chosen apnea-hypopnea-index threshold. Among the studies of type IV home polysomnography, the “high-quality” home polysomnographies had false negative rates similar to that of type III, and false positive rates of 0–12%.

The AASM made the following new conclusions about home polysomnography:

- Home polysomnography is appropriate for certain indications (Table 2).
- A portable polysomnograph must record certain parameters to be of acceptable quality (Table 3).
- Home polysomnography should be done only in conjunction with a comprehensive sleep evaluation.
- Home polysomnography must be supervised by a certified or eligible sleep-medicine specialist.
- Home polysomnography is not recommended for patients with comorbidities such as moderate to severe chronic obstructive pulmonary disease; neuromuscular disease; congestive heart failure; or other sleep disorders

(eg, central sleep apnea, insomnia, parasomnia, chronic renal disease, or narcolepsy).

- Home polysomnography is neither validated nor intended for screening of asymptomatic subjects.

Following the new recommendations, the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) met on September 12, 2007, where pivotal commentary occurred, such as a realization that the accepted or “gold” standard of sleep-laboratory polysomnography was, apparently, full of “lead.” Studies showed there was pronounced night-to-night¹⁶ and inter-technician variability.¹⁷ The MEDCAC attendees expressed moderate to high confidence that there was adequate evidence to conclude that CPAP is reasonable and necessary for adults with OSA diagnosed via clinical examination that included a positive home polysomnography that measured ≥ 3 channels. MEDCAC published its decision memorandum on CPAP for OSA (CAG-00093R2) on March 3, 2008,

The committee was swayed more by the work done by Mulgrew and colleagues¹⁸ than by any other study, and this was also the paper that the AASM had added in their evidence review of 2007. In that study, there were 81 eligible patients, and 68 were enrolled. They compared the outcomes of 35 patients diagnosed via sleep-laboratory polysomnography to those of 33 patients diagnosed via home polysomnography (conducted with a Remmers Sleep Recorder, SagaTech, Victoria, British Columbia), with 2,135 subjects who had a high pre-test probability of moderate to severe OSA (sleep-apnea clinical score > 15).¹⁹ They excluded those who were not excessively sleepy (Epworth sleepiness score < 10), had prior OSA treatment, used sedatives, or had major cardiovascular or psychiatric disorders. They first performed a type III home polysomnography in all subjects and confirmed a respiratory-disturbance index of > 15 events/hour. They then randomized patients to either sleep-laboratory diagnostic and titration polysomnography or an auto-titrating CPAP regimen in which the patient went directly home with an auto-titrating CPAP device adjusted by the device software and home oximetry as needed. At the end of 3 months, the mean hours of CPAP use was slightly but significantly better in the group who had home polysomnography and went directly to auto-titration with CPAP (6 vs 5.4 h/night), but the clinical improvement in sleepiness and sleep-disordered breathing was virtually identical in all other ways. No cost analysis was done, but the study strongly supported the pathway of home polysomnography and auto-titrating CPAP for highly selected patients.

The portable polysomnograph that uses pulsatile arterial tonometry (Watch-PAT 100), which emerged after the original classification of portable polysomnographs, has 4–6 channels, including pulsatile arterial tonometry, heart rate, pulse oximetry, actigraphy, snoring (optional), and

body position (optional). It was difficult to classify this portable polysomnograph with the 1994 criteria, but it most closely aligned with a type III.

Berry and colleagues compared a clinical pathway with the Watch-PAT 100 for diagnosis and unattended auto-titrating CPAP for selecting an effective CPAP to sleep-laboratory polysomnography for diagnosis and treatment of OSA.²⁰ After 6 weeks of CPAP initiation, 40 patients in the home-polysomnography/auto-titrating-CPAP group, and 39 in the sleep-laboratory arm were using CPAP treatment with no significant differences. Mean nightly adherence to CPAP was nearly identical, at approximately 5.2 hours/night, with equivalent decrease in Epworth sleepiness scale score, and CPAP satisfaction did not differ between the groups. Berry and colleagues concluded that their clinical pathway with the Watch-PAT 100 resulted in clinical outcomes and CPAP adherence that was essentially equivalent to that with sleep-laboratory polysomnography.

In summary, the important question about home polysomnography was best explained by the CMS Coverage Decision Memorandum for Sleep Testing for Obstructive Sleep Apnea (CAG-00405N), posted on March 3, 2009,²¹ which proposed the question, “for which unattended, out-of-facility sleep test technologies is the evidence adequate to determine that sleep testing accurately identifies patients with OSA who will benefit from CPAP treatment?” The memorandum expressed concern that persons with comorbidities associated with OSA may be at more risk than is suspected with home polysomnography, and just because there is presently an absence of evidence of harm does not reliably exclude the likelihood of harm if a rigorous assessment for harm has not been done. Such concerns include the possibility of missing the diagnosis of a non-OSA condition, and potential harm from CPAP, though there is little evidence of harm from CPAP, as those who do not benefit from it typically simply discontinue CPAP.

CMS’s ultimate conclusion was that the evidence is sufficient that home polysomnography can be used to diagnose OSA, and that either sleep-laboratory or home polysomnography followed by CPAP treatment improves outcomes in patients with OSA, so both sleep-laboratory and home polysomnography are reasonable and necessary.

Con: Home Polysomnography is Not Appropriate

Ever since the time of its founding fathers, the United States has prided itself as a nation of progress, particularly in technological advances (eg, the first country to fly an airplane or land a man on the moon). While advances in technology are often beneficial and improve human existence, sometimes technology gets ahead of the needs of the populace. Advances in technology in respiratory care are no exception. Our profession is often guided by advances

in mechanical ventilation, and companies compete to come up with better methods of mechanical ventilation, while the clinician scratches his head as to how and why these might benefit patient care. It is not uncommon that when a new ventilation mode or technology is compared to conventional mechanical ventilation, the latter seems to benefit the patient and is often generally more cost-effective than the new mode or technology. In the field of sleep medicine, home polysomnography for OSA should come under such scrutiny, because the need for home polysomnography is not evident, and there are several myths about the contention that home polysomnography is a better way to diagnosis OSA. To start with, CMS refers to home polysomnography as “home sleep testing,” but none of the typically used portable polysomnographs actually measure sleep. The various professional organizations related to sleep medicine have rightly termed this “portable polysomnography,” but even that is inadequate, as the monitoring is not all-inclusive, certainly when compared to a traditional sleep-laboratory polysomnography attended by a trained sleep technologist.

The number of sleep-laboratory centers has grown substantially since the late 1970s (see Fig. 1),¹⁴ and arose out of a need to identify and treat patients with sleep apnea, not only to improve the quality of their sleep and daytime functioning, but because of the now known contribution of untreated OSA to coexisting illnesses, some of which are life-threatening (eg, diabetes, hypertension, myocardial infarction, and stroke). The growth of the number of sleep laboratories and the identification of patients with sleep apnea cannot be attributed to advances in technology, but, rather, to increased education of health-care professionals and the public on the potential morbidity and mortality associated with untreated sleep apnea. The increase in the diagnosis of sleep apnea is a result of the patient being identified by a physician knowledgeable in sleep disorders, not because there are new technical ways of identifying sleep apnea. It is the expertise in sleep medicine and the associated clinical skills that benefit the patient, before, during, and after the diagnosis, and after a treatment plan is put into place by this knowledgeable physician and sleep technologist—not the technology. There seems to be misguided enthusiasm for more sleep tests, without regard to understanding that, more importantly, we need more sleep physicians. The portable sleep test is only a tool that a skilled physician needs to understand, to know how to interpret, and to use on the patient’s behalf.

Advances in diagnosis and treatment of sleep apnea have occurred largely based on data from sleep laboratories. It is unclear why providing less information to a physician, as is provided by a portable polysomnograph, would aid in better and more reliable diagnosis or care.

Table 4. Myths About Home Polysomnography

Sleep-laboratory polysomnography availability is limited
Change in Medicare/Medicaid National Coverage Decision will increase access to home polysomnography
Home polysomnography is appropriate for all patients
Home polysomnography is more cost-effective
Physician can interpret home-polysomnography results
Patient outcome same as sleep-laboratory studies
Home polysomnography doesn't require an accredited sleep laboratory

(Adapted from Reference 22.)

Myths About Home Polysomnography in Sleep Apnea

There are several myths about the benefits of portable polysomnography (Table 4).²² The principal driving force behind these is seemingly to address the fact that many patients with sleep apnea are not being identified because of the lack of an available sleep laboratory, but that is negated by the substantial increase in the number of sleep laboratories, by all of them being busy, and by the new sleep laboratories appearing in many regions. Because of this, the wait time for getting a sleep-laboratory polysomnography continues to drop, fueled by competition between sleep laboratories in various communities: another example of how competition can improve services.

Proponents have indicated that portable polysomnography is a more cost-effective way to diagnosis sleep apnea. Close examination refutes that claim.²³ Portable polysomnography does not allow for titration of CPAP, the primary treatment for sleep apnea. In contrast, a sleep-laboratory can perform a split-night polysomnography and achieve both diagnosis and CPAP titration in a single study. When you take into account the limited number of variables that can be monitored in portable polysomnography, that a repeat polysomnography often has to be done because of data that cannot be collected in portable polysomnography or because there are less than 4 hours of data, then portable polysomnography does not appear to lower costs.²⁴⁻²⁶

Patient safety has been a major focus in evaluating all advances of medicine. Whereas it appears that portable polysomnographs are not necessarily unsafe, the limited nature of the technology does not allow identifying sleep events that would be identified in a sleep-laboratory polysomnography (eg, malignant arrhythmias). CMS addressed this by stating that they would not reimburse for home polysomnography in patients who have comorbidities such as congestive heart disease, but this does not guarantee safety, as a patient with perhaps nothing more serious than essential hypertension can have malignant arrhythmias that would not be identified by a portable polysomnograph. In addition, a sleep laboratory will identify patients with other

Table 5. Limitations of Home Polysomnography

Risk of data loss
Different software among different portable polysomnographs
Some portable polysomnographs can exclude OSA, some can confirm OSA, and some can do both
Not possible to diagnose disorders other than simple OSA (eg, complex or central sleep apnea, or upper-airway-resistance syndrome)
No measurement of sleep
Not possible to review all the raw data, which is the AASM accreditation standard
False negatives and false positives
Fewer research studies on home polysomnography in females
Best for apnea-hypopnea index of ≤ 5 or ≥ 30 events/hour
Not useful for split-night polysomnography
Unclear how to titrate CPAP
May generate future AASM certification criteria

OSA = obstructive sleep apnea
 AASM = American Academy of Sleep Medicine
 CPAP = continuous positive airway pressure

sleep events that could cause injury (eg, sleep walking, rapid-eye-movement sleep behavior disorder, and seizure). Sleep laboratories occasionally have to call in paramedics or an emergency team to care for patients who develop serious medical problems in the middle of the night.

Limitations of Home Polysomnography

The combined experience of sleep laboratories throughout the country is that sleep apnea is a serious medical disorder that needs appropriate identification and treatment. This finding is based on data from a small number of computer-based sleep-measurement technology products that have served the sleep-medicine field well. How portable polysomnography can improve on that experience is unclear because of the substantial limitations of this technology (Table 5). At recent count, over 30 different portable polysomnographs have come, and some gone, in attempts to capture this market of unidentified sleep apnea patients. The intent is to serve these patients, but portable polysomnography is also a "reduced-expense technology" and thus can be associated with a higher profit margin, which is especially important in a managed-care environment.

Each portable polysomnograph has different software, which the provider needs to understand to realize what the device is and is not measuring. Some are equipped to exclude OSA, some can confirm OSA, and some can do both. The limitations include the fact that data can be lost. In recent studies as much as 14% of the sleep time data was lost.²⁴

In addition, different portable polysomnographs have different sensitivities and specificities that the provider

needs to understand. None of the available portable polysomnographs measures sleep stages, which are measured in a sleep laboratory. While it is standard for a sleep physician to review the raw polysomnography data, these data are not always reviewed from portable polysomnography. Basically, you need to trust that the software will capture the appropriate data. Reviewing the raw data is required to achieve AASM accreditation and receive payment from CMS, so one might wonder how that may be universally achieved.

The available literature on portable polysomnography is limited by the fact that few studies have included women. Essentially none of the studies identified other sleep disorders that may be incidentally found during a sleep-laboratory polysomnography (eg, periodic-limb-movement disorder; complex sleep apnea manifest as a combination of obstructive and central sleep apnea; and respiratory-related arousals, as in the upper-airway-resistance syndrome).

In short, portable polysomnographs are primarily designed to rule in or rule out OSA, focusing on the patient who has less than 5 or more than 30 respiratory events per hour of sleep. This makes the group with 5 to 30 events/hour difficult to identify, which may require a sleep-laboratory polysomnography.

Summary

Whereas portable polysomnography may benefit patients who are unable to come to a sleep laboratory because of infirmity or lack of access, overall this remains a question. The primary message of our assessment is that it is the trained physician who makes the diagnosis, not the polysomnograph, although both are essential in establishing the correct diagnosis. For the future, clinicians will be most usefully guided not by more studies of the technical comparability of home versus sleep-laboratory polysomnography, but by outcomes studies, which should focus most prominently on relief of signs, symptoms, and comorbidities; patient adherence to CPAP; and cost-effectiveness in applicable broader-based populations.

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Discussion

MacIntyre: None of us here are sleep physicians, so we're at a disadvantage in trying to get into complicated questions. I was impressed, Peter; you gave us a wonderfully balanced view. After the first part of your presentation I was convinced that portable polysomnographs are a good thing, and after the second part I was concerned that maybe they should only play a limited role. I was struck that neither you nor Paul is inclined to use portable polysomnographs. Do you see that changing in your practice in the next few years, now that the rules have changed, or are you going to hold out and insist that patients come to the sleep laboratory?

Gay: That's a difficult question to answer for the nation; it's a very easy question for us at Mayo Clinic because of our referral patient populations. For example, if somebody comes to the Mayo Clinic and has to spend \$200 a night waiting in a hotel to discuss their portable polysomnography, as opposed to coming in and the next day they have a diagnosis and a treatment plan. Paul also has that type of referral, although he does more inner-city kind of work, but then those patients have to come a long way; driving from one place to another in Los Angeles is \$50 worth of gas. So putting the onus on the patient to pay more out of pocket is not very appealing to them, especially when you know you're also going to lose quite a bit of money for that.

I'll tell you where I think this practice is going to change: we are gearing up to be able to do portable polysomnographs, because it is a reality. I don't

think it's going to come from CMS. I think it's going to come from large employers that have a lot of young employees with a high likelihood of OSA and who don't need a complete laboratory polysomnography, and they don't want to pay the 90% differential for the sleep-laboratory study. I think we'll be forced to do these mostly by big employers.

MacIntyre: You implied that portable polysomnographs can be used to effectively rule out sleep apnea, or to find it in the very severe forms of sleep apnea. Is it reasonable to use it as a screen, if you will, to diagnose the obvious, to exclude the clearly normal, and refer to you and Paul the ones in the middle?

Gay: I think this is where the treating physician is most important in making the assessment of what side of the scale are they on. The way we use that decision is the assessment of comorbidities and the presence of sleepiness. With a patient who is clearly very sleepy and has some comorbidities, they should go right to the sleep laboratory, because I'm trying to rule in the disease and get to a treatment plan. For someone who's not sleepy and doesn't have substantial comorbidities it would not be unreasonable to do a portable polysomnography, with the higher interest in ruling out OSA and using a very low apnea-hypopnea index for that.

Epstein: Are portable polysomnographs difficult to set up at home?

Gay: It depends on the polysomnograph, but a general technique is mandated by CMS. You must get an ed-

ucational session in a center. With this new ruling—and I've got to get more clarification on this, because it is very surprising to me—they turned this over to the general practitioner. If you're going to have to have somebody who can properly teach these patients to do this setup, I think you'd have 10% failure at the most.

Epstein: Could you mail it to the patient with a CD that describes how to do it, and have them do their own study and mail it in?

Gay: Some protocols are doing that.

Gentile: With turning this over to general practitioners, do you see the prescriptions for CPAP skyrocketing?

Gay: It's going to skyrocket anyway. A huge number of patients have undiagnosed sleep-disordered breathing. Whether they get there through an unacceptable portable polysomnography and are inappropriately put on CPAP is not the right question. I don't think it will be that hard, once we figure this out. I think portable polysomnography is not going to be inappropriately used for a long time if they go this route, because I think there will be protocols whereby we ensure that we do this better, because the patient population gets the word that, "Oh, I did that and it was a complete waste of time," and it is obviously bad if they just end up in the sleep laboratory anyway or never use CPAP again.

Durbin: Clinically, and in the operating environment, I think that undiagnosed OSA is becoming a major concern. Most of these patients will present the day of or within a couple of days of a surgery. Many will have

some findings that suggest OSA. Is there any role for perioperative screening of these patients? How much does the perioperative environment or the postoperative state affect test outcomes?

Gay: We just published a study¹ that looked at a randomized trial that preoperatively used the Sleep Apnea Clinical Score and Ward Flemons's criteria,² which include neck measurement, hypertension, and observed disordered breathing. If you combine those with 2 other features, the importance of first putting them in a risk category helps give you an idea of who's going to desaturate. We also learned to have increased postoperative monitoring to look for desaturation incidences. We've confined this to patients who've had hip and knee replacement, because they're a very uniform population for this, so it allows us to control for that.

The most important predictor for complications, re-intubation, and staying extra days is desaturations and apneic events in the post-anesthesia care unit. We monitor them for 90 minutes, and if they have recurrent desaturation or apneic events, it's important. If they have 2 out of 3 events in a 30-minute epoch, then the odds of a complication are 20 times greater. If they have just desaturation events after they're out of the post-anesthesia care unit, they may be more likely to have some OSA, but they are less likely to have an important complication.

We're asking a different question here. We want to know who's going to have a bad problem. Who might have sleep-disordered breathing that will cause a major event? The next step is what intervention will prevent that?

1. Gali B, Whalen FX, Schroeder DR, Gay PC, Plevak DJ. Identification of patients at risk for postoperative respiratory complications using a preoperative obstructive sleep apnea screening tool and postanesthesia care assessment. *Anesthesiology* 2009;110(4):869-877.

2. Flemons WW, Whitelaw WA, Brant R, Remmers JE. Likelihood ratios for a sleep apnea clinical prediction rule. *Am J Respir Crit Care Med* 1994;150(5 Pt 1):1279-1285.

Sessler: What's the best way to evaluate these non-intubated patients who have chronic respiratory failure, for example, from morbid obesity? How can portable polysomnography be applied in the ICU?

Gay: Let me preface this. There is a difference between trying to prevent postoperative complications in a patient with missed OSA and those who go into, or have a high likelihood of, frank respiratory failure. The patients we're screening for OSA—if, indeed, as you said, they have these positive criteria—you might say, why don't you just put all of them on CPAP? The bariatric surgery group's study¹ was quite positive when putting all of them on CPAP. The difficulty with that is that it's in a monitored study environment.

When we tried to preemptively identify the patients with a high Sleep Apnea Clinical Score and simply said they're going to be randomized to be put on an auto-PAP, about 50% of the time you'll find the patient has removed the mask and it fell to the floor, and then they just have this replaced with supplemental oxygen alone, and then some of them develop hypercapnia on that basis and end up being moved over to noninvasive ventilation.

What's flabbergasting to me is how difficult it is to pick these people out. You look at very obese people who you know have OSA, and you put them on supplemental oxygen, and their saturation is fine, and they sail through it. Someone very similar to that may have a catastrophe, but it's a minority and you can't put everybody in the ICU on a monitor just for that minority. You will after your first lawsuit, but you'll get over it. That's the difficulty. We can't afford to monitor all

these people. But we also can't afford a mistake. How you figure that out in your hospitals is going to be crucial. Our study is an attempt to do that.

1. Huerta S, DeShields S, Shpiner R, Li Z, Liu C, Sawicki M, et al. Safety and efficacy of postoperative continuous positive airway pressure to prevent pulmonary complications after Roux-en-Y gastric bypass. *J Gastrointest Surg* 2002;6(3):354-358.

MacIntyre: Maybe this is oversimplifying it, but an ICU environment has nurses at the bedside. Is that a good enough monitor, or do we have to get something with bells and whistles and electrodes?

Gay: I think observation by somebody who's trained to look for this is excellent. The problem is, how many times do you go into your ICU and ask them if anybody's heard [the patient] snore or saw him obstruct? Nurses aren't trained to focus on obstruction events. If there is desaturation, turn up the oxygen, but the question to ask is, why did it happen? Look for OSA. I have to train nurses to do that.

MacIntyre: Or therapists.

Gay: They're much better at it now, with their protocols.

Siobal: They rescinded the rule that you need a board-certified sleep physician. How's that going to affect the accreditation process? I guess they'll have to change their requirements.

I coordinate the sleep program at San Francisco General Hospital, and we've been using type II and type III polysomnographs for many years during in-house observed sleep studies, and they work fine for us and help us identify patients with really severe OSA and high respiratory-disturbance and apnea-hypopnea indexes. Our waiting list is 5 months, because we're a poor county hospital with a lot of

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uninsured patients, and we're afraid that, with some of them, if we send them home with a device, we'll never see them again.

Gay: That's a real concern. For us, where we have a 24-bed sleep labo-

ratory and don't have strong pressure to do portable polysomnography, we don't have to worry about those problems. In your situation it's a real risk that the laboratory won't see the device again if you just give it to a home patient.

Siobal: On the flip side, if these patients don't get treated, their disease process will progress, they'll develop right-heart failure, and it will hurt everyone in the long run.

Gay: I agree.



Photograph by David J Pierson