Unattended Cardiopulmonary Sleep Studies to Diagnose Obstructive Sleep Apnea

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As the prevalence of obstructive sleep apnea rises, so too does public and professional awareness of the condition and the demand for diagnostic testing, which can be quite costly. Here's how one VA medical center managed to meet the demand despite limited resources.

Obstructive sleep apnea (OSA) is a treatable condition associated with significant morbidity and mortality. About 10% of patients with congestive heart failure have OSA, which is independently associated with systemic arterial hypertension.[1] Untreated OSA is associated with a tenfold increased risk of motor vehicle accidents,[2] an effect that is reversed with treatment.[3]

The most common clinical presentation of OSA is obesity accompanied by excessive daytime sleepiness. About 30% of adults in the United States are obese—that is, they have a body mass index (BMI) greater than 30[4]—and it's estimated that up to 20% of these individuals have OSA.[1] The obesity epidemic, along with a growing public and professional awareness of OSA, has increased markedly the demand for diagnosing and treating this condition.

The conventional means of diagnosing and initiating treatment for OSA is overnight polysomnography (PSG), which is relatively expensive—on average, $1,435 per test at our facility, the Minneapolis VA Medical Center, Minneapolis, MN. In addition to cardiorespiratory monitoring, a standard PSG includes an electroencephalogram (EEG), an electromyelogram (EMG), and an electrooculogram (EOG). Standard PSG testing also requires a trained technician to titrate treatment with continuous positive airway pressure (CPAP) when OSA is detected. Today, however, the technology for limited, unattended, diagnostic cardiopulmonary (CP) sleep studies is available.[5–7] Because the sole purpose of the CP study is to diagnose OSA and not other sleep-related conditions, the CP study does not include EEGs, EMGs, or EOGs, and automated CPAP titration (auto CPAP) devices eliminate the need for an around-the-clock technician.[8–16]

In 2001, resource limitations and a growing demand for PSGs at our facility had resulted in waiting times of more than six months for sleep studies. In response, we piloted a program utilizing CP studies with auto CPAP titration for selected patients.

This article describes our program, its initial diagnostic outcomes, and the results of our six- and 12-month follow-up after CPAP prescription. It also discusses the impact the program has had on the number of sleep studies we perform, our average waiting time for sleep studies, and our sleep study costs since, subsequent to the pilot, we adopted the protocol as our standard approach to all referrals for suspected OSA.

STUDY DESIGN

The study protocol was approved by the Minneapolis VA Medical Center Human Studies Committee (Figure 1). Written, informed consent for the CP study, the auto CPAP titration, and follow-up surveys were obtained from all participants.

A pulmonary physician reviewed sleep evaluation requests. If the information provided suggested a diagnosis other than OSA or severe or unstable CP disease (primarily decompensated right or left ventricular heart failure refractory to medical management), patients were scheduled for pulmonary appointments and referred for PSG testing as indicated. If the information suggested a likely OSA diagnosis, patients were referred for screening by a trained nurse or respiratory therapist, who asked patients whether they experienced excessive daytime sleepiness or had a history of witnessed apnea or snoring. They also used a ques-

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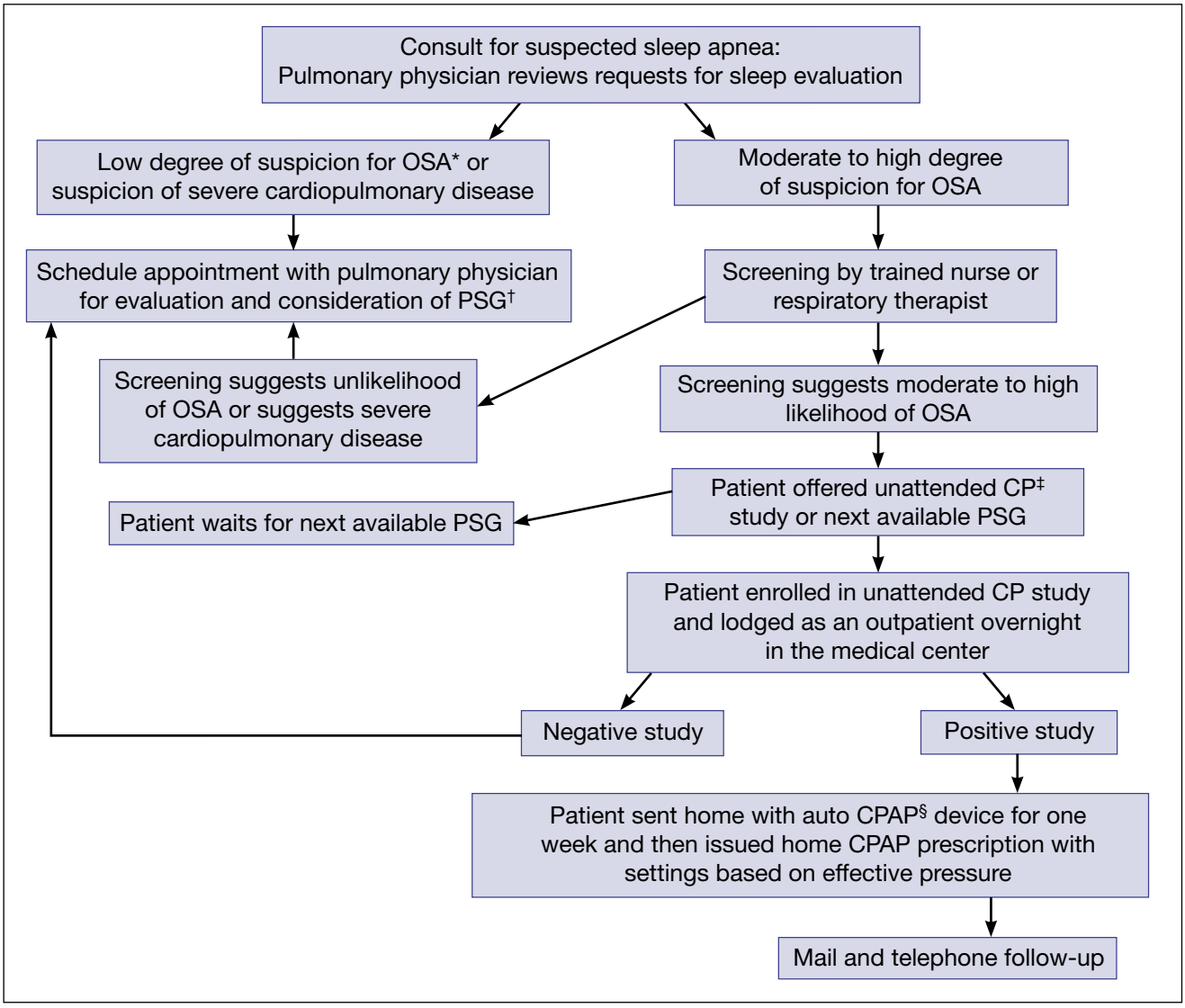

Figure 1. Study protocol for unattended cardiopulmonary sleep studies approved by the Minneapolis VA Medical Center Human Studies Committee. *OSA = obstructive sleep apnea. †PSG = polysomnography. ‡CP = cardiopulmonary. §CPAP = continuous positive airway pressure.

tionnaire to determine patients' Epworth Sleepiness Scale (ESS) scores,[17] sleep symptoms, and sleep schedule (Figure 2). Patients whose symptoms suggested a moderate to high likelihood of OSA were offered a CP study or the option of waiting for the next available PSG. Patients with symptoms suggesting a diagnosis other than OSA and those with severe or unstable CP disease were referred for further consultation with the pulmonary physician and PSG testing as indicated after physician evaluation.

Patients were lodged as outpatients overnight in the medical center for the CP study, which employed a portable diagnostic system (PDS) manufactured by Embletta (Medcare Flaga, Reykjavik, Iceland). The Embletta PDS included an oral thermistor, a nasal flow sensor, a snore microphone, a pulse oximeter, and strain gauges for thoracic and abdominal expansion. The specific parameter for apnea was a flow less than or equal to 10% of the baseline amplitude for a duration of at least 10 seconds; the parameter for hypopnea was a flow less than or equal to 70% of the baseline amplitude with an associated oxygen desaturation of at least 4% for a duration of at least

Name _____ Date _____

Patient Weight _____ Height _____ BMI _____ Shirt collar size _____

EPWORTH SLEEPINESS SCALE
How likely are you to DOZE OFF or FALL ASLEEP in the following situations?

CHANCE OF DOZING OFF

NEVER 0	SLIGHT 1	MODERATE 2	HIGH 3	
☐	☐	☐	☐	Sitting and reading
☐	☐	☐	☐	Watching TV
☐	☐	☐	☐	Sitting, inactive in a public place
☐	☐	☐	☐	As a passenger in a car for an hour
☐	☐	☐	☐	Lying down to rest in the afternoon
☐	☐	☐	☐	Sitting and talking to someone
☐	☐	☐	☐	Sitting quietly after lunch without alcohol
☐	☐	☐	☐	In a car, stopped for a few minutes in traffic

A score of $\geq$ 10 indicates excessive sleepiness.

BRIEF SLEEP SYMPTOM CHECKLIST* (Please check the boxes that best describe you.)

Never	Rarely	Frequently	Always	
☐	☐	☐	☐	My snoring wakes others
☐	☐	☐	☐	I awaken in the morning unrefreshed
☐	☐	☐	☐	I fall asleep behind the wheel of a car
☐	☐	☐	☐	I awaken gasping or choking for breath
☐	☐	☐	☐	I awake with the bedding all twisted about
☐	☐	☐	☐	I have problems falling asleep or staying asleep
☐	☐	☐	☐	I have nightmares, vivid dreams, or sleepwalk
☐	☐	☐	☐	I've been told that I stop breathing in my sleep

SLEEP SCHEDULE
How many hours of sleep do you get a night? _____
Do you have to limit your activity due to sleepiness? [Yes] [No]
Do you nap? [Yes] [No]
How often do you nap? _____ times per week.
How long are the naps? _____ minutes.

Figure 2. Questionnaire used by a trained nurse or respiratory therapist to determine patients' Epworth Sleepiness Scale scores, sleep symptoms, and sleep schedule. *Any answer of "Frequently" or "Always" suggests excessive sleepiness.

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10 seconds. Data from the CP studies were downloaded the morning following the test, screened by a respiratory therapist, and reviewed by a staff pulmonologist.

Patients with a negative CP study—that is, an apnea-hypopnea index (AHI) of less than five events per hour—were referred to a pulmonary physician for consideration of a PSG. Patients with a positive CP study—that is, an AHI of five events per hour or more—were sent home with a REMstar auto CPAP System (Respironics, Inc., Murrysville, PA) and a mask that was custom-fitted by a trained respiratory therapist. The REMstar auto CPAP System adjusts to the patient's pressure needs by analyzing the shape curve of his or her airflow signal and peak flow. Patients used auto CPAP nightly for a week, and then were issued a home CPAP machine with settings based on the pressure that was effective for at least 90% of the trial. All CPAP machines included a humidification system. Patients who refused home CPAP were seen in consultation by the pulmonary physician for consideration of an oral repositioning device or surgery; referral to a board certified polysomnographer for consideration of CPAP desensitization; or, for patients whose oxygen saturation levels were below 90% for more than 10% of the CP study, prescription of nocturnal home oxygen.

ESS scores were measured at baseline and after six months of home CPAP use. Patients who had been prescribed home CPAP were assessed for global sleepiness at 12 months. Specifically, they were asked if their symptoms were: (1) no better, (2) slightly better, (3) moderately better, or (4) much better. Self-reported adherence to the CPAP prescription was assessed at six and 12 months: Patients were asked if they were using CPAP for at least four hours per night on most nights of the week. Follow-up was conducted by mail survey; nonrespondents to the surveys were contacted by telephone.

Statistical analysis was performed with the Microsoft Office 2000 SR-1 professional version of Excel (Microsoft Corporation, Redmond, WA). ESS scores at baseline and at six months were compared by two-tailed student *t* test.

CP studies were performed on 106 patients between August 27, 2002 and April 10, 2003. All patients were male, with a mean age of 59.9 ± 10.1 years (SD; range, 31 to 82), a mean BMI of 33.5 ± 6 (range, 17.7 to 53.1), and a mean ESS score of 13.1 ± 5.2.

APPLYING THE PROTOCOL

Of the 106 patients, 95 (90%) had an AHI of at least five events per hour during the study (mean AHI, 31 ± 24 events per hour). Auto CPAP titration was performed for 92 of the 95 (three patients declined), and home CPAP was prescribed on the basis of these results. Prescribed home CPAP was initiated for 84 of the patients; the other eight who had undergone auto CPAP titration declined home CPAP because they either could not tolerate the mask or believed their symptoms were insufficiently severe to warrant wearing a CPAP mask at night.

The 11 patients who had declined either auto CPAP titration or home CPAP were provided consultation with a pulmonary physician. Afterward, two of them were referred to the otolaryngology service to be evaluated for possible surgery or an oral repositioning device, and one had a repeat auto CPAP titration. At one-year follow-up, one of the remaining eight patients had experienced a resolution of OSA symptoms with a 50-lb weight loss, one had developed severe dementia, two had died, and four continued to decline further evaluation.

CP OUTCOMES SIMILAR TO PSG

Among our patients, improvement in OSA symptoms and long-term adherence to prescribed CPAP was similar to published reports of patients who had undergone conventional PSG testing.[18–23]

Six months after home CPAP was initiated, 82 of the 84 patients who had agreed to use home CPAP were available for follow-up. The other two had died: one in a nursing home six weeks after the CPAP was prescribed, and the other of complications from an emergency abdominal surgery two months after CPAP initiation.

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For the 82 patients provided with home CPAP whose ESS scores were obtained at both baseline and six-month follow-up, mean scores were 14 ± 4.6 and 10 ± 5.6, respectively ($P < .001$). Adherence to prescribed

Continued on page 29

Continued from page 20

CPAP was reported by 69 (84%) of these patients.

At 12 months, we were able to contact only 81 patients (one patient had become homeless and was lost to follow-up). At that juncture, 23% of patients using home CPAP reported that their symptoms were much better; 40%, that they were moderately better; 27%, that they were slightly better; and 10%, that they were not better. Two patients had achieved sufficient weight loss to enable CPAP discontinuation. Of the remaining 79 patients, 59 (75%) reported adhering to prescribed CPAP.

Of the 106 patients on whom CP studies were performed, 11 (10%) had an AHI of fewer than five events per hour. Four declined PSG testing because they considered their symptoms to be insufficiently bothersome. Of the seven who had PSG, two tested positive for OSA—one with an AHI of six events per hour and one with an AHI of 48 events per hour. Both were treated with home CPAP. Five patients had negative PSGs for OSA (with AHIs of less than five events per hour). In one of these five cases, the polysomnographer who interpreted the PSGs and interviewed the patients was strongly suspicious of OSA on clinical grounds. The patient, therefore, had a trial of auto CPAP, which established an effective pressure for a subsequent prescription for home CPAP. The final clinical diagnoses for the remaining four patients who had negative PSGs were depression, insufficient sleep with possible idiopathic hypersomnolence, snoring with minimal daytime symptoms, and insomnia.

COMPARING DIAGNOSTIC ACCURACY

Since PSG testing is considered to be the gold standard for diagnosing sleep-related maladies, the relative accuracy of CP studies with auto CPAP titration in diagnosing OSA is of primary concern. At least 26 trials have compared the diagnostic accuracy of the two methods directly. The sensitivity and specificity of CP studies for the diagnosis of OSA is reported to range from 82% to 94% and 82% to 100%, respectively.[5–7] CPAP titration in the PSG lab has, likewise, been the standard approach. Prior to developing our protocol, we were aware of six randomized trials involving a total of 296 patients that found the two methods to be similarly efficacious.[8–13] Since the development of our protocol, two more randomized trials—one with 360 patients—have reported the equivalence of auto CPAP titration in the home to titration in the PSG lab.[15–16]

Our protocol algorithm specified that patients with a negative CP study be referred for PSG testing, an approach that has been recommended in recently published guidelines.[24] One of our CP studies was clearly a false negative. This is not unexpected, as false-negative rates of 14% to 25% have been reported even with PSG.[25,26] The other patient with a false-negative CP study by our definition had an AHI of six events per hour with PSG testing, a borderline result that probably falls within the intrinsic variability of either test. One patient had CP and PSG studies that were both negative yet went on to receive home CPAP treatment after auto CPAP titration. Although, generally, this approach would not be considered the standard of care, the clinical outcome suggests that both CP and PSG tests should be considered false negatives in this case.

STUDY LIMITATIONS

We did not perform confirmatory PSGs on patients with positive CP studies in order to determine the rate of false positives. There are, however, several lines of evidence that provide indirect support for the accuracy of our positive CP studies. First, the mean AHI from our CP studies was very similar to that reported in published series of patients who had PSGs.[7,27,28] Second, the magnitude of the ESS score improvement in our series is similar to that reported for patients who were prescribed CPAP after a PSG.[18–23,29]

Other limitations included our inability to calculate the diagnostic accuracy of a negative CP study for OSA (since not all patients whose CP study was negative went on to have a PSG) and the fact that all participants were male (reflecting our medical center demographics). Finally, our assessment of long-term adherence to prescribed CPAP, while similar to the results of a recent metanalysis of patients who had PSGs,[9] is not based on objective data but rather on self-report, which could result in an overestimation. We now have the capability to download objective CPAP adherence data from a "Smart Card" that is mailed to the medical center for analysis.

The technology we employed is limited in that CP studies cannot be used to diagnose conditions associated with daytime hypersomnolence other than OSA. When a diagnosis other than OSA—such as periodic limb movement disorder or narcolepsy—is suspected, a PSG with or without multiple sleep latency tests may be required. Although our CP studies were not 100% sensitive for OSA, neither is PSG,[25,26] and the option to perform a subsequent PSG remains if the clinical suspicion for OSA is high.

MEETING A RISING DEMAND

To meet the rising demand for sleep evaluations within the context of

limited resources, we implemented a pilot program of CP studies with auto CPAP titration to diagnose and treat suspected OSA. Cost savings and reduced waiting times with similar clinical outcomes were the primary benefits of the program (Figure 3). After the pilot study, we adopted the program algorithm as our standard approach to suspected OSA.

From 2001 to 2005, the demand for sleep studies increased about 540%, and we met that demand with a total expenditure rise of just over 60%. Despite the sharp increase in demand, the average waiting time decreased from six months to six weeks.

In fiscal year 2001, we performed 264 PSGs, at an average cost of $1,435 per test, for a total cost of $379,000. In fiscal year 2003, we performed 638 sleep studies (522 CP studies, at an average cost of $279 per test, and 116 PSGs, at an average cost of $1,589 per test) for an estimated total cost of $330,000. In fiscal year 2004, we performed 914 sleep studies (780 CP studies, at an average of $279 per test, and 134 PSGs, at an average cost of $1,435 per test) for an estimated total cost of $410,000. In fiscal year 2005, when we faced more than five times the demand level of fiscal year 2001, we performed 1,425 sleep studies (1,256 CP studies, at an average cost of $279 per test, and 169 PSGs, at an average cost of $1,590 per test) for an estimated total cost of $619,134. Total costs include CP study and auto CPAP equipment amortized over 10 years, recurring costs related to supplies and repairs, salaries for 1.5 respiratory therapists and one clerk, and the cost of PSGs performed on patients with negative CP studies and on patients who were deemed inappropriate for a CP study.

Patients with a moderate to high clinical likelihood of OSA who have a CP study with auto CPAP titration have clinical outcomes that are similar to that of patients who have PSGs. This limited, targeted approach has enabled us to meet the growing demand for sleep studies, while markedly reducing waiting times and controlling costs. It also has reduced the overall demand for PSGs, thus making those tests more readily available for patients who are suspected of having OSA but have a negative CP study and for patients who are suspected of having sleep disorders other than OSA. Based on these observations, we conclude that a limited diagnostic approach is reasonable when resources are limited. Ideally, these results would be confirmed in a large, randomized trial comparing CP studies with auto CPAP titration against PSG testing in the diagnosis of OSA. ●

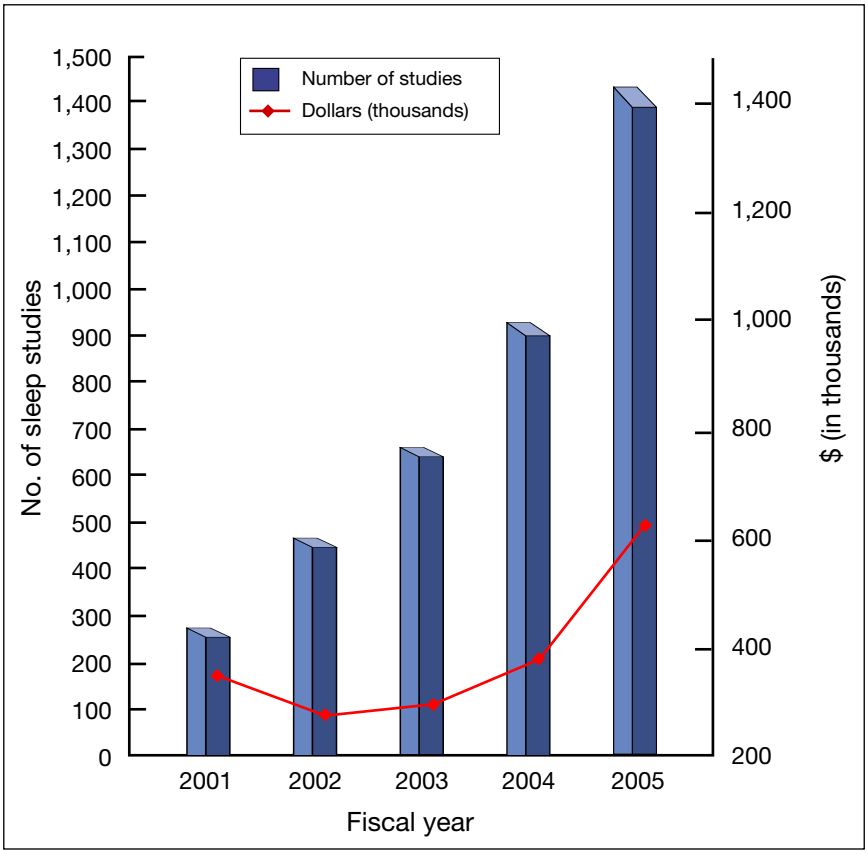

Figure 3. Effects on costs and productivity of implementing an unattended cardiopulmonary sleep study protocol in 2001. The number of studies includes all polysomnograms and unattended sleep studies performed. Dollars represent the total cost of the sleep diagnostic program.

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