

SCIENTIFIC INVESTIGATIONS

Centers for Medicare and Medicaid Services Positive Airway Pressure Adherence Criteria May Limit Treatment to Many Medicare Beneficiaries

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Study Objectives: Centers for Medicare and Medicaid Services (CMS) reimbursement for positive airway pressure (PAP) devices for obstructive sleep apnea treatment is dependent on patients meeting adherence expectations within the first 3 months on therapy. Adherence is defined as usage of the device for at least 4 hours per night on 70% of nights during a consecutive 30-day period. We hypothesize that the adherence pattern may be established beyond this initial period, which may limit the opportunity to treat many patients.

Methods: Treatment and adherence data from PAP devices were monitored via wireless modems for 42 consecutive PAP-naïve military veterans who completed 1 year of nightly monitoring. Their baseline characteristics were as follows: age (mean \pm standard deviation) 58.5 ± 12.5 years; body mass index 33.7 ± 5.7 kg/m²; diagnostic apnea-hypopnea index (pretreatment) 28.1 ± 18.5 events/h; apnea-hypopnea index on PAP: 4.3 ± 3.3 events/h. We examined daily, monthly, quarterly, semiannual, and annual reports, and the best 30-day adherence report for each quarter.

Results: In the first 3 months, 19 of 42 participants were adherent by CMS criteria, and 23 of 42 participants were not. Of the 19 adherent participants, 13 remained adherent and 6 became nonadherent or stopped PAP treatment for the remainder of the year. In the 23 initially nonadherent participants, 16 stopped PAP treatment, and 7 participants (30.4%) became adherent (using CMS criteria) during the rest of the year. Thus, PAP adherence during the first 3 months was predictive for the rest of the year in only 68.4%. PAP nonadherence during the first 3 months was predictive for further nonadherence in only 69.6% of the cases. Overall, this led to a 65% sensitivity and 72% specificity of using adherence at 3 months in predicting adherence at 1 year.

Conclusions: CMS adherence criteria affecting PAP coverage are restrictive and can result in the withholding of therapy in many patients who otherwise might become adherent.

Clinical Trial Registration: Registry: ClinicalTrials.gov, Title: Remote Monitoring in Obstructive Sleep Apnea, Identifier: NCT01678560, URL: <https://clinicaltrials.gov/ct2/show/NCT01678560>

Keywords: Centers for Medicare and Medicaid Services, obstructive sleep apnea, PAP adherence

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Positive airway pressure (PAP) adherence is defined as usage of the device for at least 4 hours per night on 70% of nights during a consecutive 30-day period. We hypothesize that the adherence pattern may be established beyond this initial period, which may limit the opportunity to treat many patients.

Study Impact: Our data show that Centers for Medicare and Medicaid Services (CMS) adherence criteria affecting PAP coverage are restrictive and can result in the withholding of therapy in many patients who otherwise might become adherent. Although pathways to “restart the clock” for CMS exist, repeated testing is expensive, can be cumbersome and discouraging to patients already struggling with this therapy.

Urgent Walk-In to the Sleep Clinic

The patient was distraught. She had just been called by the durable medical equipment company that had supplied her positive airway pressure (PAP) machine that she had to return the device. She had not met Centers for Medicare and Medicaid Services (CMS) adherence criteria. She came to the sleep clinic, without an appointment to ask for help. She was desperate.

The patient is a 43-year-old woman on Medicaid with a history of obesity (body mass index [BMI] 47.9), snoring, wheezing, observed apnea, sleepiness (Epworth Sleepiness

Scale = 15), bipolar disease, and diabetes, who only a few months ago received a first-time diagnosis of obstructive sleep apnea (OSA) with an apnea-hypopnea index (AHI) of 46 events/h, nadir SaO₂ 67% and who spent 49% of sleep time with an SaO₂ less than 90%.

She was started on PAP and thought that she was doing splendidly when she was notified that she had to return her device. She had not met CMS criteria of 4 or more hours of PAP usage per night for 70% of night in a 30-day period. The download in clinic revealed that in the last 30 days she had used PAP 27 nights (90%), but on the average used PAP for 3 hours,

57 minutes and 39 seconds. The computer in PAP system calculated that she did not meet the 70% threshold. Had the patient increased her PAP usage on the average by 2 minutes and 29 seconds nightly she would have been adherent. The fact that she has done splendidly with improvement in her alertness, resolution of the pitting edema, weight loss, and that the AHI on the device was now 0.8 were of no consequence. Rules were rules. In order for her to be restarted on PAP, she would have to be “requalified” by first having an in-laboratory study, issuance of another PAP device, and then waiting for authorization. Patients should never be put into such a medically dangerous situation. Doctors should never be put into such a situation. Both patient and doctor are helpless. This type of story plays out in every large sleep clinic almost every day.

INTRODUCTION

PAP therapy has been the gold standard in the initial treatment of OSA. However, effectiveness is limited to due to poor adherence to therapy. Numerous authors have demonstrated that adherence to PAP is influenced by many factors including disease severity, anatomic features (nasal airways resistance), type of education received, spousal involvement, and degree of clinical support a patient receives in follow-up.¹⁻⁴

The CMS guidelines dictate that the cost of PAP is covered only for the first 3 months after the initial diagnosis of OSA for their beneficiaries. Coverage beyond that period is contingent on adequate adherence to and adequacy of treatment with PAP.⁵ Adherence was defined as using PAP for 4 or more hours per night for at least 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial use. CMS currently does not provide coverage beyond 12 weeks if patients do not meet both (adherence and self-reported clinical improvement) guidelines. When patients fail to meet both these criteria, current care algorithms mandate that the patient have a face-to-face visit with a clinician and have a repeat in-laboratory polysomnogram to “requalify.” This results in a delay of care, increase in healthcare costs, and increased work for the health care provider and the provider of the PAP, generally a durable medical equipment (DME) provider.⁶

The assumption being made is that meeting the CMS guidelines would predict long-term usage and benefit from PAP. Given the complex nature of PAP acceptance, we hypothesize that adherence patterns may be established beyond the first 3 months. Our specific aim was to determine adherence (or nonadherence) within the initial 3-month period and compare it to adherence at 1 year. Remote monitoring of PAP devices allows us to study usage patterns continuously, even when the patient is not able to return for follow-up in a timely fashion. In this study, we provided PAP devices with remote monitoring capabilities to a group of patients to examine patterns of daily adherence over 1 year.

METHODS

Prior to enrollment, patients were seen by a clinician at the Veterans Administration (VA) Hospital in West Haven,

Connecticut. Either a facility-based diagnostic polysomnogram or unattended home sleep testing was performed at the evaluating clinician’s discretion. Clinicians that saw the patient determined whether PAP therapy was needed, and either auto-titrating positive airway pressure (APAP) or set pressures of PAP were ordered for the patient. Patients received education about OSA and about their equipment from a respiratory therapist and physician’s assistant within the VA who then provided the equipment for them. Patients coming to this internal DME provider were screened for participation in the study. This study was registered on ClinicalTrials.gov as “Remote Monitoring in Obstructive Sleep Apnea” trial (Study number NCT01678560). Participants were recruited to be a part of a randomized controlled trial that was terminated. A possible limitation is that participants choosing to enroll in a randomized controlled trial (RCT) may not be representative of all patients; however, the RCT was designed to emulate VA clinical practice with no burden of additional visits for research purposes. Further, monitoring procedures and follow-up care were consistent across participants. The study was overseen by the Institutional Review Board at the Veterans Affairs Connecticut Health Care in West Haven, Connecticut. Informed consent was obtained from all participants.

Patients were included in the study if OSA was diagnosed (defined as AHI > 5 events/h with symptoms, or AHI > 15 events/h), and if they were being exposed to PAP for the first time. Patients who were previously treated with PAP had severe somatic or psychiatric disorders, central apnea, chronic respiratory failure, recent in-patient hospital admissions (≤ 2 weeks), or were living outside cellular network coverage area were excluded from the study.

Patients that met study inclusion criteria were provided ResMed S9 devices with wireless modems. Their usage and treatment data was tracked using AirView, a cloud-based system for the ResMed devices. After the initial setup and educational settings, the patients received supplies as needed and troubleshooting of side effects of treatment as needed. Devices were not removed after 3 months if they were not adherent. We then determined adherence using CMS criteria at 3 months, and at 12 months. To obtain these data, adherence patterns were initially assessed visually (Qualitative) and were confirmed by the analysis of the downloaded reports from the PAP devices (Quantitative). We evaluated whether the PAP devices were used for 4 or more hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial use, and then a consecutive 30-day period in months 4 through 12. We also examined the daily use from the first to last day looking of overall patterns of utilization monthly, quarterly, semiannually, and annually. Data was collected and maintained in a REDCap database. Sensitivity and specificity calculations were then performed to evaluate predictability of adherence at 1 year using adherence at 3 months. Participants who were adherent to PAP use at 3 months and 1 year using CMS criteria were labeled “true positive.” Those patients with nonadherence at 3 months, but became adherent at 1 year were labeled “false negative.” Sensitivity was calculated by dividing true positive over the sum of true positive and false negative results. Participants with PAP adherence at

3 months who became nonadherent at 1 year were labeled false positive. Those who were nonadherent at 3 months and at 1 year were labeled true negative. Specificity was calculated by dividing true negative over the sum of true negative and false positive. Fisher exact test was also used to evaluate the association between adherence at 3 months and 1 year and the association between AHI and adherence.

RESULTS

A total of 262 charts of patients being initiated on PAP were reviewed, and 70 met inclusion criteria. A total of 53 of these patients agreed to participate in the study and signed a consent form. We assessed 42 active participants after 1 death, 2 withdrawals (patient preference) and 8 terminations by the principal investigator (PI). Patients were terminated from the study if they continued to not answer phone calls, letters, or come to visits over a 3-month period of time. Baseline characteristics of our patient population are summarized in **Figure 1**. Overall, these were male military veterans with obesity with moderate OSA, who had reduction in AHI to less than 5 events/h with PAP therapy. We found that PAP adherence during the initial 3 months (using CMS criteria) had a 65% sensitivity and 72% specificity in predicting adherence at 1 year. That is, adherence at 3 months was predictive of adherence for the year in 68.4% of patients. Although there was a strong association between use at 3 months and use at 1 year ($P = .0286$), approximately one-third of patients who were adherent at 3 months were not adherent by the end of the year of use (**Figure 2**).

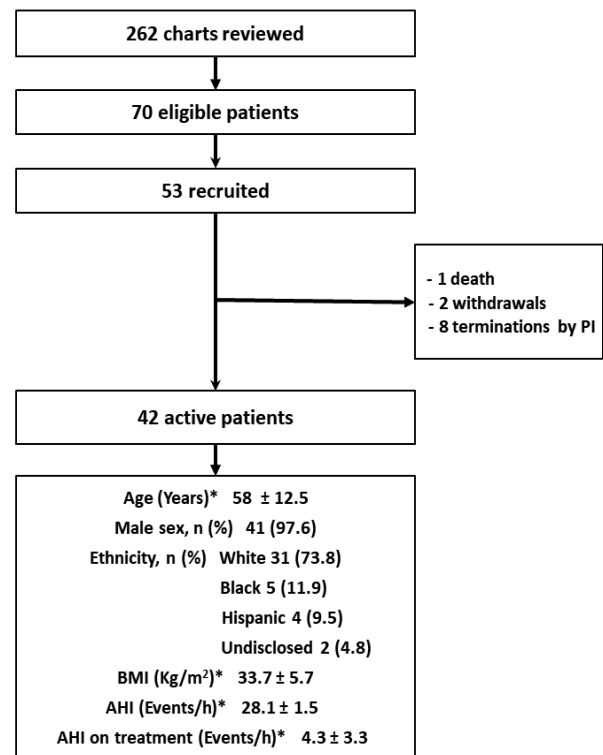
PAP nonadherence was not predictive of further nonadherence in 31.4% of patients. This indicates that about a third of patients who would have had their PAP devices removed would ultimately have learned to use PAP eventually.

We also evaluated the relationship between adherence and AHI and found that patients with an AHI greater than 20 events/h are more likely to meet adherence criteria at least once in a year compared to patients with AHI less than 20 events/h ($P = .0039$) (**Figure 3**).

The determination of adherence using CMS criteria can result in inconsistent, and at times paradoxical outcomes. **Figure 4A** shows 30 consecutive days of data from a patient who was adherent by CMS criteria. **Figure 4B** shows downloaded data from another patient who was nonadherent. The latter patient who actually used PAP for many more hours over the month would have had their device removed.

In addition to the associations previously described, several patterns of usage seemed to emerge as we examined PAP use over the year. Patients were either adherent from the start, periodic PAP users, PAP learners (where adherence started with poor or absent use, and eventually accepted PAP, or patients whose PAP use faded with time becoming ultimately absent. **Figure 5** shows the pattern of the ideal patient who is almost perfectly adherent from the start with some PAP usage every night, and exceeding 4 hours usage almost every night. **Figure 6** shows the pattern of PAP usage almost every night, but occasionally does not meet the 4-hour threshold. **Figure 7**

Figure 1—Study flowchart, and baseline characteristics of the study population.



* = results are reported in mean and standard deviation. AHI = apnea-hypopnea index, BMI = body mass index, PI = principal investigator.

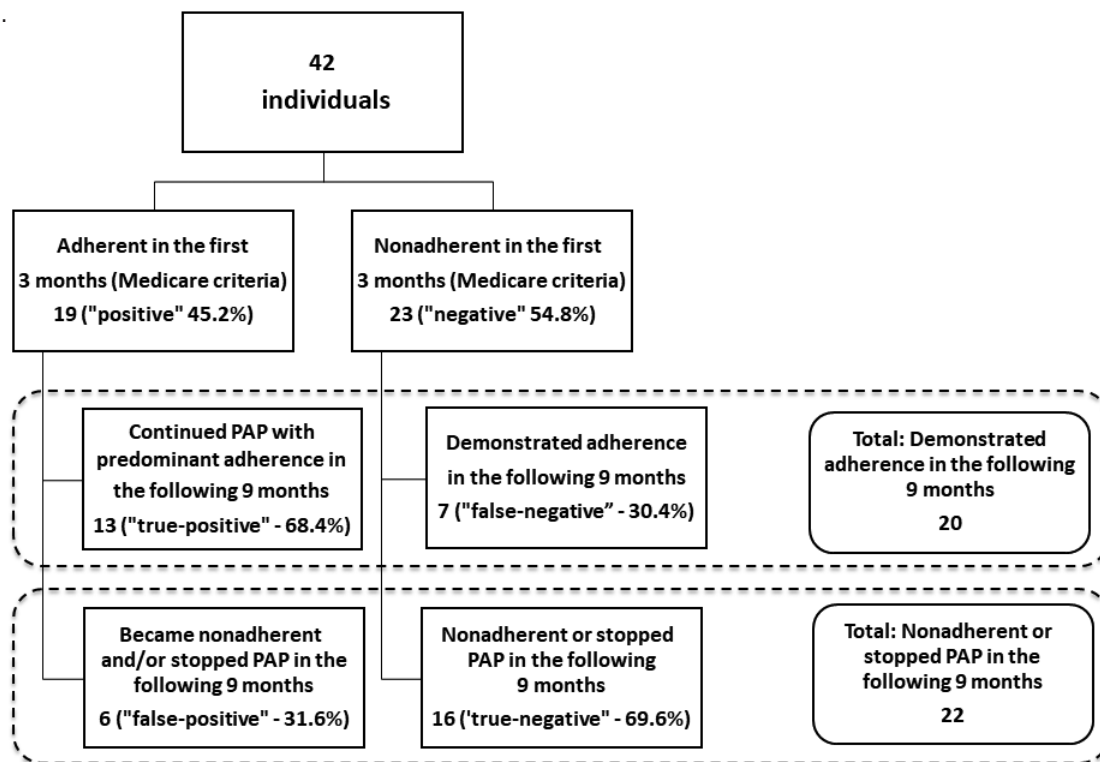
shows patients who begin adherent (and would have met CMS standards for continued payment), but some of who became nonadherent. **Figure 8** shows “PAP learners,” patients that were nonadherent in the first 3 months whose PAP use met adherence criteria during the rest of the year. Finally, **Figure 9** and **Figure 10** shows a pattern of nonadherence over the year.

DISCUSSION

Our study demonstrated that adherence to therapy at 3 months has poor sensitivity and specificity in predicting adherence at 1 year. A large number of patients who might otherwise not meet criteria for continued PAP use by CMS criteria may still learn to use PAP over time. That is, our data showed that although use of PAP at 3 months was predictive of subsequent use in most patients, as many as a third of initially nonadherent patients still learned to use PAP over time.

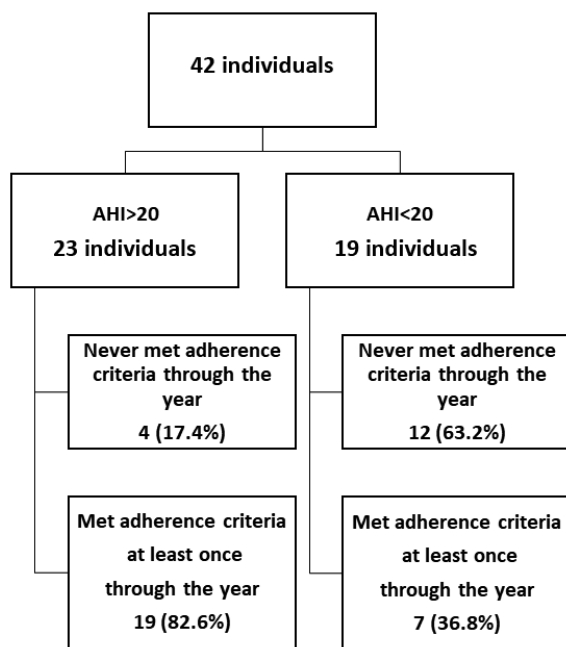
Our study is unique in that it tracks PAP usage behaviors in the initial year after PAP introduction in all users (regardless of the degree of adherence) through wireless technology to demonstrate more long-term patterns of adherence. Advances in PAP devices, now with internal modems, allow practitioners to review usage data (duration and timing of use) and therapy data (including machine-calculated AHI and breath to breath waveform display) as quickly as the morning after use. Many studies have now examined the role of remote

Figure 2—PAP adherence at 3 and at 12 months using the Centers for Medicare and Medicaid Services definition of adherence.



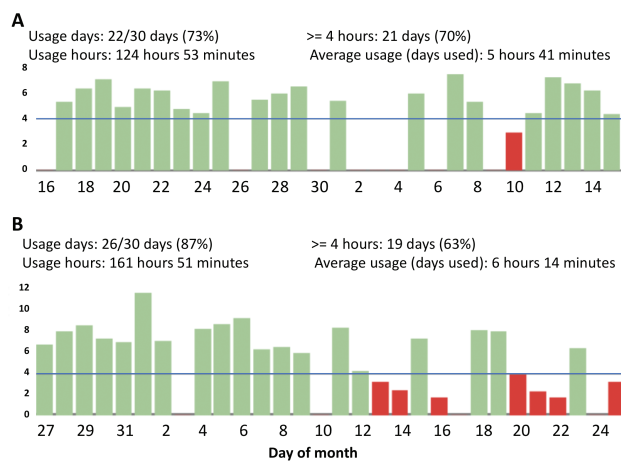
PAP = positive airway pressure.

Figure 3—Positive airway pressure usage of patients with AHI greater than 20 and AHI less than 20.



AHI = apnea-hypopnea index.

Figure 4—Usage patterns.



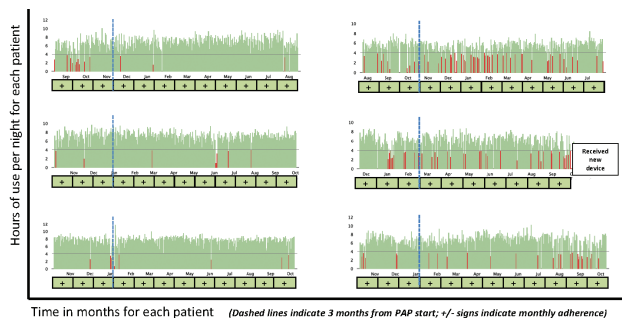
Usage patterns of an adherent patient (A) by Centers for Medicare and Medicaid Services criteria demonstrating fewer hours of total usage than a nonadherent patient (B). The green bars indicate nights of greater than 4 hours of use. The red bars indicate nights when positive airway pressure use was less than 4 hours.

monitoring in the treatment of OSA.⁷⁻¹⁰ However, our study spans the longest duration, allowing us to examine usage behaviors over the year.

Overall adherence rate at 3 months in our study were similar to those reported in the literature.¹¹ We also found a strong association between adherence and AHI, supporting results demonstrated by other authors.^{7,8}

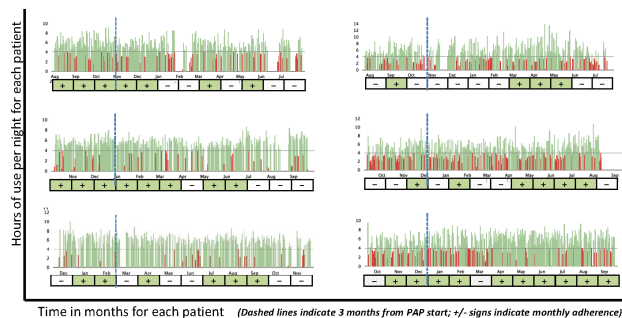
Very few studies have examined long-term adherence patterns as evaluated in our study. Other authors have shown that usage as early as the first few days to weeks of PAP introduction

Figure 5—Adherent from the start.



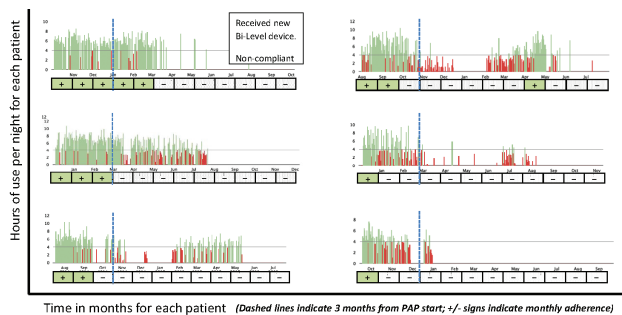
Patterns of PAP use for an entire year for 6 patients who were adherent at 3 months using CMS criteria. The green lines indicate nights of greater than 4 hours of use. The red lines indicate nights when PAP use was less than 4 hours. CMS = Centers for Medicare and Medicaid Services, PAP = positive airway pressure.

Figure 6—Predominant and periodic adherence.



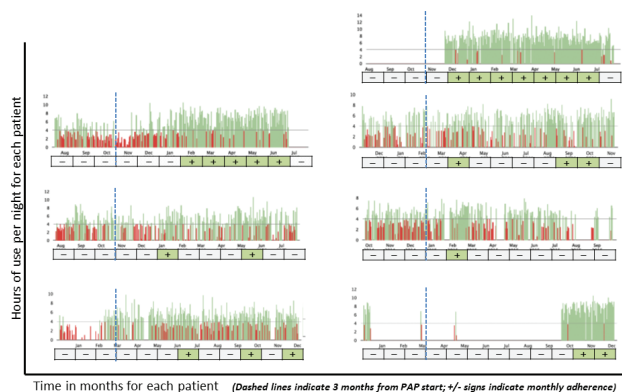
Patterns of PAP use for an entire year for six patients with predominant and periodic PAP adherence through the entire year. The green lines indicate nights of greater than 4 hours of use. The red lines indicate nights when PAP use was less than 4 hours. PAP = positive airway pressure.

Figure 7—Fading adherence.



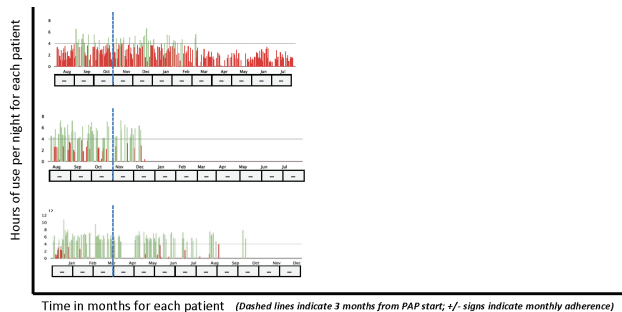
Patterns of PAP use for an entire year for 6 patients whose adherence faded with time and was nonexistent by the end of the year. Some were adherent at 3 months. The green lines indicate nights of greater than 4 hours of use. The red lines indicate nights when PAP use was less than 4 hours. PAP = positive airway pressure.

Figure 8—PAP learners.



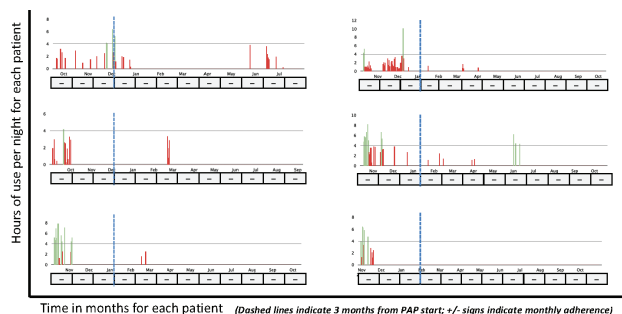
Patterns of PAP use for an entire year for 7 patients whose PAP use improved as the year progressed. None met CMS criteria at 3 months. The green lines indicate nights of greater than 4 hours of use. The red lines indicate nights when PAP use was less than 4 hours. CMS = Centers for Medicare and Medicaid Services, PAP = positive airway pressure.

Figure 9—Nonadherent patients.



Patterns of PAP use for an entire year for 3 subadherent patients becoming nonadherent. The green lines indicate nights of greater than 4 hours of use. The red lines indicate nights when PAP use was less than 4 hours. PAP = positive airway pressure.

Figure 10—Consistently nonadherent.



A pattern of immediate nonadherence. Patterns of PAP use for an entire year for 6 patients who may have made some early attempts but very quickly disengaged. The green lines indicate nights of greater than 4 hours of use. The red lines indicate nights when PAP use was less than 4 hours. PAP = positive airway pressure.

was predictive of adherence at 3 months.^{12,13} One-month adherence was also shown to be predictive of adherence at 3 and 6 months.¹⁴ Our data show that patients who were adherent during the first 3 months were more likely to maintain adherence for the rest of the year.

A study evaluating more long-term adherence by traditional (nonwireless) means by McArdle and colleagues spanned 7

years.¹⁵ In this study, nearly 100% of patients that used PAP more than 4 hours at 3 months still used PAP at 1 year, and over 90% used PAP at 7 years. Of patients who had been using

PAP 2 to 4 hours, about 90% were still using PAP at 1 year and over 40% were using PAP after 7 years. Among those patients who used PAP less than 2 hours nightly at 3 months, about 50% were still using PAP at 1 year, and about 22% were still using PAP at 7 years.

Although much of these data, as well as ours, identify some patients that will be “good PAP users” from the start, there are several reasons to continue treatment of subadherent patients. First, the CMS threshold of adherence was rather arbitrarily chosen, and it has not been demonstrated to have a significant effect on objective or self-reported outcomes. Next, subadherent patients may also have good outcomes. Last, these subadherent patients can become “PAP learners” and meet the threshold for adherence in the long term.

Part of the rationale for the CMS definition of adherence (4 hours for more than 70% of nights) comes from a report examining PAP usage of 35 patients in 1993 by Kribbs.¹⁶ Although the author drew from the classical works describing the physiology of sleep,^{17–19} ultimately, the threshold for adherence was determined based on opinion rather than improvement objective or self-reported outcomes. In the absence of a standardized adherence criteria early on, the Kribbs definition was used in numerous studies,²⁰ and it ultimately came to be used as part of the CMS adherence definition.

A few authors have also shown increasing self-reported and objective improvement in sleepiness and mortality with increasing PAP use, although a 4-hour per night threshold was not specifically identified in their work.^{21,22} In fact, these authors showed improved sleepiness (relative to baseline or controls) even in those patients that were subadherent, or using PAP for less than 4 hours per night.

In the course of our study, we found patients who did not meet the CMS threshold of adherence, but were certainly using PAP for more hours than patients who did meet the CMS definition. For example, there was a patient using PAP for 161.8 hours per 30-day period (**Figure 4B**) who would be nonadherent by CMS definition, whereas a patient using PAP for 124.8 hours per 30-day period (**Figure 4A**) who was considered adherent.

Our study recognizes that there are various patterns of use upon PAP exposure, and even subadherent patients may ultimately learn to use PAP. This supports the findings of McArdle and colleagues that subadherent patients may also have continued long-term use. Treatment of this subadherent population of patients would have been more complex under CMS care algorithms, which would result in withdrawal of PAP until additional clinical evaluation and facility-based testing. This has the unintended effect of delaying treatment, increasing health care costs, and being inconvenient to the patient. This pathway may also discriminate against patients, particularly those of patients of low socioeconomic status, who may not necessarily be able to afford costs (transportation and co-pays) to see the provider again, and be retested.

Based on our study and review of the literature, it is suggested that CMS reevaluate their adherence criteria and treatment algorithms for the care of patients with OSA in order to alleviate barriers affecting patient care and to curb rising health care costs.

Limitations

The authors acknowledge that the sample size was relatively small which, coupled with the fact that the population studied was predominantly male veterans, has implications for generalizability to the broader population.

CONCLUSIONS

CMS adherence criteria affecting PAP coverage have poor sensitivity and specificity in predicting long-term adherence at 1 year; they are restrictive, and can result in the withholding of therapy in many patients who otherwise might become adherent.

ABBREVIATIONS

AHI, apnea-hypopnea index
 APAP, auto-titrating positive airway pressure
 CMS, Centers for Medicare and Medicaid Services
 DME, durable medical equipment
 PAP, positive Airway Pressure
 VA, Veterans Administration

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DISCLOSURE STATEMENT

All authors have seen and approved the manuscript. The authors report no conflicts of interest.