The New Local Coverage Determination Criteria for Adherence to Positive Airway Pressure Treatment

Testing the Limits?

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Background: To our knowledge, the new local coverage determination (LCD) adherence criteria for continued reimbursement of continuous positive airway pressure after 90 days has heretofore not been validated, including the effects of the policy on care for patients with obstructive sleep apnea.

Methods: We examined a retrospective database of 150 patients who received neuropsychologic testing prior to treatment and 3 and 6 months post treatment. We categorized participants using the new LCD criteria. Comparisons of neuropsychologic variables were made between adherent and nonadherent groups.

Results: Fifty-five participants (37%) failed to meet the new criteria, although this number may not reflect the actual rates of adherence in clinical settings because some efforts beyond standard care were made to ensure adherence to treatment among many of the participants. Of the 50 patients who did not receive any special adherence intervention, only 28 (56%) met the criteria. On most measures, patients with poor adherence demonstrated neuropsychologic improvements similar to their adherent counterparts. Nonadherent patients realized additional improvements in working memory between 3 and 6 months post treatment.

Conclusions: This study highlights the potential effects of the new criteria for adherence on patients with obstructive sleep apnea and their clinical care. These data were taken from a study that was not designed to examine these criteria, so controlled trials are needed to better understand the effect of the guidelines on adherence and treatment outcomes.

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Abbreviations: ANOVA = analysis of variance; CPAP = continuous positive airway pressure; HVLt-R = Hopkins Verbal Learning Test-Revised; LCD = local coverage determination; OSA = obstructive sleep apnea; PAP = positive airway pressure; PASAT = Paced Auditory Serial Addition Test

Obstructive sleep apnea (OSA) is a serious health problem with both medical and psychologic consequences.¹ Positive airway pressure (PAP) is the most common treatment of OSA. Adherence rates are low, however. Recently, all four Durable Medical Equipment Medicare Administrative Contractors

decided to base local coverage determination (LCD) criteria for reimbursement of PAP on demonstrated, objective adherence. The new criteria state:

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“Continued coverage of a PAP device beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy,

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the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:

1. Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,
2. Objective evidence of adherence to use of the PAP device, reviewed by the treating physician.

Adherence to therapy is defined as use of PAP greater than or equal to 4 h per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.”

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not medically necessary. Beneficiaries who fail the initial 12-week trial are eligible to requalify for a PAP device but must have both:

1. Face-to-face clinical reevaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and,
2. Repeat sleep test in a facility-based setting (type 1 study).

This definition has never been examined empirically. The goal of this article was to determine the relative outcome of the application of these guidelines on clinically relevant outcomes using a sample of archival data.

MATERIALS AND METHODS

The study being retrospectively analyzed (NIH RO1 HL67209) consisted of 150 participants newly diagnosed with OSA and recruited consecutively from the Sleep Disorders Center of Lifespan Hospitals of Rhode Island. All participants were treatment naïve prior to initiation of PAP treatment. Eligibility for participation included age 25 to 85 years, polysomnography-derived diagnosis of OSA, English speaking, lack of serious comorbid medical conditions (eg, renal failure, congestive heart failure, neurologic condition), and no previous treatment with PAP. The apnea-hypopnea index, an index of the number of apneas plus hypopneas per hour of sleep, provided a measure of OSA severity. Apneas and hypopneas were scored using American Academy of Sleep Medicine Task Force recommended guidelines,² with hypopneas defined as a 10-s 30% to 50% drop in nasal pressure airflow associated with a 4% drop in oxygen desaturation and/or American Sleep Disorders Association-defined arousal from sleep. An apnea-hypopnea index of 15 events per hour served as the lower limit for entry into the study. Fifty participants in the study were delivered a two-session educational intervention designed to improve adherence to treatment. This intervention included a discussion with a nurse clinician on the management of OSA and the proper use of PAP, as well as a detailed discussion about the pathophysiology of OSA and the potential consequences of the disorder. Another 50 participants were delivered a motivational

intervention designed to improve adherence. This intervention followed the tenants of motivational interviewing, a psychological approach to encouraging behavior change in patients. Patients were involved in discussions with a nurse clinician about the importance of using PAP and their confidence that they could adhere to prescribed use. The data from these interventions and a full description of them are presented elsewhere.³ All participants underwent a neuropsychologic assessment prior to PAP initiation (baseline), and again at 3 and 6 months posttreatment. Specifics about eligibility, diagnosis, and titration are explained elsewhere.⁴

Adherence Monitoring

Adherence was monitored using the Smart Card technology provided with the REMstar Pro continuous PAP (CPAP) machines (Respironics, Inc; Murrysville, PA). The devices were set up and maintained through a single home health-care company. This microprocessor detected the amount of time that the CPAP operated at the proper pressure, suggesting that the device was properly affixed to the face of the patient, and reported the results as the total number of hours of therapy at the prescribed pressure. Adherence data were downloaded from the PAP devices at each follow-up. We applied the new LCD criteria to the daily adherence data, resulting in adherent and nonadherent groups. The decision was made a priori not to inform participants that their PAP use was being monitored unless they asked for this information directly; however, this did not occur for any participants in this study.

Procedures and Measures

Neuropsychologic Evaluation: All testing was administered by trained research assistants who were blind to apnea severity and adherence and who were not involved with participant clinical care. All measures included alternate forms, where available, to minimize the effects of practice on test performance. Finally, all measures had met high standards for reliability and validity in previous testing. The measures follow.

Trail-Making Test Part A: This test is designed to measure visual search and attention. The dependent variable is the time to completion. Lower scores indicate more rapid attentional processes.⁵

Paced Auditory Serial Addition Test: This is a test of rapid serial addition of a list of numbers heard on audiotape. The test is designed to assess vigilance and working memory. The dependent variable is the total number correct across four trials. High scores are indicative of better functioning.⁶

Controlled Oral Word Fluency Test: This test is designed to measure rapid word generation. The dependent measure is the total number of exemplars generated. High scores denote good word retrieval.⁷

Trail-Making Test Part B: This test is designed to measure visual search and set-shifting abilities. The dependent variable is the time to completion. Lower scores indicate more rapid attentional processes.⁵

Hopkins Verbal Learning Test-Revised: This test is designed to assess verbal-list learning, free recall, and recognition memory. This test yields dependent measures of the total number of words acquired over three learning trials and the number of words recalled following a delay. Higher scores denote good memory and recall.⁸

Epworth Sleepiness Scale: This scale is the most widely used subjective measure of daytime sleepiness in the clinical setting. The dependent variable is the total score, with higher scores indicating excessive sleepiness.⁹

Statistical Analysis

Analyses were conducted using SPSS, version 17.0, statistical software package (SPSS Inc; Chicago, IL). We used 2×2 repeated-measures analyses of variance (ANOVAs) with group and time serving as the independent variables and each test score serving as a dependent variable. Eight ANOVAs were run in total, with Bonferroni adjustments for multiple comparisons ($P < .00625$). These analyses speak to the differential rate of improvement among the groups over the period of the first 90 days, when adherence would be monitored under the new guidelines. Three-way repeated measures ANOVAs were employed for the nonadherent group only to identify differences in the changes in functioning from 3 to 6 months ($P < .00625$). This represents the period when individuals could have had their devices deemed not medically necessary.

RESULTS

Nine participants did not complete all assessments. We used a completer analysis because we were only interested in the cognitive changes associated with documented levels of adherence (Table 1). From this sample ($N = 150$), 55 participants (37%) failed to meet the new LCD criteria for adherence. This number may not reflect the actual rates of adherence in clinical settings because some efforts were made to ensure adherence to treatment among many of the participants. Twenty-two participants (44%) those receiving only standard care for adherence to PAP (eg, no individual time with a PAP adherence specialist) failed to meet the new criteria. Table 2 shows the means and standard deviations for each dependent variable over time and by group.

Table 1—Demographic and Disease Severity Measures for Local Coverage Determination-Defined Adherent and Nonadherent Groups Among Standard Treatment Group From Original Study

	Adherent, Mean (SD) (n = 95)	Nonadherent, Mean (SD) (n = 55)	t Value	P Value
Age, y	53.6 (10.9)	50.6 (11.4)	1.08	.28
Education, y	15.2 (2.5)	14.8 (2.7)	0.52	.61
BMI	34.2 (8.6)	36.8 (8.3)	-1.18	.24
AHI	38.9 (19.9)	49.2 (28.5)	-1.57	.12
% time below 90% O ₂	19.6 (18.6)	34.7 (32.8)	-1.87	.07
PAP pressure	9.8 (2.6)	10.9 (3.0)	-1.30	.20
ESS	11.9 (4.8)	12.3 (4.7)	-0.30	.77
Avg h used 3 mo	5.57 (1.6)	1.71 (1.3)	10.2	.00
Avg h used 6 mo	5.51 (1.6)	2.00 (1.8)	7.76	.00

AHI = apnea-hypopnea index; Avg = average; ESS = Epworth Sleepiness Scale; PAP = positive airway pressure.

Baseline to 3 Months

Most dependent variables demonstrated a main effect for time with improvements in the outcome made between baseline and 3 months (Fig 1). Only delayed recall on the Hopkins Verbal Learning Test-Revised (HVLTR) did not meet the Bonferroni-adjusted P value, demonstrating a P value of .01. No variable demonstrated a main effect for group. No interaction met the adjusted P value, but one (the total score on the Paced Auditory Serial Addition Test [PASAT]) was significant at the $P < .03$ level. This suggests that individuals who were more adherent improved more on the PASAT than those who were less adherent, but these results did not meet our Bonferroni-adjusted P value. However, improvements were noted in both groups over time.

Improvements From 3 to 6 Months in the Nonadherent Group

Only one test demonstrated any change, in either direction, between 3 and 6 months of treatment in the nonadherent group. The total score on the PASAT test continued to improve in nonadherent patients over the next 3 months of treatment ($P < .005$).

DISCUSSION

Four primary findings from this study are notable. First, a significant portion of participants failed to meet the new standards in our sample and would have either had their PAP coverage discontinued or been required to undergo further sleep evaluation. An additional evaluation could come at considerable expense, with a full night of monitored polysomnography

Table 2—Outcome Variables by Group Over Time

	Baseline	3 Months	6 Months
Adherent users			
Trails A, min	31.7 (12.8)	27.4 (9.8)	27.2 (10.2)
Trails B, min	72.1 (31.7)	66.0 (28.7)	63.7 (29.0)
COWA total	40.8 (11.8)	42.8 (12.9)	43.6 (13.3)
PASAT total	117.6 (40.1)	131.6 (37.4)	138.8 (36.9)
HVLT total recall	25.4 (5.3)	26.6 (4.7)	28.0 (4.7)
Delayed recall (/12)	9.1 (2.3)	9.6 (2.0)	9.7 (2.1)
ESS total	11.7 (4.8)	8.9 (4.1)	8.7 (4.3)
Nonadherent users			
Trails A, min	30.5 (14.3)	28.3 (11.0)	28.0 (12.8)
Trails B, min	77.9 (49.2)	68.5 (44.7)	64.7 (38.3)
COWA total	40.5 (12.6)	42.0 (12.7)	44.5 (12.7)
PASAT total	124.4 (36.6)	133.6 (44.8)	140.4 (45.9)
HVLT total recall	25.4 (4.7)	27.2 (5.0)	28.0 (4.9)
Delayed recall(/12)	9.0 (2.4)	9.4 (2.5)	9.5 (2.1)
ESS total	11.4 (5.0)	9.0 (4.3)	8.5 (4.6)

Data are presented as presented as mean (SD). COWA = Controlled Oral Word Fluency Test; HVLT = Hopkins Verbal Learning Test; PASAT = Paced Auditory Serial Addition Test. See Table 1 for expansion of other abbreviation.

Adherent:

Non-adherent:

FIGURE 1. Changes in cognitive scores with time by adherence group. Note that lower scores reflect improvement on the Epworth Sleepiness Scale and trail-making test parts A and B. COWA = Controlled Oral Word Fluency Test; HVL T = Hopkins Verbal Learning Test; PASAT = Paced Auditory Serial Addition Test.

and possibly a more sophisticated PAP device. Whether a repeat sleep study would uncover any underlying cause for nonadherence remains unclear. Second, there were no obvious differences between patients with poor and good adherence based on demographics or disease-specific measures. Third, patients with poor adherence demonstrated improvements similar to their adherent counterparts on most outcome measures. Finally, gains in working memory were realized in the nonadherent users from 3 to 6 months when they were allowed to keep their devices, suggesting a cumulative effect of treatment. These gains may not be realized under the new guidelines, and decrements could be realized with the removal of treatment.¹⁰

The finding that improvements were made almost equally in both groups from baseline to 3 months might seem contrary to recent studies demonstrating greater improvement and normalization of function with higher levels of PAP use. It is true that greater levels of use have been demonstrated to result in greater improvements. This does not mean, however, that limited use carries with it no benefit. In fact, Campos-Rodriguez and colleagues^{11,12} demonstrated reduced cardiovascular morbidity and mortality in individuals using PAP 2-5 h a night compared with those using ≤ 1 h a night. Additionally, Weaver et al¹³ found that the Epworth Sleepiness Scale scores normalized after only 4 h of average nightly use, and Bennett and colleagues¹⁴ found no correlation between

CPAP adherence and change in health status. Although the best outcomes were consistently obtained with high use, each of these studies illustrated improvement (or a relatively equal potential for improvement) in individuals who would be classified as nonadherent under the new criteria.

The gains in working memory with minimal adherence from 3 to 6 months could be attributed to increased familiarity with the test. Indeed, both groups improved on this test from 3 to 6 months. However, adherent users were also receiving greater doses of treatment. We would argue that practice effects would be minimal between the second and third testing, especially when separated by 3 months, and would not be specific to memory only. Moreover, previous studies using such neuropsychologic tests have demonstrated resistance to practice effects.¹⁵

This study highlights the potential negative effects of the new LCD guidelines for adherence on patients with OSA. Even in light of these findings, many may assume that these new guidelines serve the role of enhancing adherence to treatment given the potential consequences of nonadherence (ie, losing one's PAP device). This assumption operates on the premise that the potential loss of the device is a factor that could change behavior. There are no data to support this. It is more likely that physicians will feel compelled to ensure that their patients are adherent to treatment. Adherence studies, however, have demonstrated that a physician's desire to change his/her patient's behavior is not sufficient to result in dependable behavior change.

There are several limitations to this study. The study was not designed to specifically test the LCD criteria or the opportunity for requalification after a failed 90-day trial. It is possible that adherence rates could increase under the operating guidelines. It also did not specifically test the effects of the adherence criteria on Medicare patients, who are likely older than the participants in this trial. The study also did not employ a no-treatment control group. The potential of these guidelines to remove treatment from patients, however, required a rapid assessment of their potential effects. These archival data suggest some clinical benefit of any adherence and serve as a reasonable baseline of adherence to these guidelines against which future studies can compare.

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Dr Aloia: contributed to data analysis and preparation of the manuscript.

Mr Knoepke: contributed to data analysis and composition of the manuscript.

Dr Lee-Chiong: contributed to composition and editing of the manuscript.

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