

# Compliance With Nasal CPAP Can Be Improved by Simple Interventions

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**Summary:** Effectiveness of continuous positive airway pressure (CPAP) as a treatment for obstructive sleep apnea can be limited by poor compliance, but little is known about how to improve compliance. We performed a randomized, controlled clinical trial among 33 subjects of two interventions to improve compliance. One group of subjects received weekly phone calls to uncover any problems and encourage use, another received written information about sleep apnea and the importance of regular CPAP use, and a third served as control subjects. We found that intervention improved CPAP compliance ( $p = 0.059$ ) and that the effect was particularly strong when intervention occurred during the first month of CPAP treatment ( $p = 0.004$ ). Although the sample size did not allow definitive investigation of other explanatory variables, subjects with lower levels of education or those with relatives who used CPAP may have benefited from intervention more than other subjects. We conclude that simple, inexpensive efforts to improve compliance with CPAP can be effective, especially when applied at the start of CPAP treatment, but optimal intervention may vary with certain patient characteristics. **Key Words:** Obstructive sleep apnea—Continuous positive airway pressure—Compliance—Clinical trial.

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Continuous positive airway pressure (CPAP) administered through a nasal mask was first shown to be an effective treatment for obstructive sleep apnea (OSA) in 1981 (1). Since then, CPAP has become the most common treatment for OSA. For many patients who use it at home regularly, CPAP eliminates apneas and hypopneas, improves sleep architecture, and reduces daytime sleepiness. However, the effectiveness of CPAP is limited by incomplete patient compliance. Initial studies used questionnaires to demonstrate that 75% or more of patients who were prescribed CPAP could be considered compliant (2). Although one subsequent study with built-in time counters confirmed these findings (3), others found lower compliance rates (4-6). The amount of CPAP use reported by patients often exceeded that recorded electronically, especially in those patients with the lowest objectively measured compliance (4-7). For example, in one study 60% of the patients reported that they used CPAP nightly, but counters showed that only 46% used it for at least 4 hours on 70% of monitored nights (4).

In part because of poor patient compliance with CPAP, physicians have developed alternative treatments, such as surgery and oral appliances, but these

create some morbidity and are not always effective (8-11). Few investigators have reported the results of efforts to improve compliance with CPAP. Fletcher and Luckett (12) performed a prospective, randomized, crossover study of the effect of frequent positive reinforcement by phone: they were unable to show any improvement in compliance with this intervention. The authors did not study whether there was any difference in outcome between patients who were new to CPAP and those continuing use at the time intervention was attempted.

To examine the possibility that we could improve CPAP compliance in patients with OSA, we performed a randomized, controlled trial in which we compared CPAP use among subjects who received an intervention consisting of frequent phone calls, an intervention consisting of brief written information about CPAP, or neither intervention. To study the importance of the timing of our intervention, we compared subjects who were new to CPAP to those who were not. This work has been reported in preliminary form (13).

## METHODS

### Subjects

Subjects were recruited in July and August 1995 from the Sleep Disorders Clinic at the University of Michigan. Recruitment took place on prescheduled

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days according to the availability of one of the investigators (S.T.), who approached each OSA patient about to start CPAP or continue on CPAP. Patients with bilevel positive airway pressure (BPAP) were included. Fewer than one quarter of patients who were approached declined to participate or had not been prescribed a CPAP unit with a built-in counter. The remainder signed informed consent and enrolled in the study. Of the 40 enrolled subjects, five were impossible to reach by phone to establish counter readings and two reported counter readings that were physically impossible, leaving 33 subjects (21 men) aged  $51.7 \pm 11.0$  years [mean  $\pm$  standard deviation (SD)] who completed the protocol and formed the basis for this report. This study was approved by the Institutional Review Board at the University of Michigan Medical Center.

### Explanatory variables

Upon enrollment, each subject completed a self-administered Epworth sleepiness scale (ESS), a validated measure of daytime sleepiness (14,15), and a brief questionnaire concerning whether the subject had CPAP at home or was just starting CPAP, the level of education attained, the subject's occupation (subsequently classified as blue collar, white collar, or other), the approximate family income (within six categorical levels), whether the subject lived alone, whether the subject understood "what CPAP is and why [he or she] needs it", and whether the subject had a close friend or relative who had used CPAP. Additional variables, obtained through polysomnography, included apnea/hypopnea index (number of apneas and hypopneas per hour of sleep), lowest oxygen saturation recorded, CPAP pressure assigned after a CPAP titration study, and (for most patients) mean sleep latency on a multiple sleep latency test (MSLT) (16).

On the basis of a random number table, each subject was assigned to one of three intervention groups. Subjects in group 1 received one telephone call each week (5–9 days) from one of the investigators. During these calls subjects were asked whether they had any problems with CPAP and were encouraged to use it nightly. Subjects who reported problems that required the attention of a physician were put in contact with the appropriate individual.

Group 2 subjects received two printed documents immediately after randomization. One was a pamphlet, designed for patient education and available through the American Sleep Disorders Association, entitled "Sleep Apnea and Snoring" (17). This pamphlet describes the symptoms, diagnosis, and treatment of sleep apnea and includes a short section on CPAP and another on good sleep habits. Group 2 subjects also

received a one-half-page document written by the authors and entitled "Guidelines for CPAP (or BiPAP) Use". These guidelines, reproduced in the Appendix, include an explanation of when to use CPAP, of the benefits of CPAP use, and of remedies for common problems with CPAP. The guidelines also remind the patient not to stop use of CPAP without contacting the Sleep Disorders Center.

Group 3 subjects received no additional intervention to improve compliance. All subjects were recruited only after visiting a sleep medicine physician, who therefore was unaware of study participation or group assignment at the time of the visit. Clinic physicians gave all subjects verbal explanations of what CPAP does, the expected benefit, and the need for regular CPAP use, and no modification of this practice was instituted during the study period.

### Outcome variable

Subjects read built-in counters on their CPAP machines and reported results by phone at two times: first at enrollment into the study and then again between 1 and 2 months after enrollment. The number of hours of CPAP use was then divided by the number of days elapsed between the two readings to obtain the mean number of hours of use of CPAP per night (compliance).

Twenty-six of the 33 subjects (79%) and a majority of those in each intervention group used the same type of CPAP machine (REMstar Choice, Respironics Inc., Murrysville, PA). One subject in each of the three groups used the Healthdyne Quest (Healthdyne, Inc., Marietta, GA), and four subjects used four other types of machines made by the same two companies. Counters in the Respironics machines registered "machine-on" time, whereas those in the Healthdyne machines registered the amount of time the patient breathed through the mask. The latter quantity does not differ greatly from the former on average (4), and the subjects with Healthdyne machines (four) were spread among the three groups, so outcome data were combined without respect to brand of CPAP machine.

### Data analysis

Data were entered into a database using StatView (Abacus Concepts, Inc., Berkeley, CA) and analyzed using that software and SAS (SAS Institute Inc., Cary, NC). Several tests of normality of the outcome variable "compliance" (number of hours of CPAP use per night), including skewness, kurtosis, a box plot, and a normal probability plot, revealed no substantial deviation from a normal distribution. Parametric analyses

**TABLE 1.** Characteristics of all subjects, those in each intervention group, and those in the control group

Variable	All subjects	Phone calls	Literature	Controls
N	33	12	14	7
New/cont.	10/22	5/7	3/11	2/5
Age	51.7 ± 11.0	53.8 ± 11.7	52.9 ± 10.7	45.7 ± 9.5
% Male	64	67	71	43
Education	14.1 ± 2.8	13.2 ± 3.0	14.4 ± 2.3	14.9 ± 3.3
Days	40.8 ± 11.9	38.7 ± 13.5	42.2 ± 11.3	41.7 ± 11.3
AHI	49.4 ± 38.9	57.2 ± 48.7	54.3 ± 33.7	27.3 ± 25.3
Lowest O2 saturation	75.6 ± 14.4	78.1 ± 15.0	69.3 ± 14.8	84.3 ± 6.2
MSLT <sup>a</sup>	6.0 ± 3.9	4.5 ± 2.6	6.6 ± 3.4	6.5 ± 5.5
ESS	10.9 ± 5.1	11.5 ± 5.5	12.4 ± 5.3	7.8 ± 2.9
CPAP setting	8.8 ± 3.7	8.8 ± 4.6	9.6 ± 3.6	7.1 ± 2.0

The differences in listed variables between groups were not statistically significant. N, number; New/cont., new to vs. continuing on CPAP; age, mean ± standard deviation; education, years of education obtained; days, mean number of days between enrollment and follow-up CPAP counter reading; AHI, equals number of apneas and hypopneas per hour of sleep; MSLT, multiple sleep latency test; ESS, Epworth sleepiness scale; CPAP setting, titrated effective CPAP pressure, in centimeters of water.

<sup>a</sup> Only 23 subjects had an MSLT.

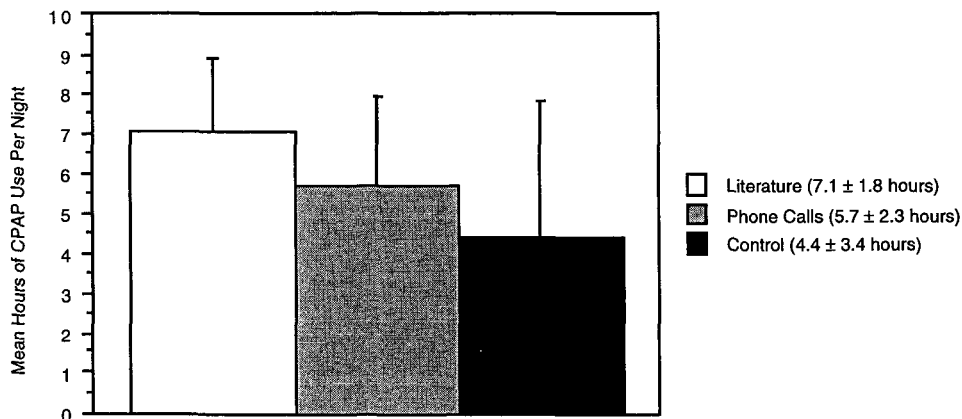
were therefore used, including a general linear regression model. The main explanatory variables were group assignment, whether the patient was new or continuing on CPAP, and an interaction variable. Additional models with other explanatory variables were tested to generate hypotheses for future studies, but these analyses cannot be taken as definitive because tests of more than one variable for each 6–10 subjects could lead to identification of spurious associations. To compare categorical variables, the chi-square or Fisher's exact test was used, as appropriate to the sample size. The significance level for each test was set at  $p < 0.05$ .

## RESULTS

Twelve subjects were randomized to the phone calls group, 14 to the literature group, and seven to the control group. All subjects used CPAP except for two who used BPAP. Although some differences in the distribution of explanatory variables among groups occurred despite randomization, none reached statistical significance (Table 1).

The mean and standard deviation of compliance for all 33 subjects was  $6.0 \pm 2.5$  hours (range 0.0–9.5); 64% of the subjects used CPAP for a mean of at least 6 hours per night. Only one subject, assigned to the control group, did not use CPAP at all. At follow-up, he had not received his CPAP machine, he had not notified anyone of this problem, and his physicians had been unaware that he did not have CPAP. This subject's data were therefore included in the analyses below. The next lowest compliance (1.1 hours per night) was achieved by a patient in the phone calls group who had reported weekly that he used CPAP on a nightly basis. After the counter readings were analyzed and the patient was asked about the results, he "recalled" that he had in fact neglected to use his machine at all for the majority of the study period.

The average compliance was 2.7 hours (61%) longer among subjects in the literature group than among subjects in the control group and 1.3 hours (30%) longer among subjects in the phone calls group than among subjects in the control group (Fig. 1). These differences among the three groups reached marginal statistical significance ( $R^2 = 0.17$ ,  $p = 0.059$ ). Tukey's stu-

**FIG. 1.** Compliance (mean ± standard deviation) in each intervention group.

dentized range test for differences between individual groups showed a marginally significant difference in compliance between the literature and control groups [95% confidence interval (CI) = (-0.03, 5.40)] but not between the phone calls and control groups [95% CI = (-1.47, 4.11)] or between the literature and phone calls groups [95% CI = (-.95, 3.67)]. There was no statistical difference between Compliance among subjects new to CPAP and those continuing on CPAP (6.29 and 5.88 hours per night, respectively).

The complete regression model used three explanatory variables: group, new versus continuing on CPAP, and an interaction term. This model showed a statistically significant relation with compliance ( $R^2 = 0.46$ ,  $p = 0.0037$ ). A type III sum of squares procedure showed the interaction term to be significant even after accounting for the other two variables ( $p = 0.0039$ ); intervention benefited subjects new to CPAP more than subjects who were already on CPAP. Results remained significant even when the data from the one control subject who did not use CPAP at all were excluded.

To explore the potential utility of other explanatory variables in predicting compliance, analogous models using group, one additional explanatory variable, and the interaction term were tested individually. The model incorporating years of education was significant ( $R^2 = 0.45$ ,  $p = 0.005$ ) and so was the interaction term ( $p = .004$ ); intervention made a more significant difference among subjects with lower levels of education. Regression of compliance on years of education alone, without group or the interaction term, showed no relation. The model that included whether or not the subject reported a friend or relative who used CPAP was also significant ( $R^2 = 0.45$ ,  $p = 0.007$ ) and so was the interaction term ( $p = 0.006$ ); subjects who had a relative on CPAP, compared to those who did not, appeared to benefit more from intervention to increase compliance.

The model that incorporated initial ESS score showed a trend toward significance ( $R^2 = 0.33$ ,  $p = 0.08$ ) and the interaction term was significant ( $p = 0.046$ ); subjects with increased daytime sleepiness may have benefited more from intervention. The model that incorporated the MSLT mean sleep latency showed no significance but was based only on the 23 subjects for whom MSLT results were available. The model that included the subjective level of understanding of CPAP was not significant ( $R^2 = 0.30$ ,  $p = 0.09$  for the whole model and  $p = 0.19$  for the interaction term), but this variable showed little variation, as subjects never indicated that they had less than a "moderate" or "good" understanding of CPAP and the need to use it. Models that incorporated each of the remaining explanatory variables failed to show a significant inter-

action between the variable and intervention group. These variables were sex, age, occupation, income, presence of another person living with the subject, apnea/hypopnea index, lowest oxygen saturation, and CPAP setting.

## DISCUSSION

This randomized, controlled clinical trial involving subjects with obstructive sleep apnea demonstrates that simple interventions can increase home compliance with CPAP. The effect is more dramatic in subjects who are about to start CPAP than in those continuing on CPAP at the time of the intervention. Although the sample size was too small to allow simultaneous definitive investigation of additional predictor variables that might affect compliance or interact with the intervention to affect compliance, exploratory analyses suggested that factors such as level of education, whether a friend or relative had CPAP, and perhaps sleepiness could have important effects.

This report is the first, to our knowledge, that shows a beneficial outcome of intervention to improve CPAP compliance. The failure of one group (12) to show an impact of frequent positive reinforcement by phone might have been due to inadequate power as the sample size was limited to 10 subjects. In addition, control subjects still received several phone calls to identify any problems with CPAP. Lastly, in our study written literature may have been more effective than frequent phone calls; although the difference did not achieve statistical significance, the statistical power to exclude the possibility that a real difference existed was too small. Other investigations of CPAP compliance in the absence of special effort to improve it have often shown rates of use comparable to that obtained in our control group and less than those in our intervention groups: the mean hours of CPAP use per night has been reported to be 4.7 (18), 4.7 (19), 4.9 (7), 4.9 (20), 5.1 (21), and 5.6 (3), each result showing no statistically significant difference in comparison to our control subjects ( $p > 0.05$ ).

We can only speculate which elements of the written information used in this study were most effective. Although the ASDA pamphlet provides a general overview of sleep apnea, the complementary three-paragraph handout we devised concisely focuses on areas that we reasoned would be important for patients to understand if they were to be motivated to use CPAP regularly. The first paragraph is designed to prevent common misconceptions among patients that CPAP can be used for only some nights each week, for part of any given night, or at night but not during naps. The second paragraph reminds patients of the benefits of CPAP use and of the potential medical benefit even

if symptomatic improvement is not noticed. The final paragraph lists problems commonly encountered with CPAP and gives patients a written reminder of remedies available.

Our finding that intervention was much more effective in patients just starting CPAP than in those who had already started it at the time of study enrollment suggests that patients may establish habits of CPAP use early on, and once established, these habits may be harder to modify. It is also possible that long-term follow-up of patients will eventually show that intervention must be repeated or reinforced to maintain an initial effect. However, studies suggest that the degree of compliance established within the first month of treatment with CPAP reliably predicts compliance at 3 or 6 months (4,18). This data, combined with our results, support proactive intervention to improve compliance at the time CPAP is first prescribed.

In addition, we suspect that efforts to improve compliance will be more effective when they are tailored to the needs of the individual. Exploratory analyses of our data set suggest that subjects with lower levels of education benefited more from our interventions. Such patients may need additional education or reinforcement about use of CPAP, as suggested by a previous report that patients who were not compliant with CPAP had fewer years of education than those who were compliant (4). We are less able to explain our finding that subjects with a relative or friend who used CPAP also appeared to benefit more by our interventions. Our data also suggest that subjects who perceive greater daytime sleepiness may be more easily influenced to use their CPAP. We did not find the same for subjects with higher levels of sleepiness as measured by the MSLT, but perceived sleepiness and the MSLT result are not necessarily congruous (22,23). Previous investigators have found the relation between initial sleepiness and compliance to be weak (4,18,24) or nonexistent (5,6,19,20), but they did not study the relation between sleepiness and efforts to improve compliance. Others have reported psychological differences between patients who are compliant and those who are not, and tests such as the MMPI depression scale and hypochondriasis scale may allow identification of patients in whom special efforts to increase compliance will be necessary (25).

The power of our investigation was limited by unequal group sizes. In retrospect, block randomization would have been a better design strategy. To better study multiple explanatory variables and their interaction with intervention, future studies should include hundreds rather than tens of patients. Such studies should also, ideally, follow patients for longer than 1 to 2 months to ensure that early benefits of intervention are maintained over time. Discrepancies we found

between compliance reported during weekly phone calls and compliance measured by built-in counters provide additional evidence to support use of objective outcome measures in studies of CPAP compliance (4-7,19). Our subjects' knowledge that their use of CPAP was under study may have affected both their phone reports and objective compliance but was unlikely to have influenced intervention and control groups differently.

Although both of the interventions we tested involved minimal time and expense, distribution of written information to the subjects required less time and less expense yet produced equal if not better results. Untreated obstructive sleep apnea is associated with excessive daytime sleepiness, cardiovascular morbidity, and increased mortality; a causal relation exists with sleepiness, probably exists with hypertension, and probably exists for at least some patients with stroke, myocardial infarction, arrhythmia, and congestive heart failure (26). Therefore, we believe that optimal compliance with CPAP is essential. In some cases, inadequate compliance is a good reason to consider alternative treatment, such as surgery (10,11) or perhaps an oral appliance (8,9). Ideally, compliance in patients with CPAP should be monitored by both subjective report and objective documentation. Lastly, simple interventions to increase compliance such as those we describe deserve serious consideration because they are likely to be extremely cost effective.

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## APPENDIX: GUIDELINES FOR CPAP (OR BIPAP) USE

### *When to use CPAP*

In order to receive the full benefits of CPAP treatment, your CPAP machine must be used whenever you

are asleep. This includes all naps. Furthermore, the mask must remain over your nose for the entire length of sleep. If you wake up and the mask is off, be sure to place it over your nose again before going back to sleep.

### *Benefits of CPAP*

There are several important reasons why your doctor has prescribed CPAP treatment for you. Many people notice a decrease in sleepiness and an increased energy level. These effects may not be immediate so do not be concerned if you do not experience them right away. Another important benefit of CPAP treatment is decreased risk for the serious medical problems caused by untreated sleep apnea. These can include hypertension, heart and lung problems, and stroke. Even if CPAP use does not significantly decrease your sleepiness, its continued use is very important in order to protect yourself from the other medical problems sleep apnea can cause.

### *If problems occur*

If you experience any problems with CPAP that cause you to stop using it, call your home care company representative and/or the sleep laboratory (telephone number). In general, you should call the home care company representative for problems with your equipment and the sleep laboratory for other types of problems. If you have any trouble contacting your home care company, please call the sleep laboratory also. Many common problems with CPAP can be eliminated or reduced. Examples of such problems which may or may not occur in your individual case include nasal congestion, nasal dryness, mask irritation, finding the mask fallen off, or machine malfunction. *Please do not stop using your CPAP machine without contacting the sleep lab.*