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Sleep-Disordered Breathing

Night-To-Night Variability in CPAP Use Over the First Three Months of Treatment

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Summary: The purpose of this study was to examine the relationship between night-to-night variability and nightly duration of continuous positive airway pressure (CPAP) therapy over the first 9 weeks of treatment and to determine when patients begin to establish a nonadherent pattern of use. Data were analyzed from a study of daily CPAP use covertly monitored in 32 diagnosed patients with obstructive sleep apnea (OSA) using a microprocessor monitor encased in a CPAP machine. Patterns of CPAP use were bimodal, based on the frequency of nightly use. Approximately half the subjects were consistent users of CPAP, applying it >90% of the nights for an average of 6.22 ± 1.21 hours per night, while the other half comprised intermittent users who had a wide range of daily use averaging 3.45 ± 1.94 hours per night on the nights CPAP was used. The percent of days skipped was significantly correlated with decreased nightly duration (rho = −0.73, p < 0.0001). Analysis of the night-to-night pattern of use revealed that the two groups differed significantly in the nightly duration of CPAP use by the fourth day of treatment (p = 0.001). Exploration of factors that potentially differentiate the two groups revealed no reliable predictors. However, intermittent users continued to report significantly greater OSA symptoms (snoring, snorting, and apnea) posttreatment, suggesting that they continued to experience sleep disordered breathing. **Key Words:** Obstructive sleep apnea—Continuous positive airway pressure—Compliance—Treatment—Outcomes.

The effectiveness of continuous positive airway pressure (CPAP) as a treatment modality for obstructive sleep apnea (OSA) has been linked to the regularity of nightly use (1,2). It has been reported that there are patients who fail to use CPAP consistently and for all night (1,3,4) and thus are at risk for negative sequelae (2). Before methods can be developed to enhance adherence to CPAP therapy in this group of patients, it is critical to determine when they begin to establish the pattern of intermittent use.

Using meters of cumulative machine on time, initial studies of adherence to CPAP therapy focused on the nightly duration of use, which averaged <6 hours per night (5,6). Covertly recorded mask-on time as well as machine-on time in real hours revealed that CPAP mask-on time averaged <5 hours per night (1). This was confirmed in other studies that also monitored mask versus machine-on time (3,4,7). Adjusting the machine-on times reported by studies using cumulative time meters (5,6,8,9) for the 10% difference between mask-on time and machine-on time reported by Kribbs et al. (1), the average duration of nightly CPAP use demonstrated collectively by these studies is 4.59 hours.

However, interpretation of empirical data indicating that the nightly use of CPAP averages <5 hours is difficult because a single daily mean confounds both night-to-night variability and variation in duration of use within nights as well as combining the use patterns of consistent and intermittent CPAP users. To better understand the nature of CPAP compliance, the relationship between nightly duration and night-to-night use needs to be established. For example, it is unclear

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whether those using CPAP for shorter durations are also those frequently skipping nights of CPAP therapy. The outcome of using CPAP for shorter durations is unknown, but the adverse consequences of skipping CPAP for even one night is established (2), suggesting that night-to-night consistency of CPAP use may be a critical dimension to defining treatment compliance. We suspected that patients who skipped days of CPAP treatment were probably not using the therapy for many hours even when they did attempt it; hence, we hypothesized that there would be a correlation between the extent to which patients skipped CPAP (night-to-night variability) and the extent of the duration of their use on nights they did use CPAP (within-night variability). Finally, despite a flurry of CPAP compliance reports in the past 5 years, there have been no systematic studies characterizing the night-to-night CPAP use of patients who eventually failed to remain compliant. Such data have considerable relevance to issues of how soon treatment failures can be detected and for developing simple criteria for the detection of such failures. These issues were systematically addressed by evaluating data from our original objective investigation of CPAP use (1).

METHODS

Sample

Data from 32 diagnosed OSA patients treated with CPAP (six female, 26 male; mean age 47 ± 10 years) who participated in a previously reported study (1) were used in this secondary analysis. Of the study sample size of 42 subjects included in the original study (1), seven subjects were dropped because of technical problems with the monitor and data from two subjects were added to the database after publication of the original paper, yielding a sample size of 37 subjects. Only those subjects who had objective CPAP monitoring data for all days during the first 9 weeks of treatment (63 days) and who used CPAP on at least one night during those first 9 weeks were retained in the sample. Five subjects were eliminated because they did not meet these criteria (three subjects did not have 63 monitored CPAP days and two subjects had not applied CPAP on any night), producing a final sample size of 32 subjects. Subjects recruited for the original study (1) had been prescribed CPAP as treatment for OSA and agreed to use the CPAP machine, which contained a covert monitor, provided to them. At the time of enrollment, subjects were not informed of the presence of the monitor. Approval was obtained from the institutional human studies review boards of the two sites from which subjects were drawn, the University of Pennsylvania and Johns Hopkins University. Subjects enrolled from the Johns Hopkins University site (n = 22) were provided free monthly follow-up visits to their physician after the initial 1-month follow-up visit. As portrayed in Table 1, the typical subject was an employed, obese, white male with a high-school education and moderately severe sleep apnea.

TABLE 1. *Sample characteristics*

Characteristic	N	Mean ± standard deviation
Age	32	46.76 ± 10.20
Gender	32	81% male
Marital status	30	70% married
Race	31	58% white
Years of education	31	38.7% ≤ high school education
Employment status	30	76.7% work full time
Body mass index	31	40.14 ± 8.66
O_2 saturation nadir during sleep	30	68.13 ± 14.65
Respiratory disturbance index	32	66.00 ± 31.66

Procedure

Details regarding equipment, measures used, and description of the procedures applied for monitoring CPAP have been previously reported (1). Subjects were recruited for the original study (1) during their initial visit to one of the two sleep centers. All subjects had diagnostic polysomnograms (PSG) that met standardized criteria (10), and 25 subjects additionally had a multiple sleep latency test (MSLT). The following night, as part of their routine clinical treatment, subjects underwent a PSG to determine the therapeutic level of CPAP. All subjects completed a brief questionnaire requesting information about demographics, overall health, sleep hygiene, daytime sleepiness, and ability to perform various tasks at work and at home. Subjects were then sent home with a Sleep Easy III™ CPAP machine containing a microprocessor that monitored 24-hour CPAP use at prescribed pressure. Monitor data was downloaded monthly by the home health care company for subjects from the University of Pennsylvania or during follow-up visits by technicians at the sleep center for subjects from Johns Hopkins University. Following the first and third months of treatment, subjects completed a follow-up questionnaire designed to obtain information about their sleep quality, OSA symptoms, and experiences and side effects of CPAP use. The routine procedure for each site was followed regarding normal treatment instruction, follow-up, and payment procedures for CPAP machine rentals. The importance of using CPAP therapy for each normal sleep period for the duration of the sleep period was emphasized to the patients by their physicians.

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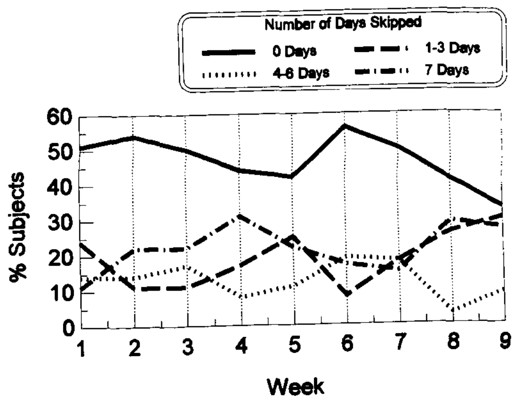

FIG. 1. The percentage of subjects who skipped continuous positive airway pressure treatment for varying numbers of days each week across the 9 weeks of treatment.

Developed at the University of Pennsylvania, the CPAP use monitor consisted of a Vitrax® IX microcontroller single-board computer (Motorola 6502 CPU) equipped with a 32K nonvolatile standard random access memory (SRAM) chip (Dallas semiconductor), a 10-bit A/D converter, battery backup, real-time clock, power-on reset circuit (CEW, Inc.) and a Sensym 142-SC-01D pressure transducer. To program the unit, the microcomputer acts as a functional slave through an integral RS232 serial port to an IBM-compatible personal computer through which program storage and data retrieval were conducted. In addition to date and time, the events detected and logged by the monitor software were power on, power off, mask on, and mask off. A pressure transducer mounted on the air outflow circuit of the Sleep Easy III™ detected that the mask was in use by recording the characteristic rise in pressure that occurs when the mask is applied to the face. Pressure maintained above the threshold level for >60 seconds logged a *mask-on* event; pressure below the threshold for >60 seconds logged a *mask-off* event. Validity testing of the monitor was conducted at the University of Pennsylvania with 15 patients studied as part of their routine clinical care. There was 97% agreement between monitor data and technicians' logs and a correlation of $r = 0.99$ between clock time on the monitor and the technician's log sheet. Field testing of the monitor on two patients with OSA using CPAP machines who completed daily logs yielded coefficients of $r = 0.99$ for one patient and $r = 0.84$ for the second patient (the lower coefficient was due to mask leaks detected by the monitor but missed by the patient) (1).

Data analysis

Overall descriptive summary statistics were calculated for the variables measured. Unless otherwise stated, for statistical comparisons between sites, consistent and inconsistent CPAP use, and patterns of use across time, parametric analyses (ANOVA and *t*-tests) were applied with continuous variables and nonparametric analyses (Wilcoxon rank sum test) with ordinal data and when variances failed to meet the assumption of homogeneity (*F* test for equal variances, $p < 0.10$). Categorical data were analyzed using chi-square or Fisher's exact test when 50% of the cells had expected counts of <5. For all analyses, statistical significance required $p \leq 0.05$. Significance levels for analyses of variance (ANOVA) were corrected for sphericity using the Greenhouse–Geisser epsilon.

RESULTS

Night-to-night variability

There were no significant differences between the two sites for demographics (age, sex, race, marital status, years of education, and employment status), physiological characteristics [body mass index (BMI) and O_2 saturation nadir during sleep], or CPAP use (frequency and duration). As CPAP treatment was initiated at a higher level of respiratory disturbance index (RDI) at Johns Hopkins University, RDI differed significantly between the two sites [University of Pennsylvania mean (± SD) RDI = 46.20 ± 27.35, Johns Hopkins University mean RDI = 77.35 ± 27.73, $p = 0.007$].

To determine the night-to-night variability in CPAP use, the proportion of subjects who skipped using CPAP zero nights, one to three nights, four to six nights, or seven nights per week (n = 32) was plotted for each of the 9 weeks. The patterns depicted in Fig. 1 suggest a bimodal distribution; about one-half of the subjects used CPAP virtually every night (i.e. 90%+ nights), while the other half skipped CPAP 1–7 days per week. When CPAP regularity was calculated, 53% (n = 17) of subjects, termed "consistent users," actually applied CPAP for >90% of the nights (during the first 3 months) for an average of 6.21 ± 1.21 hours per night. In contrast, the remaining 47% (n = 15) of subjects, termed "intermittent users," exhibited greater variability with a wide range of daily use (2–79% of days) and a mean nightly hourly use when CPAP was applied of only 3.45 ± 1.94 hours per night. Thus, the average nightly duration of CPAP use of 4.88 hours reported by Kribbs et al. (1) was the product of CPAP use by two distinctly different groups of patients in terms of night-to-night use of CPAP.

Not surprisingly, we found that when examining the proportion of days CPAP was used compared to nights of skipped treatment, intermittent users skipped treatment significantly more than consistent users ($z =$

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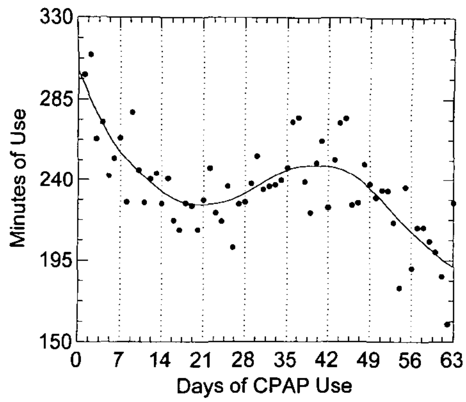

FIG. 2. Mean daily hours of continuous positive airway pressure (CPAP) use across 63 days of CPAP treatment for 32 subjects. Vertical lines indicate weekly intervals. The decrease in CPAP use across the first 14 days of treatment was not significant ($F_{13,390}$ = 1.74, p = 0.10). However, across the first 14 days of CPAP treatment, there was a significant interaction between type of user (consistent or intermittent) and day of CPAP therapy ($F_{13,390}$ = 2.20, p = 0.04). For intermittent, but not consistent, users, mean CPAP use during week 1 was significantly different than mean use during week 2 (T = 2.68, p = 0.02).

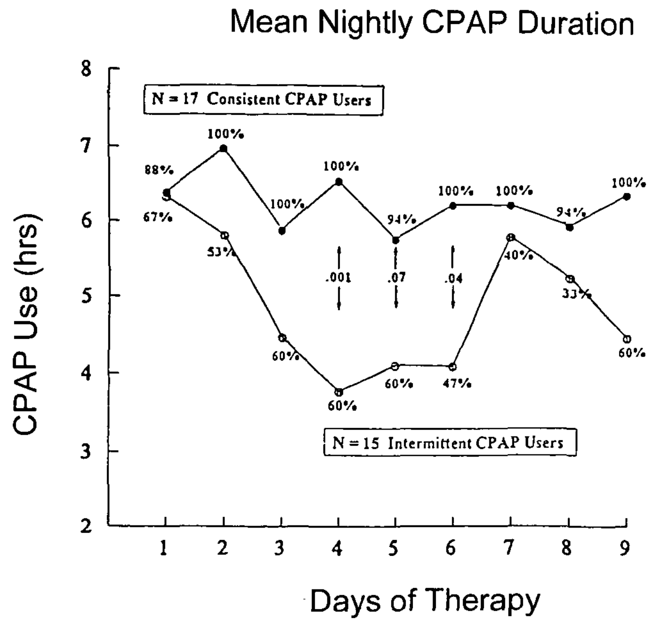

FIG. 3. Mean hours of continuous positive airway pressure (CPAP) use for the first nine nights of treatment for two groups of subjects. Consistent users were those who used CPAP on 90% or more of nights during a 63-day period, while intermittent users where those who used CPAP on 79% or fewer of the nights. The figure shows the percent of subjects in each group who used CPAP on a given day of therapy and the mean duration of that CPAP use only for that proportion of subjects who used CPAP that day. Probabilities indicating differences in mean nightly duration of CPAP use between the two groups are shown in the middle of the figure.

4.82, p = 0.0001). Across all 32 patients, the extent to which treatment was skipped (percent of days skipped) was significantly correlated with nightly duration when CPAP was used (rho = −0.73, p<0.0001). Thus, patients who skipped CPAP on the greatest proportion of nights actually used it for the shortest durations on the nights they applied CPAP.

With the recognition of two distinct patterns of night-to-night variability in CPAP use and the high correlation between use during the first and third months of treatment (r = 0.77) (1), we sought to determine when these patterns of use were established. An ANOVA performed on the first 14 days of the 63 days plotted in Fig. 2 of the mean daily hours of CPAP use for the total sample yielded significant differences between consistent and intermittent users ($F_{1,30}$ = 43.56, p = 0.0001) with an interaction effect between type of user and day of CPAP use ($F_{13,390}$ = 2.20, p = 0.04). Intermittent users (T = 2.68, p = 0.02), but not consistent users (T = 0.02, p = 0.98), demonstrated a significant difference in the mean minutes of CPAP use for the first and second weeks of treatment. This suggested that increased skipping of CPAP therapy and reduced hours of nightly use occurred very early in treatment. To illustrate this, we plotted mean nightly duration of CPAP use for consistent and intermittent users for the first 9 days of therapy. As depicted in Fig. 3, on the first day of therapy, the majority of subjects (88% consistent users and 67% intermittent users) in both groups exhibited comparable durations of use (i.e. mean >6 hours). However, over the next 3 days, proportionately more intermittent users skipped CPAP and the nightly duration of CPAP use by this group declined, producing significant differences in duration of use (of those who used CPAP on a given night) between the two groups by the fourth night posttreatment (p = 0.001). Thus, the pattern of use was established early in the treatment period. Although >94% of the consistent users maintained a mean duration of use of ~6 hours over the 9 days of treatment, use by 33%–67% of intermittent users who used CPAP on any given night was generally 4 hours or less. The differences between these two patterns of use were maintained and, with the exception of days 7 and 8 (when 40% or fewer intermittent users actually used CPAP), were significant (p < 0.05) or approached significance over the remaining 5 days.

Differences in sample characteristics between consistent and intermittent users

A retrospective, exploratory analysis involved comparison of sample characteristics between consistent and intermittent users. There were no significant differences in demographics (age, gender, years of education, marital status, employment status, or type of employment), physiological characteristics (RDI, BMI, or SaO_2 nadir during sleep), chief complaint, pretreatment, or level of CPAP pressure (cm H_2O) between

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TABLE 2. *Proportions of consistent and intermittent continuous positive airway pressure users who reported specific symptoms at 1 month post-treatment*

Symptom	Consistent users		Intermittent users		
	N	Proportion[a]	N	Proportion	p^b
Snoring	6/16	38%	8/13	62%	0.01
Snorting, gasping	4/16	25%	6/15	67%	0.007
Tossing, turning	4/16	25%	8/15	53%	0.01
Breathing stops, choking	3/16	19%	5/15	33%	0.01
Jumpy legs	3/16	19%	2/15	13%	—
Difficulty falling asleep	6/16	38%	7/15	47%	—
Frequent awakenings	7/16	44%	12/15	80%	—
Excessive daytime sleepiness	8/16	50%	11/14	79%	—
Headaches	4/15	27%	4/15	27%	—
Fallen asleep driving	0/15	0%	4/15	27%	0.04
Fallen asleep at work	2/15	13%	9/15	60%	0.07
Awaken feeling paralyzed	1/15	7%	0/15	0%	—
Dreamlike state	5/15	33%	7/15	47%	—

[a] Categories defined as: 0) never; 1) rarely; 2) 1–2 times per week; 3) 3–4 times per week; 4) 5–7 times per week; and 8) do not know. Proportions indicate categories 1–4.
[b] Wilcoxon rank sum test carried out on ordinal data.

the two groups. Although routine clinical follow-up and monitor data retrieval differed for the two sites, there were no significant differences in the proportion of days skipped or proportion of consistent or intermittent users between the two sites. Subjective and objective (mean sleep latency on the MSLT) assessments of pretreatment sleepiness or quality of life also did not differ.

Based on subject responses on the follow-up questionnaire, subject or spousal satisfaction with CPAP therapy did not appear to influence CPAP use. Neither did an index reflecting the number and frequency of reported side effects associated with CPAP use. Of the various side effects surveyed, only discomfort from the mask on the bridge of the nose ($p = 0.04$) produced a significant difference between the two groups. Increased awareness of this problem would most likely be related to the frequency of CPAP use that was higher in the consistent-user group.

We also explored whether the two patterns of CPAP use affected self-reported symptoms after 1 month of treatment. As shown in Table 2, significant differences were found between the two groups with regard to those symptoms most often associated with OSA: snoring, snorting, tossing and turning, and apnea and choking. Although there were no differences in reports of excessive daytime sleepiness (EDS) posttreatment between the two groups, intermittent users reported increased frequency of sleepiness while driving and on the job. Intermittent users also reported experiencing significantly lower performance levels than consistent users ($p = 0.04$).

DISCUSSION

Earlier work established that skipping CPAP for even one night can lead to a return of sleep-disordered breathing and daytime sleepiness (2). Analyzing the night-to-night variability in CPAP use over the first 9 weeks of treatment, we found that the significant decline in mean nightly use resulted from contributions of two patterns of adherence. Approximately half of those patients used CPAP consistently for >6 hours per night while the other half had trouble using this therapy within the first week of treatment, resulting in a dramatic decline in CPAP nightly duration and frequency of use. Thus, skipping CPAP for two or more nights within the first week of treatment signals potential nonadherence and emphasizes the need for close follow-up during this period of time.

Comparison of the posttreatment profiles of consistent and intermittent users yielded few distinguishing characteristics. Consistent with the work of Reeves-Hoché et al. (3), it appears that tolerance to CPAP has little to do with demographic and physiologic characteristics or pretreatment symptoms. Although during the study subjects from Johns Hopkins University received monthly follow-up visits to the physician while subjects from the University of Pennsylvania received monthly follow-up visits in the home by representatives from home-health-care agencies, this difference in clinical follow-up did not produce differences in the proportion of adherent subjects. It might appear that this suggests that type of follow-up produces minimal influence on adherence to CPAP treatment. However, specific information regarding the content and nature of the follow-up provided by the physicians and home-health-care providers was not obtained during this study, making it difficult to draw a conclusive interpretation of this finding. With the recognition that the extent and type of follow-up care patients receive may play a critical role in the promotion of adherence to CPAP therapy, we are currently collecting this data in

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a follow-*on* study of CPAP treatment adherence that we are conducting.

Examination of the posttreatment experience with CPAP indicated that although a majority of each group found CPAP inconvenient and reported nasal stuffiness and eye irritation, only nasal bridge discomfort associated with mask use appeared to distinguish the two groups. Although the contribution of certain types of masks or nasal pillows to CPAP adherence has received minimal attention, one study found that 50% of CPAP users complained of at least one side effect related to use of the nasal mask (11). When individually molded masks were used, there was a significant reduction in complaints of nasal bridge discomfort. This did not, however, result in higher levels of CPAP adherence (11). One must consider, however, that it is possible that retrospect reports of the salience of CPAP side effects from patients who only used CPAP for a night or two may not be reliable.

After 1 month of treatment, the effectiveness of CPAP therapy to alleviate OSA symptoms was evident in reported frequencies of snoring, snorting, apnea and choking, and tossing and turning. Consistent users reported fewer of these symptoms than intermittent users, suggesting that the latter continued to experience sleep-disordered breathing. Moreover, a smaller proportion of consistent users reported sleepiness on the job and while driving. Consistent users also reported significantly higher levels of performance than intermittent users. However, there were no differences between groups in posttreatment self-report ratings of EDS, although of the 50% of consistent users who continued to experience EDS, 25% reported having this symptom only rarely. Reports of EDS may not reflect the physiological changes that occur with CPAP treatment (3,8). Moreover, asking questions regarding situations where sleepiness is more readily manifested and the benefits of consistent CPAP use are more apparent, such as driving and working on the job, may produce more accurate responses than asking whether or not patients experience EDS. Alternatively, the persistence of EDS in consistent users may indicate insufficient CPAP titration, although it would be unlikely that sites at two different institutions would inadequately titrate CPAP. For this analysis, a power of 0.27 may also have affected the level of significance achieved.

In summary, this is the first report to analyze the night-to-night changes in CPAP use over time. Since the generation of this data, originally obtained using the Sleep Easy III™ CPAP machine, new CPAP and mask technologies have been developed, and little information is known about the effect of these advances on adherence. Currently, we have a multicenter investigation underway using an external monitor of effective CPAP pressure that can be applied to any mask, pillow, or CPAP machine or mode (BiPAP vs. CPAP), that will enable us to evaluate the influence of developing technology on CPAP compliance.

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