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The Assessment of Sleep and Quality of Life During CPAP/BiPAP
Treatment for Obstructive Sleep Apnea

by

Julie L. Johnson, M.S., R.N.

THESIS

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Nursing

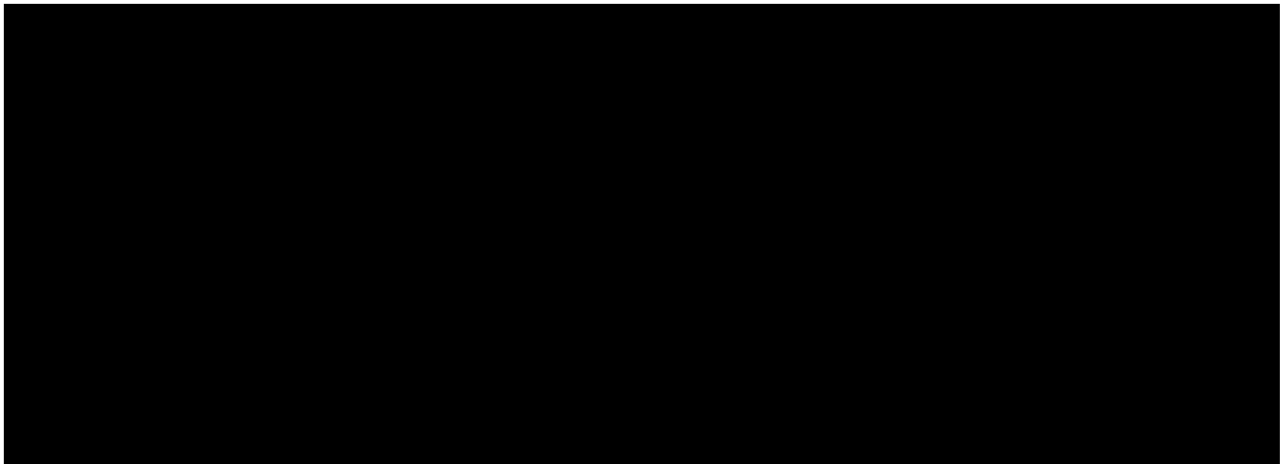
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ABSTRACT

THE ASSESSMENT OF SLEEP AND QUALITY OF LIFE DURING
CPAP/BiPAP TREATMENT FOR OBSTRUCTIVE SLEEP APNEA

Julie L. Johnson, M.S., R.N.

University of California, San Francisco, 1996

Sleep disordered breathing is a relatively common condition in primary care practices, affecting 4 to 15% and 2 to 9% of men and women respectively. Obstructive Sleep Apnea Syndrome (OSAS), a type of sleep disordered breathing, is characterized by repetitive episodes of upper airway obstruction that occur during sleep, usually associated with snoring and reduction in blood oxygen saturation. The most common and effective forms of treatment for OSAS are continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BiPAP). Quality of sleep, quality of life and daytime sleepiness may all be affected in subjects suffering from OSAS. There have been few studies done on patient's perception of these measurements looking at before and after treatment as well as how the length of time using CPAP/BiPAP may affect these outcomes. Therefore, the purpose of this study was to describe the perception of improvement in sleep and life quality in adults with OSAS who are treated with CPAP/BiPAP.

Measurements of daytime sleepiness, quality of sleep, quality of life and perceived work performance were measured in 30 OSAS subjects with a mean age of 52.37 ± 12.59 years and an average diagnosed apnea/hypopnea index (DxAHI) of 51.03 ± 38.11 events per hour ($n= 17$). All questionnaires were administered via telephone interviews, and were consistently reviewed individually with each subject, first pre-treatment followed by same questions

on post-treatment. Results indicated that daytime sleepiness improved with treatment as did the majority of quality of life components (physical, social, and role functioning, energy/fatigue levels, mental and general health), yet global quality of sleep did not improve in this sample. However, certain components of quality of sleep (sleep disturbances, daytime dysfunction) improved with treatment. A subsample of 14 actively working subjects believed work performance improved with treatment of CPAP/BiPAP.



Susan Janson, R.N., D.N.Sc
Chairperson, Thesis Committee

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CHAPTER 1: THE STUDY PROBLEM

Sleep disordered breathing is a relatively common condition in primary care practices, affecting anywhere from 4 to 15% and 2 to 9% of men and women respectively (Phillips et al., 1992; Young et al., 1993). The usual presenting complaints are fatigue, daytime sleepiness and waking up with a sense of choking. The diagnosis of Obstructive Sleep Apnea Syndrome (OSAS), a type of sleep disordered breathing, is often overlooked except in those few individuals who pursue consultation with pulmonary and/or sleep experts. The nonsurgical treatment of choice for OSAS is continuous positive airway pressure (CPAP) by nasal mask (Hoffstein, Viner, Mateika, & Conway, 1992; Kribbs et al., 1993). In overnight formal sleep studies, nasal CPAP has been shown to reduce the frequencies of apneas, improve sleep quality and the symptoms of daytime sleepiness (Sanders et al., 1994; Sullivan, Issa, Berthon-Jones, & Eves, 1981). The results of treatment are sometimes dramatic, especially for those who are severely affected.

OSAS is a chronic disease characterized by repetitive episodes of upper airway obstruction that occur during sleep, usually associated with snoring and reduction in blood oxygen saturation (Kryger, Roth, & Dement, 1994). Because it disrupts normal sleeping patterns, it is often associated with poor sleep quality. The result is sleepiness during the day and a potentially significant impact on quality of life and the ability to be productive at work. Affected individuals often complain of difficulties at work and at home prior to diagnosis and treatment. The relationships between OSAS and daytime sleepiness, quality of sleep, quality of life and work productivity are not well understood. It is important to study these relationships from the patient's

perspective to assess the impact of nasal CPAP as a cost effective treatment. Therefore, the purpose of this study was to describe the perception of improvement in sleep and life quality in adults with OSAS who are treated with CPAP/BiPAP.

CHAPTER 2: REVIEW OF THE LITERATURE

Background and Significance

Historical Background

The periodic cessation of breathing during sleep was first recognized in 1919 as a distinct clinical entity when a syndrome characterized by an "uncontrollable tendency to sleep" in young obese persons was described (Osler & McCrae, 1919). Subsequently, Burwell and colleagues (1956) labeled this condition the "Pickwickian syndrome," and in 1966, Gastaut and colleagues reported a series of case studies of obese hypersomnolent patients with frequent apneic events during sleep. In the early 1970's, Guilleminault and colleagues described sleep apnea as a syndrome associated with insomnia, and Tilkian and colleagues (1977) reported the presence of cardiac dysrhythmias secondary to sleep-related apnea, with improvement in these derangements after tracheotomy.

Clinical Background

Apnea has been defined as the total cessation of airflow at the nose and mouth for at least 10 seconds and is associated with at least a 2-4% oxygen desaturation (Kryger et al., 1994). Hypopnea is generally defined as a 50% or greater decrease in airflow and/or thoracoabdominal movement, lasting at least 10 seconds, associated with a decrease in oxygen saturation of 4% or greater (Gould, Whyte, & Rhind, 1988). The Apnea/Hypopnea Index is the average number of apneas and hypopneas which occur during 1 hour of sleep (Kryger et al., 1994). In OSAS, cycles of apneas and hypopneas may repeat themselves over and over, sometimes up to 500 times per night.

Over the last several decades, many remarkable advances have been

made in our understanding of sleep and its effect on physiologic processes (Weil, Cherniack, & Dempsey, 1987). In addition, the last decade specifically has focused on OSAS and its pathogenesis. Many early researchers suspected that upper airway obstruction played a crucial role in the development of sleep-related breathing disorders, a suspicion confirmed by the fact that symptoms subsided with a tracheotomy (Chua & Chediak, 1994). Medical knowledge of the nature of normal breathing is also becoming increasingly sophisticated. It is now common knowledge among both researchers and clinicians that the muscles of the upper airway and thorax play a major role in maintaining adequate ventilation and oxygenation during sleep (Chua & Chediak, 1994).

Prevalence

Sleep disordered breathing is the most common organic disorder of excessive daytime somnolence seen in sleep disorder clinics today and its prevalence has been steadily increasing (Kryger et al., 1994). A large portion of those patients who fall into the category of sleep disordered breathing actually have OSAS (Kryger et al., 1994). Young and colleagues (1993) performed overnight sleep studies in 602 working men and women, age 30-60, who had no history of sleep disorders, in order to estimate the prevalence of sleep disordered breathing. Young defined sleep disordered breathing as an apnea-hypopnea score of 5 or higher; this measurement is similar to the measurement many experts in the field use to define OSAS. The researchers found sleep disordered breathing to be quite common, affecting 24% of men aged 30-60, and 9% of women aged 30-60. These participants were then questioned about excessive sleepiness. Of the 24% of men with sleep

disordered breathing, 15% complained of symptoms of hypersomnolence, yielding an estimated 4% in men. Of the 9% of women with sleep disordered breathing, 22% complained of hypersomnolence, yielding an estimated prevalence of 2% in women. Thus, it would appear that sleep disordered breathing is a fairly common disorder in both men and women.

Phillips and colleagues (1992) also studied 92 healthy adults, ages 50-79, with polysomnography to determine the prevalence of OSAS within a selected convenience sample. Using an Apnea-Hypopnea Index (AHI) greater than 5 as diagnostic of OSAS, they found an incidence of 15%. Hoch and colleagues (1990) performed polysomnograms on 105 primarily healthy adults and found that 25% had an AHI of 5 apneas/ hour or greater.

Clinical Features

Clinical features commonly associated with OSAS include obesity, snoring, systemic hypertension, witnessed apneas, excessive daytime sleepiness, waking up with a sense of choking, and increasing age (Kryger et al., 1994). Yet, recent studies have not been able to accurately predict the absence or presence of OSAS based on clinical features (Crocker et al., 1990; Kump et al., 1994), therefore requiring some form of diagnostic study to accurately predict if one has OSAS.

OSAS has also been identified as potentially life threatening and has been associated with extreme hypersomnolence, automobile accidents and cardiovascular morbidity and mortality (He, Kryger, Zorick, Conway, & Roth, 1988; Hung, Whitford, Parsons, & Hillman, 1990; Partinen & Guilleminault, 1990). In addition, reports that snoring is associated with myocardial infarction, stroke and hypertension (D'Alessandro, Magelli, & Gamberini,

1990; Koskenvou et al., 1987; Schmidt-Nowara, Coultas, Wiggins, Skipper, & Samet, 1990; Seppala et al., 1991) have suggested that even a mild degree of sleep disordered breathing may have adverse health affects (Young et al., 1993).

Treatment

Treatment of OSAS depends primarily on the mechanism underlying the disorder and its severity. Because many OSAS patients are obese, mild to moderate OSAS can often be managed effectively with modest weight reduction to increase area in the airway. Avoidance of alcohol and sleeping in the supine posture may also help. With severe OSAS, tricyclic medications, particularly Protriptyline which acts as a CNS stimulant and anticholinergic, have been beneficial (Sanders, 1994).

Uvulopalatopharyngoplasty (UPPP) has also proven successful with severe cases in which other forms of treatment have not been beneficial (Isono & Remmers, 1994). UPPP involves removing a small portion of the soft palate and uvula and any residual tonsillar tissue that may be present (Kryger et al., 1994).

Yet, by far the most widely used and successful treatment for patients with moderate to severe OSAS is the use of nasal CPAP during sleep (Kryger et al., 1994). CPAP acts predominantly by providing a physical "pressure splint" to the upper airway, an explanation supported by endoscopic visualization (Popper, Ledlinger, & Williams, 1986). CPAP's effects include improved oxygen saturation, relief of apneic episodes, and a consolidated sleep pattern. Nasal CPAP was first described by Sullivan and colleagues in 1981, but it was

not until 1985 that it began to be recognized as a realistic form of long term therapy.

Another very similar treatment for OSAS is bi-level positive airway pressure or BiPAP where different pressure is exerted during expiration than inspiration within the respiratory cycle. Unlike CPAP which exerts continuous pressure throughout the respiratory cycle, BiPAP is a system which allows use of lower expiratory pressure (Kryger et al., 1994). On average, the expiratory pressure is about 5 cm H₂O less than the inspiratory pressure (Sanders & Kern, 1990). BiPAP is often used in patients requiring high CPAP levels and because the average pressure throughout the cycle can be reduced, it is considered a safer approach for these patients.

Previous OSAS Studies using Nasal CPAP

Objective Measurement of Patterns of Nasal CPAP Use by Patients with Obstructive Sleep Apnea . Because CPAP requires wearing a tightly fitting mask over the nose which exerts continuous positive airway pressure, compliance remains an issue with many patients using this treatment (Kribbs, et al., 1993). Kribbs et al. (1993) studied 35 OSAS patients from two sleep centers (University of Pennsylvania, n = 21, and Johns Hopkins University, n = 14) to determine objective measurements of nasal CPAP use. An internal time counter was placed inside the CPAP mask and patients were not aware of its existence. Monitor output was then compared with pre-treatment clinical and demographic characteristics. The ultimate purpose was to identify if actual CPAP use by OSAS patients correlated with the patients own self-reporting using a questionnaire and if the therapeutic goal of quality sleep was being achieved.

The study was prospective in nature and descriptive correlational and survey-type in design. These designs were found to be appropriate based on the comparison between objective measurements of the CPAP monitor and the subjective information gathered via the follow-up questionnaire. The follow-up questionnaire was designed to measure patients' self-reports of CPAP use on a monthly basis. Self-report measures were subject to potential response bias in which patients may have tailored their answers in a set way. In addition, recall bias also posed a threat because patients had to recall the past month's events, and there were no methods of recording the amount of CPAP use on a nightly basis. There was also no mention of previous validation of this questionnaire; therefore, its reliability and validity characteristics were unknown.

Strengths of the study included its generalizability to the target population and its lack of Hawthorne effect because patients were not aware of the time monitor within the mask. Although the only inclusion criteria were that the patients had been diagnosed with OSAS and had been prescribed CPAP by their physician, the sex (29 male and 6 female) and age (mean 46.2 ± 9.6 years) was representative of patients with OSAS. The reliability of the rating methods was established by comparing the responses of four patients, two of whom were regular CPAP users at night, one was a rotating shift worker who regularly used CPAP during sleep, and one infrequent user who was noncompliant. The accuracy of the self-report on the frequency and duration of CPAP use over time was assessed by comparing covert monitor data from 20 of the patients who were monitored for at least 3 months.

The study concluded that actual CPAP use by OSAS patients falls short of the therapeutic goal of CPAP, that being, getting a "quality" night of uninterrupted sleep, and that compliance is a problem. Patients attempted to use CPAP an average of $66 \pm 37\%$ of the days monitored. When CPAP was used, the mean duration of use was only 4.88 ± 1.97 hours. However, patients' report of the duration of CPAP use overestimated actual use by 69 ± 110 minutes ($p < .002$). Although the majority (60%) of patients claimed to use CPAP nightly, only 16 of 35 (46%) met the criteria for regular use, defined by at least 4 hours of CPAP administered on 70% of the days monitored.

Predictive Factors of Long-term Compliance with Nasal CPAP Treatment in Sleep Apnea Syndrome . Yet, many studies indicate that CPAP compliance is high. In a French study by Meurice and colleagues (1994), 44 patients with OSAS were studied for a mean of 14 months (range 8 to 39 months). The study's purpose was to evaluate compliance based on self-reporting of patients using the same questionnaire, at 1 month, and every 6 months thereafter, and by the use of a time counter connected to the CPAP machine. Patients were aware of the time counter and were given educational information and instructions regarding CPAP. In addition, technicians from the sleep center also made regular visits to ensure proper use and functioning of the machine.

After 14 months of CPAP treatment, 30 patients (68%) were found to be compliant with the therapy. The daily use of CPAP was significantly correlated to the initial apnea/hypopnea index (AHI > 15 apneic events per hour of sleep) ($r = .37, p = .01$) as well as to the percentage of light sleep ($r = .30, p = .04$) and slow-wave sleep ($r = -.31, p = .04$). Further analysis indicated

that patients used CPAP much more if they had a significant clinical handicap, if they were aware of the beneficial effects of CPAP, and if they knew that they were being monitored.

This study performed by Meurice et al. (1994) demonstrates that compliance can be accomplished if proper supervision, education and regular encouragement regarding CPAP is given. The study's strengths include an appropriate sample size and representative patient population (39 men and 5 women, with an age range from 40 to 82 years) which increase generalizability to the target population of patients with OSAS who use CPAP on a daily basis. The descriptive correlational design was also study-appropriate in that researchers were allowed to observe events as they naturally occurred and then compared their objective findings to that of the patient's own self-reporting of hours spent on CPAP. Again, patients' estimates of CPAP usage per night (mean 7 ± 1.65 hours) was higher than actual usage per the time counter (mean 6.02 ± 2.48 hours). In addition, the study's duration (2 years, 5 months, mean of 14 months) strengthened the research design.

Limitations to Meurice and colleague's (1994) study include threats to internal validity such as maturation and testing. Because the study was conducted over almost 2.5 years, and heart disease (39%) and hypertension (70%) were fairly predominant in the patient sample, compliance may have been affected by these other health problems. Patients' were also aware of the time counter and knew they would be filling out the same questionnaire at specific intervals; these factors lessen the external validity due to Hawthorne effect and internal validity due to repeated testing.

Long Term Compliance with Nasal CPAP in OSA Patients and Nonapneic Snorers . Krieger (1992) prospectively studied 233 OSAS patients (AHI > 10 apneic events per hour) and 36 non-apneic snorers to assess compliance with CPAP use. All patients were encouraged to try to use nasal CPAP, even when it was not in accordance with their lifestyle. Compliance was measured with a built-in time counter of which the patients were aware. The CPAP units were regularly serviced by technicians and mean rates of use were calculated by dividing the difference between two consecutive counter readings by the corresponding interval in days. The mean rate of use was used as an index of compliance to treatment. Questionnaires were also used to subjectively measure patients estimates of CPAP use.

Nineteen patients refused CPAP. Of the 214 patients who accepted CPAP, 181 (84.6%) were still using the treatment after 2 years, and had a mean daily rate of use of 5.6 ± 0.1 hours. This observed daily rate was in the same order of magnitude as in another study based on counter readings for the evaluation of treatment accepted (Fletcher & Luckett, 1991). Based on a rate of use for noncompliance as less than 3 hours per day, the data indicated a range from 77% to 89% for compliance.

Kreiger's study on long-term compliance with nasal CPAP in OSAS patients has been cited in other similar studies of OSAS patients and their level of compliance using CPAP. The study has been referenced because of its many strengths which include a large sample size and the use of a control group. Subjects were not randomly assigned to study groups and therefore, interventions were not truly controlled. Patients' motivation to use therapy was not measured and may have significantly affected compliance rates.

In addition, the prospective nonexperimental design was considered appropriate for the type of data gathered. The sample (214 patients: 199 male, 15 female; mean age 53 ± 1 year) was also representative of patients with OSAS. Yet, there were limitations to the study. Testing, mortality and maturation threatened the study's internal validity. Potential testing effects were created by repeated exposure to questions related to outcomes of interest. There was also serious attrition in this study. Mortality affected a total of 32 patients, 10 (4.7%) of whom died during the study and 22 (10.3%) dropped out. Threats to external validity included Hawthorne effect and measurement effects. Again, there was no mention of the validity of the questionnaires or the reliability of the time counters used.

In summary, the rate of nasal CPAP compliance ranges between the three studies are from 46% to 89%. Compliance increases when patients have more severe OSAS, receive thorough education regarding CPAP and its benefits and when patients have the benefit of knowing they are being monitored via the use of a time counter. Compliance appears to be decreased when patients have less severe OSAS and are not aware of the time counter built inside the CPAP apparatus.

All three studies (Kreiger, 1992; Kribbs et al., 1993; & Meurice et al., 1994) address compliance from a medical perspective but how nasal CPAP has benefited the patients' using it from their own perspective has not. Specifically, assessing improvement in quality of sleep and level of daytime sleepiness, which is commonly associated with OSAS, is essential. In addition, improvement in quality of life after starting CPAP treatment should be documented. Presently, there are little data on these outcomes. All three

of these outcome variables may be affected by the length of time the patient has been using CPAP treatment. The relationships between quality of sleep, level of daytime sleepiness, quality of life and the length of time on CPAP are not known.

Purpose

The overall objective of this descriptive correlational study was to describe the impact of nasal CPAP/BiPAP treatment on quality of sleep and life in patients with OSAS from the their own perspective.

The specific aims are to:

1. Describe the level of daytime sleepiness during treatment with CPAP, as measured by the Epworth Sleepiness Scale.
2. Describe the quality of sleep during treatment with CPAP, as measured by the Pittsburgh Sleep Quality Index.
3. Describe the quality of life during treatment with CPAP, as measured by the SF-36 Health Status Questionnaire.
4. Determine the relationship between the length of CPAP treatment and daytime sleepiness, quality of sleep, and quality of life.
5. Compare the outcomes of treatment with retrospective self-reported perceptions of sleepiness, sleep quality, and quality of life.

CHAPTER 3: METHODS

Sample

After CHR approval, a chart review of 250 patients at the UCSF Sleep Disorder Center was performed to determine the population to be evaluated. Subjects meeting the inclusion criteria ($n = 100$) were contacted by mail to see if they were interested in participation. A consent form and copy of the questionnaire were included in the mailed packet (See Appendices A, B, C, and D). Each subject who mailed in the acceptance postcard ($n = 35$) was telephoned by the investigator in order to verify their interest, answer their questions, and conduct the telephone data collection. Diagnosed OSAS patients treated with nasal CPAP or BiPAP who met the inclusion criteria were included in the study. Subjects were included if they were: over 18 years of age, English speaking, had access to a telephone, diagnosed with OSAS, and receiving treatment with CPAP or BiPAP. The UCSF Sleep Disorder Center was selected because of the close proximity of the center and the accessibility of the moderate-sized data base.

Design

The study used a cross-sectional, descriptive design. A packet that included the Epworth Sleepiness Scale, the Pittsburgh Sleep Quality Index and the SF-36 Health Status Questionnaire was mailed to subjects and then read over the telephone item by item by a single interviewer. The interviewer also used a demographic form to obtain additional information. Subjects were asked to recall retrospectively their perceptions of how they felt prior to the onset of CPAP/BiPAP as well as how they felt presently using the treatment.

Variables and Instruments

The Epworth Sleepiness Scale, the Pittsburgh Sleep Quality Index and the SF-36 Health Status Questionnaire were used to measure level of daytime sleepiness, quality of sleep and quality of life respectively. The Epworth Sleepiness Scale (Johns, 1991), the Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman, & Kupfer, 1988) and the SF-36 Health Status Questionnaire (McHorney, Ware, & Raczek, 1993) are all previously validated questionnaires which have been used in medical research by other investigators in similar studies (Brown, Barbieri, & Heffner, 1995; Gall, Isaac, & Kryger, 1993; Hirshkowitz et al., 1995; Stewart, Hays, & Ware, 1988; Weistein, Dement, Redington, & Guilleminault, 1983). The correlation of these three measurements was then compared to the length of time each individual subject has used CPAP or BiPAP.

Each instrument required a specific procedure for scoring. The Epworth Sleepiness Scale contained eight questions and simply required adding up the scores to form a total score. The maximum total score for the Epworth Sleepiness Scale was 24. An additional three questions (numbers 9, 10, and 11) addressing work related issues were added to the end of the questionnaire, were computed separately and not tallied into the final score. The Pittsburgh Sleep Quality Index contained 19 self-rated questions and 5 questions rated by the bed partner or roommate (if one was available). Only the self-rated questions were included in the scoring. The 19 self-rated items were then combined to form seven component scores. Finally, the seven component scores were added together to yield one "global" score. The maximum global score for the Pittsburgh Sleep Quality Index was 21.

The SF-36 Health Status Questionnaire also required adding up questions to form component scores (e.g. physical functioning score, mental health score). All 36 questions were recoded and added together with other questions which were similar in nature (with the exception of question 2 which had been reworded to "Compared to before you started on CPAP/BiPAP, how would you rate your health in general now?" from "Compared to one year ago, how would you rate your health in general now?") This question was scored separately because of this alteration and was not included in any component score. The component scores were then transformed into percentage scores which described the quality of life measure. There were no total or "global" scores for this instrument. The maximum component percentage score for the SF-36 Health Status Questionnaire was 100 percent.

Internal consistency for the Epworth Sleepiness Scale was measured by Cronbach's alpha. Alpha reliability pre and post treatment for questions one through eight measured .865 and .859 with a homogeneity ratio of .443 and .420 respectively . The added questions (numbers 9, 10, and 11) on work also yielded pre and post treatment alpha reliability of .932 and .874 with homogeneity ratios of .820 and .697 respectively. These results demonstrate a high degree of internal consistency within this instrument for the given sample. Alpha reliability coefficients could not be calculated for the Pittsburgh Sleep Quality Index and the SF-36 Health Status Questionnaire total scores because both scales use component scoring systems. Individual item analysis was not attempted.

Procedures

Each questionnaire was administered twice, first asking how the patient felt before CPAP or BiPAP started and then how they felt using CPAP or BiPAP presently. Each questionnaire was completed individually with the Epworth Sleepiness Scale given first, followed by the Pittsburgh Sleep Quality Index, and finally the SF-36 Health Status Questionnaire. The Epworth Sleepiness Scale measured eight variables, all of which included specific situations where the subject may or may not "doze." The Pittsburgh Sleep Quality Index measured 19 variables which evaluated frequency of situations involving usual sleep habits. The SF-36 Health Status Questionnaire measured 36 variables which described usual activities related to health status.

Statistical Analysis

Descriptive measures of central tendencies (e.g. mean standard deviations and ranges) were used to analyze the first three aims of the study. Pearson correlation was used to analyze the fourth aim, that being the relationship between length of time on CPAP and daytime sleepiness, quality of sleep, and quality of life. Paired t-tests were used to compare the outcomes of treatment with retrospective self-reported perceptions of sleepiness, sleep quality and quality of life.

CHAPTER 4: RESULTS

Sample Characteristics

Thirty of the 35 (85%) subjects who responded by sending in an acceptance letter were interviewed by telephone. Two subjects (5.7%) were not able to be contacted due to lack of a proper phone number. An additional 2 subjects (5.7%) dropped out. One subject (2.8%) was never placed on CPAP or BiPAP and, therefore was ineligible. Of the 30 subjects, 22 (73.3%) were men. The mean age was 53.1 years (range 23-84). Seventeen of the 30 subjects (56.6%) had a documented AHI > 10, the other 13 individuals were diagnosed based on subjective history, clinical symptoms and polysomnography studies looking at the post-treatment AHI only.

Tables 1 and 2 describe the characteristics of the sample. Many of the 30 subjects had concurrent medical diagnoses including hypertension (n = 17) and COPD (n = 5). Obesity was a significant characteristic with a mean weight of 237.52 ± 75.41 lbs. This is representative of subjects with OSAS. In addition, 28 subjects (93.3%) were snorers before treatment and only two subjects (6.6%) currently smoked.

The mean number of months on CPAP/BiPAP treatment at the time of the study was 11.43 ± 11.33 . The treatment was worn an average of 6.20 ± 1.71 nights per week and 6.38 ± 1.68 hours per night. These values suggest a compliance level consistent with previous studies which assessed both subjective and objective measurements of these variables (Krieger, 1992; Meurice et al., 1994).

Treatment Affect on Work

Assessment of employment status revealed 14 subjects currently working,

9 retired subjects and 5 who were disabled. Two subjects were unemployed due to inability to find suitable work; they were not disabled or retired. All 14 workers reported impact of treatment on work (Table 3). Chi-square analysis suggests a significant improvement in work performance with treatment. For example, three subjects rated work performance as "poor" pre-treatment and no workers reported a "poor" performance with treatment. A rating of "excellent" was rated by three individuals pre-treatment and by seven subjects post or with treatment. Chi-square (3.89 with 1 df; $p < .049$) demonstrated that 57% reported either a poor or fair work performance pre-treatment and only 14% reported a poor or fair work performance post-treatment. Furthermore, 43% reported a good or excellent work performance pre-treatment and 86% reported a good or excellent work performance post-treatment.

Daytime Sleepiness and Quality of Sleep

Table 4 describes pre and post treatment results of daytime sleepiness as measured by the Epworth Sleepiness Scale (Questions 1 through 8) and quality of sleep as measured by the Pittsburgh Sleep Quality Index. Total mean daytime sleepiness score pre-treatment was 13.07 ± 6.38 and 6.83 ± 4.81 post-treatment. Daytime sleepiness in the group of eight women also greatly improved. This is important because a large majority of the studies done on OSAS patients using CPAP have been performed on men alone. This data suggests that like men, women are strongly affected by treatment and because little data is available on women, more studies need to be done to evaluate OSAS in this population.

The mean global sleep quality score was 10.90 ± 3.75 pre-treatment and

8.70 ± 4.08 post-treatment. This would suggest that although daytime sleepiness is reduced with treatment, overall sleep quality does not necessarily improve with the use of CPAP or BiPAP. However, there was improvement in certain components of total sleep quality.

Table 5 is a breakdown of those sleep quality components (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medications, and daytime dysfunction) as measured by the Pittsburgh Sleep Quality Index. Sleep disturbances were decreased and daytime dysfunction improved with treatment. Sleep efficiency remained unchanged. Sleep latency scores in women improved as sleep onset was longer than pre-treatment. This is important in the OSAS population because many times patients fall asleep instantaneously even during active hours.

Quality of Life

The SF-36 Health Status Questionnaire used to evaluate quality of life does not provide a total raw score. Instead, all questions/answers are re-coded and added together with other questions/answers addressing similar aspects of quality of life. Finally, the raw score is transformed into a percentage score. Table 6 shows the means and standard deviations of the percentage scores for each component of the questionnaire.

All total quality of life components demonstrated improvement in status with treatment. Of noted importance was the fatigue/energy level which improved from a mean of 31.83 ± 25.91 pre-treatment to 60.83 ± 25.63 post-treatment for all subjects. This improvement in energy levels was especially dramatic in women (mean 16.25 ± 15.29 pre-treatment to mean 60.00 ± 25.21

post-treatment). In addition, women, more than men demonstrated great improvements in social functioning and physical role functioning with treatment.

Correlation between Treatment and Daytime Sleepiness, Quality of Sleep, and Quality of Life

Correlations between daytime sleepiness, quality of sleep, quality of life and time treatment used were not significant (Table 7). Yet, the study revealed a negative correlation between nights per week treatment worn and daytime sleepiness. In addition, a significant ($p < .05$) correlation between nights per week treatment worn and mental health improvement was found. (Table 8). Correlations were also demonstrated between age and pre-treatment fatigue levels ($r = .40$, $p = .03$), diagnosed AHI and pre-treatment work performance ($r = -.80$, $p = .02$), and weight and COPD ($r = .44$, $p = .01$).

Outcomes of Treatment compared to Self-reported Perceptions of Sleepiness, Sleep Quality, and Quality of Life

Paired t-tests were also performed pre and post treatment on the total Epworth score, the Pittsburgh global sleep score and its seven components as well as on all components of the SF-36 Health Status Questionnaire. The total Epworth score ($t = 5.82$, $p < .01$), the Pittsburgh global sleep score ($t = -3.13$, $p < .01$) and two out of the seven individual component scores (sleep disturbance: $t = -2.8$, $p < .01$ and daytime dysfunction: $t = -5.8$, $p < .001$) demonstrated improvement with treatment. In addition, six of the SF-36 component scores demonstrated significant improvement: physical functioning ($t = 2.5$, $p = .02$); social functioning ($t = 2.5$, $p = .02$); physical role

($t = 2.25, p = .03$); mental role ($t = 3.2, p = .04$); fatigue ($t = 5.55, p < .001$); and general health ($t = 3.5, p < .0005$).

CHAPTER 5: DISCUSSION

The study demonstrated that a) daytime sleepiness lessened after treatment, b) total sleep quality did not improve with treatment yet sleep disturbances were decreased and daytime dysfunctioning improved with treatment, c) physical functioning, social functioning, role functioning (physical and mental), energy levels, mental health and general health all were rated higher after treatment, d) pain levels were higher after treatment and, e) work performance improved with treatment. In addition, the number of nights per week that treatment was worn was negatively correlated with daytime sleepiness and positively correlated with mental health. This suggests that nights per week that treatment was worn is important and that the more treatment was worn on a nightly basis, the better the subjects felt (less sleepy, improved mental health). Finally, there was no relationship observed between duration of treatment and daytime sleepiness, quality of sleep, and quality of life.

Limitations of the study included a small sample size, lack of a control group, and inability to compare subjective measurements with objective findings. The presence of other co-existing medical conditions such as hypertension, COPD and coronary artery disease may have affected the quality of life scores. In addition, the findings could have been biased by subjects' ability to accurately recall perceptions of pre-treatment variables. The study could be greatly improved with a prospective design following subjects forward from the time of treatment onset.

There were also large variations between subjects responses to questions regarding quality of life, quality of sleep and level of daytime sleepiness. This

variability may be due to wider differences in health status, from little or no health problems to total disability. In addition, the severity of OSAS varied greatly (range DxAHI = 10.5 to 126.8). These characteristics potentially had a great impact on how subjects answered questions and may have contributed to the variability of responses. Yet, because subjects had a wide range of perceived disabilities, this study sample was more generalizable to a primary care population.

Despite a small sample size and a wide range of variability in subjects' perceptions, many of the findings support the impression that CPAP or BiPAP treatment improves level of functioning and quality of day to day life. This outcome corroborates findings by Tousignet and colleagues from a 1993 study investigating impact of CPAP treatment in 19 patients with OSAS. Tousignet and colleagues measured quality adjusted life years (QALYs) and found an average gain of 5.4 QALYs with treatment.

Findings from this study also agree with findings in another study about daytime sleepiness after long-term CPAP treatment in 58 OSAS patients (Sforza & Krieger, 1991). CPAP improved daytime alertness and was significantly correlated with reduction in sleep fragmentation and with baseline sleep latency. Their results support the hypothesis that sleep disruption related to respiratory events plays a role in the pathogenesis of daytime sleepiness.

In conclusion, the results of this study demonstrate a positive impact of CPAP/BiPAP treatment on daytime sleepiness, quality of life and work performance. Global quality of sleep does not appear to improve with treatment within this sample of OSAS subjects. Yet, as previously

mentioned, this may be due to many factors including sample size, variability in health status of the subjects, as well as subjective reporting of responses. Correlations between duration of treatment and quality of sleep and life variables would be potentially more detectable with a larger, more homogeneous sample. Future prospective studies with a larger sample of individuals analyzing both subjective self-reporting of information and objective measurements needs to be performed and will contribute new insight about the global effects of treatment for OSAS.

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APPENDIX A

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO BE A RESEARCH SUBJECT

A. PURPOSE AND BACKGROUND

Julie Johnson, RN and David Claman, MD in the UCSF Sleep Disorders Center are conducting a research study to evaluate sleep and quality of life in people with Obstructive Sleep Apnea. I am being asked to participate in this study because I have Obstructive Sleep Apnea, and I am currently being treated with Continuous Positive Airway Pressure (CPAP) or Bi-level Positive Airway Pressure (BiPAP). These treatments are often used for Obstructive Sleep Apnea and include wearing a mask over the nose while sleeping.

B. PROCEDURES

If I agree to be in the study, the investigator will fill out an intake demographic form and three (3) questionnaires with my verbal responses verbatim during a telephone interview. The questions will relate to my sleepiness, quality of sleep, and quality of life. It will take approximately 30 minutes for the telephone interview to take place.

C. RISKS AND DISCOMFORTS

1. Confidentiality: Participation in research may involve a loss of privacy; however my records will be handled as confidentially as possible. Only the researchers will have access to my study records. No videotaping will be performed. No individual identities will be used in any reports or publications that may result from this study.

D. BENEFITS

There will be no direct benefit to me from participating in this study. However, the information that I provide may help health professionals better understand people with Obstructive Sleep Apnea.

E. COSTS

There will be no costs to me as a result of taking part in this study.

F. PAYMENT

I will not receive any payment for my participation in this study.

G. QUESTIONS

I have talked to Julie Johnson or to Dr. Claman about this study, and have had my questions answered. If I have further questions, I may call (415) 885-7886 to have these questions answered.

If I have any comments or concerns about participation in this study, I should first talk with the investigator. If for some reason I do not wish to do this, I may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. I may reach the committee office between 8:00 am and 5:00 pm, Monday through Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, San Francisco, CA 94143.

H. CONSENT

I will be given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. I am free to decline to be in this study, or to withdraw from it at any point. My decision as to whether or not to participate in this study will have no influence on my present or future status as a patient at UCSF.

If I agree to participate, I should sign below.

Date

Signature of Participant

Date

Signature of Person Obtaining Consent

APPENDIX B

Name _____

Date _____

EPWORTH SLEEPINESS SCALE

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. Use the following scale to chose the most appropriate number for each situation:

- 0 = would never doze
 1 = slight chance of dozing
 2 = moderate chance of dozing
 3 = high chance of dozing

<u>Situation</u>	<u>Chance of dozing</u>
Sitting and reading	_____
Watching TV	_____
Sitting, inactive in a public place (e.g. a theater or meeting)	_____
As a passenger in a car for an hour without a break	_____
Lying down to rest in the afternoon when circumstances permit	_____
Sitting and talking to someone	_____
Sitting quietly after a lunch without alcohol	_____
In a car, while stopped for a few minutes in the traffic	_____
Sitting alone during a break at work	_____
Sitting, interacting with co-workers at a work meeting	_____
Sitting, passively observing a work meeting	_____

APPENDIX C

Name _____

Date _____

PITTSBURGH SLEEP QUALITY INDEX

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions by circling the appropriate number or letter.

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
1. Cannot get to sleep within 30 minutes.	0	1	2	3
2. Wake up in the middle of night or early morning.	0	1	2	3
3. Have to get up to use the bathroom.	0	1	2	3
4. Cannot breathe comfortably.	0	1	2	3
5. Cough or snore loudly.	0	1	2	3
6. Feel too cold.	0	1	2	3
7. Feel too hot.	0	1	2	3
8. Had bad dreams.	0	1	2	3
9. Have pain.	0	1	2	3
10. Taken medicine (prescribed or "over the counter") to help you sleep?	0	1	2	3
11. Had trouble staying awake while driving, eating meals, or engaging in social activity?	0	1	2	3
12. Other reason(s):	0	1	2	3
Please describe: _____				

13. During the past month, how would you rate your sleep quality overall?

- a. Very good
b. Fairly good

- c. Fairly bad
d. Very bad

14. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

- a. No problem at all
- b. Only a very slight problem
- c. Somewhat of a problem
- d. A very big problem

15. Do you have a bed partner or roommate?

- a. No bed partner or roommate
- b. Partner/roommate in other room
- c. Partner in same room, but not same bed
- d. Partner in same bed

If you have a roommate or partner, ask him/her how often in the last month you have had.....

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
16. Loud snoring.	0	1	2	3
17. Long pauses between breaths while asleep.	0	1	2	3
18. Legs twitching or jerking while you sleep.	0	1	2	3
19. Episodes of disorientation or confusion while you sleep.	0	1	2	3
20. Other restlessness while you sleep.	0	1	2	3

Please describe: _____

21. During the past month:

- a. When have you usually gone to bed at night?
Usual bed time_____
- b. How long has it usually taken you to fall asleep each night?
Number of minutes_____
- c. When have you usually gotten up in the morning?
Usual getting up time_____
- d. How many hours of actual sleep did you get at night?
(This may be different than the number of hours you spent
in bed).
Hours of sleep per night_____

- walking several blocks
- walking one block
- bathing and dressing yourself

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Please respond with:

- a. yes
- b. no

- cut down the amount of time you spent on work or other activities
- accomplish less than you would like
- were limited in the kind of work or other activities
- had difficulty performing the work or other activities (for example, it took extra effort)

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Please respond with:

- a. yes
- b. no

- cut down the amount of time you spent on work or other activities
- accomplished less than you would like
- didn't do work or other activities as carefully as usual

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends neighbors or groups?

- a. not at all
- b. slightly
- c. moderately
- d. quite a bit
- e. extremely

7. How much bodily pain have you had during the past 4 weeks?

- a. none
- b. very mild
- c. mild
- d. moderate
- e. severe
- f. very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?

- a. not at all
- b. a little bit
- c. moderately
- d. quite a bit
- e. extremely

9. These questions are about how you feel and how things have been with you during the past month . For each question, please indicate that one answer that comes closest to the way you have been feeling. How much of the time during the past month.

Please respond with the appropriate letter:

- a. all of the time
- b. most of the time
- c. a good bit of the time
- d. some of the time
- e. a little of the time
- f. none of the time

- did you feel full of pep?
- have you been a very nervous person?
- have you felt so down in the dumps nothing could cheer you up?
- have you felt calm and peaceful
- did you have a lot of energy?
- have you felt downhearted and blue?
- did you feel worn out?
- have you been a happy person?
- did you feel tired?
- has your health limited your social activities (like visiting with friends or close relatives)?

10. Please choose the answer that best describes how true or false each of the following statements is for you.

Please respond with:

- a. definitely true
- b. mostly true
- c. not sure
- d. mostly false
- e. definitely false

- I seem to get sick a little easier than other people
- I am as healthy as anybody I know.
- I expect my health to get worse.
- My health is excellent.

Table 1

Demographic and Diagnostic Characteristics of Adults (N = 30) with OSAS

	Men (n= 22)		Women (n= 8)		Total (N= 30)	
Mean age (SD)	52.74	(11.18)	51.50	(16.32)	52.37	(12.59)
Mean weight (SD)	236.00	(69.69)	241.13	(92.81)	237.52	(75.41)
Mean height (SD)	69.95	(2.93)	64.13	(2.30)	68.22	(3.84)
Employment						
status:						
yes	9		5		14	
no	2		0		2	
retired	6		3		9	
disabled	5		0		5	
HTN	13		4		17	
COPD	3		2		5	
Smoke	2		0		2	
Snore	21		7		28	

Table 2

Treatment Characteristics for Adults (N = 30) with OSAS

	Men (n= 22)		Women (n= 8)		Total (N= 30)	
CPAP	21		5		26	
BiPAP	1		3		4	
Mean DxAHI* (SD)	50.95	(35.01)	51.33	(59.47)	51.03	(38.11)
Mean months used (SD)	11.00	(11.82)	12.63	(10.51)	11.43	(11.33)
Mean nights/ week (SD)	6.09	(1.82)	6.50	(1.41)	6.20	(1.71)
Mean hours/night (SD)	6.07	(1.83)	7.25	(0.71)	6.38	(1.68)

Note. * Diagnosed Apnea-Hypopnea Index

Table 3

Number of Subjects Reporting Impact of
Treatment on Work (n = 14)

	pre tx	post tx
Work Performance		
Poor	3	0
Fair	5	2
Good	3	5
Excellent	3	7

Table 4

Mean Scores and SD of Daytime Sleepiness (Epworth Scale) and Sleep Quality (Pittsburgh Scale)

	Daytime Sleepiness				Global Sleep Quality			
	pre tx		post tx		pre tx		post tx	
	M	SD	M	SD	M	SD	M	SD
Men (n=22)	12.78	(6.60)	7.14	(5.31)	11.14	(3.82)	8.73	(3.76)
Women (n=8)	13.88	(6.06)	6.00	(3.16)	10.25	(3.73)	8.63	(5.15)
Total (N=30)	13.07	(6.38)	6.83	(4.81) *	10.90	(3.75)	8.70	(4.08) *

Note. * $p < .05$ paired t-test

Table 5

Pre to Post Treatment Improvement in Pittsburgh Sleep Quality Index Component Scores

	Men (n=22)						Women (n=8)						Total (N=30)					
	pretx		post tx		pretx		post tx		pretx		post tx		pretx		post tx			
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD		
Subjective Sleep Quality	0.52	(0.90)	0.32	(0.65)	0.25	(0.46)	0.25	(0.71)	0.45	(0.81)	0.30	(0.65)	0.45	(0.81)	0.30	(0.65)		
Sleep Latency	1.50	(1.57)	1.14	(1.08)	0.88	(1.36)	1.00	(1.93)	1.33	(1.52)	1.10	(1.32)	1.33	(1.52)	1.10	(1.32)		
Sleep Duration	1.55	(1.01)	1.18	(1.05)	1.13	(0.99)	0.75	(0.89)	1.43	(1.01)	1.07	(1.01)	1.43	(1.01)	1.07	(1.01)		
Habitual Sleep Efficiency	2.78	(0.74)	2.74	(0.75)	3.00	0.00	2.88	(0.35)	2.84	(0.64)	2.77	(0.67)	2.84	(0.64)	2.77	(0.67)		
Sleep Disturbances	1.95	(0.79)	1.59	(0.80)	2.00	(0.53)	1.63	(0.74)	1.97	(0.72)	1.60	(0.77) *	1.97	(0.72)	1.60	(0.77) *		
Use of Sleep Med	0.55	(1.44)	0.41	(1.05)	0.75	(1.04)	1.38	(1.41)	0.60	(1.33)	0.67	(1.21)	0.60	(1.33)	0.67	(1.21)		
Daytime Dysfunction	2.09	(0.97)	1.00	(0.98)	2.25	(0.89)	0.75	(0.71)	2.13	(0.94)	0.93	(0.91) *	2.13	(0.94)	0.93	(0.91) *		

Note. * p < .05 paired t-test

Table 6

Pre to Post Treatment Improvement in SF-36 Quality of Life Scores (in percent)

	Men (n=22)				Women (n=8)				Total (N=30)			
	pretx		post tx		pretx		post tx		pretx		post tx	
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Physical Functioning	61.36	(36.09)	67.50	(31.39)	43.13	(37.70)	51.25	(35.23)	56.50	(36.79)	63.17	(32.66) *
Social Functioning	63.27	(36.72)	71.41	(30.14)	46.75	(26.78)	61.88	(21.95)	58.87	(34.71)	68.87	(28.15) *
Role Functioning (physical)	43.18	(42.39)	55.68	(41.50)	25.00	(32.73)	53.13	(45.19)	38.33	(40.33)	55.00	(41.73) *
Role Functioning (mental)	44.29	(41.27)	63.33	(40.74)	54.00	(43.43)	79.00	(30.72)	46.97	(41.32)	67.66	(38.37) *
Energy/Fatigue	37.50	(26.89)	61.14	(26.36)	16.25	(15.29)	60.00	(25.21)	31.83	(25.91)	60.83	(25.63) *
Pain	63.73	(31.95)	68.14	(20.20)	41.38	(22.32)	48.25	(28.42)	57.77	(30.99)	62.83	(23.88)
Mental Health	65.90	(18.92)	68.73	(21.58)	62.00	(24.47)	78.50	(19.24)	64.83	(20.21)	71.33	(21.12)
General Health	56.14	(24.30)	65.19	(20.57)	43.65	(15.80)	55.52	(19.31)	52.81	(22.78)	62.61	(20.38) *

Note. * p < .05 paired t-test

Table 7

Correlation of Daytime Sleepiness, Quality of Sleep and its
Components, and CPAP Use

	Time Used Hours/night Nights/week (mo)		
	r	r	r
Daytime Sleepiness	.06	-.21	-.58*
Quality of Sleep	-.12	-.24	-.33
Subjective Sleep Quality	-.07	-.19	-.24
Sleep Latency	-.37*	-.28	.01
Sleep Duration	.02	-.23	-.33
Habitual Sleep Efficiency	.03	.23	.49*
Sleep Disturbances	-.04	-.32	-.23
Use of Sleep Med	.12	.29	-.03
Daytime Dysfunction	-.15	-.30	-.44*

Note. * $p < .05$

Table 8

Correlation of Quality of Life and CPAP Use

	Time Used (mo)	Hours/night	Nights/week
	r	r	r
Physical Functioning	-.33	-.04	.07
Social Functioning	-.20	.20	.20
Role Functioning (physical)	.00	.28	.05
Role Functioning (mental)	-.23	.08	.05
Energy/Fatigue	.07	.35	.12
Pain	-.22	-.04	-.10
Mental Health	.08	.08	.51*
General Health	.01	.12	-.07
Change in Health	-.06	-.11	-.08

Note. * $p < .05$

