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Published in final edited form as:

J Sleep Res. 2016 December ; 25(6): 731–738. doi:10.1111/jsr.12430.

IMPACT OF CONTINOUS POSITIVE AIRWAY PRESSURE (CPAP) ON QUALITY OF LIFE IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA (OSA)

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Summary

Obstructive Sleep Apnea is a chronic illness with increasing prevalence. In addition to associated cardiovascular comorbidities, obstructive sleep apnea syndrome has been linked to poor quality life, occupational accidents, and motor vehicle crashes secondary to excessive daytime sleepiness. Although continuous positive airway pressure is the gold standard for sleep apnea treatment, its effects on quality of life are not well defined. In the current study we investigated the effects of treatment on quality of life using the data from a subset of the Apnea Positive Pressure Long-term Efficacy Study (APPLES), a randomized controlled trial of continuous positive airway pressure (CPAP) vs. sham CPAP. The Calgary Sleep Apnea Quality of Life Index (SAQLI) was used to assess quality of life. We found that long-term improvement in quality of life occurs with the use of CPAP in persons with severe and possibly moderate sleep apnea. However no demonstrable improvement in quality of life was noted among participants with mild obstructive sleep apnea.

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Keywords

Continuous positive airway pressure; sleep apnea quality of life; daytime sleepiness; obstructive sleep apnea

Background

Interest in quality of life (QoL) measures for chronic diseases has increased in recent years. In the United States, the Healthy People 2020 initiative identified QoL improvement across all life stages as a central public health goal(Sondik et al.). Obstructive sleep apnea (OSA) syndrome is one of the chronic illnesses specifically targeted, with an estimated prevalence in the range of 2–5% to 3–7% among women and men respectively(Punjabi, 2008, Punjabi et al., 2009). In addition to its strong association with cardiovascular co-morbidities and an increased risk for motor vehicle crashes(Terán-Santos et al., 1999), several studies have reported an association between OSA and poor QoL(Yang et al., 2000). Moreover, the main reasons patients seek medical attention are daytime sleepiness, fatigue, and social or emotional difficulties, all of which are likely to negatively affect quality of life.

Continuous positive airway pressure (CPAP) is the most efficacious and commonly used treatment for patients with OSA(Task Force of the American Academy of Sleep Medicine, 2009). It has been shown to improve daytime sleepiness, reduce blood pressure, and ameliorate cardiovascular risk(Durán-Cantolla et al., Becker et al., 2003, Kribbs et al., 1993). Some studies have demonstrated a dose response relationship with greater benefit accruing with increased nightly use although the amount of improvement is relatively less for usage exceeding 4 hours(Sawyer et al.). Although improvement in QoL with CPAP therapy has been demonstrated(Engleman et al., 1997), whether this benefit is maintained over an extended period of time remains to be determined. Furthermore, it is unclear if the impact of CPAP on QoL is limited to only those with the more severe manifestations of this condition or if there are benefits to those with mild OSA as well. Results of the few studies that have addressed this issue have been discordant(Engleman et al., 1999, Barnes et al., 2004, Akashiba et al., 2002, Baldwin et al., 2001, Gall et al., 1993).

The Calgary Sleep Apnea Quality of Life Index (SAQLI) was developed as a sleep apnea-specific quality of life instrument responsive to changes in treatment(Ward Flemons and Reimer, 1998). It has been shown to have high internal consistency and reliability, and construct validity as shown by its positive correlation with the more generic Medical Outcomes Survey Short Form-36 (SF-36). SAQLI items are organized into domains assessing daily functioning, social interactions, emotional functioning, symptoms potentially related to OSA, and treatment-related symptoms(Flemons and Reimer, 2002). Research suggests that the SAQLI measures components of health-related QoL important to sleep apnea patients and can be used to measure within patient change following treatment intervention.

The objective of this investigation was to extend the results of previous studies and determine whether the effects of CPAP on QoL are maintained over a prolonged period of time using a sleep apnea specific QoL instrument. An additional goal was to assess whether

there are benefits across the entire spectrum of OSA severity. The analysis was conducted using the data from a subset of the Apnea Positive Pressure Long-term Efficacy Study (APPLES), a randomized controlled trial of CPAP vs. Sham CPAP over 6 months(Kushida et al., 2006) We hypothesized that treatment with CPAP would be associated with improvement in overall QoL as assessed by the SAQLI and that the association would be mediated by baseline OSA severity.

Methods

Study Population and Protocol

APPLES was a 6-month multicenter, randomized, double-blinded, 2-arm, sham-controlled, intention-to-treat study of CPAP efficacy on three domains of neurocognitive function in OSA. A detailed description of the protocol has previously been published(Kushida et al., 2006). Briefly, the participants were either recruited through local advertisement or from those attending sleep clinics for evaluation of possible OSA. The initial clinical evaluation included administering informed consent, screening questionnaires, a history and physical examination, and a medical assessment by a study physician. Participants subsequently returned 2–4 weeks later for a 24-h sleep laboratory visit, during which polysomnography (PSG) was performed to confirm the diagnosis, followed by a day of neurocognitive, mood, sleepiness, and QoL testing.

Inclusion and exclusion criteria have been published previously and included age ≥ 18 years and a clinical diagnosis of OSA, as defined by American Academy of Sleep Medicine (AASM) criteria and an apnea hypopnea index (AHI) ≥ 10 by PSG. Exclusion criteria included: previous treatment for OSA with CPAP or surgery, oxygen saturation on baseline PSG <75% for >10% of the recording time, history of motor vehicle accident related to sleepiness within the past 12 months, presence of chronic medical conditions, use of various medications known to affect sleep or neurocognitive function, and various health and social factors that may impact standardized testing procedures (*e.g.,* shift work).

Following the PSG, participants with an AHI ≥ 10 who met other enrollment criteria were randomized to CPAP or sham CPAP for continued participation in APPLES. After randomization, participants returned to the sleep laboratory for a CPAP or sham CPAP titration PSG. Subsequent assessments were made at 2, and 6 months post-randomization at which time a test battery was re-administered including QoL questionnaires.

Assessment of Quality of Life

Calgary Sleep Apnea Quality of Life Index (SAQLI)—The SAQLI was developed as a sleep apnea-specific QoL instrument that assesses components deemed important to patients(Ward Flemons and Reimer, 1998). It was designed as an interview administered by trained staff. The first 35 items capture responses assessing daily functioning, social interactions, and emotional functioning. Next, symptoms are reviewed that may be experienced by patients with sleep apnea, and participants are asked to select up to five symptoms they consider the most important for evaluation. Once treatment has been initiated, five treatment-related symptoms are also selected and evaluated. Items are scored

on a 7-point scale where the wording varies slightly depending on the question; examples of the most extreme responses are “all of the time” and “not at all.” Item and domain scores are averaged, taking into account the impact of treatment-related symptoms, to yield a composite total score between 1 and 7. Higher scores represent better QoL.

Assessments of Mood and Sleepiness

Beck Depression Inventory II (BDI)—The BDI is a validated 21-question multiple choice self-reported inventory, and is one of the most widely used instruments for measuring the severity of depression(Beck and Steer, 1987). Items are scored on a 4-point severity scale, where a higher BDI total score suggests a higher level of depression. A score of 14 or above is consistent with at least mild depression.

The Profile of Mood States (POMS)—The POMS is an established measure of transient mood states with high reliability and validity. The scale consists of 65 self-rated adjectives on a 5-point scale with the instruction to rate each item “at the present time” (McNair et al.). Possible responses are: not at all, a little, moderately, quite a lot, or extremely. Six mood states are measured in the POMS: tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment. These factors can be combined to form the POMS total mood disturbance (TMD) score. Higher scores represent more negative mood states.

Hamilton Rating Scale for Depression (HMD)—The HMD is a validated 21-item clinician-administered assessment of the severity of depression. APPLES used a modified version of this test administered by trained staff. In this psychometrician-administered interview, 17 questions (*e.g.*, depressed mood, suicide, work and anhedonia, retardation, agitation, gastrointestinal or general somatic symptoms, hypochondriasis, loss of insight or weight) were asked to identify and monitor depressive symptomatology. Interviews were scored using either a 3- or 5-point scale based on intensity and frequency, and were summed to provide a single total score(Hamilton, 1960).

Epworth Sleepiness Scale (ESS)—The ESS is a validated 8-item questionnaire designed to measure subjective sleepiness. It was originally designed to distinguish normal patients from those with sleep disorders such as OSA and narcolepsy(Johns, 1991). This self-administered instrument rates how likely a patient is to doze off or fall asleep during certain situations (*i.e.,* no chance of dozing, slight chance of dozing, moderate chance of dozing, high chance of dozing), and averages the responses to derive a total score. Higher scores represent a higher level of subjective sleepiness.

Polysomnography

The PSG montage included monitoring of the electroencephalogram (EEG, C_3-A_2 or C_4-A_1, O_2-A_1 or O_1-A_2), electrooculogram (EOG, ROC-A_1, LOC-A_2), chin and anterior tibialis electromyograms (EMG), heart rate by 2-lead electrocardiogram, snoring intensity (anterior neck microphone), nasal pressure (nasal cannula), nasal/oral thermistor, thoracic and abdominal movement (inductance plethysmography bands), and oxygen saturation (pulse oximetry). All PSG records were electronically transmitted to a centralized data

coordinating and PSG reading center. Sleep and wakefulness were scored using Rechtschaffen and Kales criteria(Rechtschaffen and Kales, 1968). Apneas and hypopneas were scored using American Academy of Sleep Medicine Task Force (1999) diagnostic criteria(Flemons et al., 1999). Briefly, an apnea was defined by a clear decrease (> 90%) from baseline in the amplitude of the nasal pressure or thermistor signal lasting ≥ 10 sec. Hypopneas were identified if there was a clear decrease (> 50% but ≤ 90%) from baseline in the amplitude of the nasal pressure or thermistor signal, or if there was a clear amplitude reduction of the nasal pressure signal ≥ 10 sec that did not reach the above criterion, but was associated with either an oxygen desaturation > 3% or an arousal. Obstructive events were scored if there was persistence of chest or abdominal respiratory effort. Central events were noted if no displacement occurred on either the chest or abdominal channels. Sleep apnea was classified as mild (AHI 10.0 to 15.0 events per hour), moderate (AHI 15.1 to 30.0 events per hour), and severe (AHI more than 30 events per hour)(Flemons et al., 1999)

Statistical Analysis

Univariate and multivariate logistic regression models were used to estimate the degree to which variables correlated with QoL scores. We examined the association between the SAQLI and the following variables: OSA severity as measured by the AHI, sleepiness as assessed by ESS, age, baseline body mass index (BMI, kg/m^2), and mood measured by HMD, POMS, and BDI. PSG sleep efficiency and total sleep time were included in the models if significant correlations were observed on univariate analysis.

A paired sample t-test was conducted to compare effects of treatment (CPAP vs. Sham CPAP) on SAQLI at 2 and 6 months. To assess factors associated with the minimum clinically relevant improvement in SAQLI total score (>1.0) (Flemons and Reimer, 2002), binary logistic regression models were constructed. For these models, dichotomous variables were created for treatment (CPAP vs. SHAM), OSA severity (AHI < 15 vs. ≥ 15), obesity (BMI <30 kg/m^2 vs. ≥30 kg/m^2), depression (BDI <14 vs. ≥14), CPAP compliance (< 4 hours/night vs. ≥4 hours/night), and excessive sleepiness (ESS <10 vs. ≥10).

Finally we used unpaired t-tests to assess the effect of gender and OSA severity on change in ESS total score in both the CPAP and Sham CPAP groups. Data for continuous and interval variables were expressed as mean ± SD, and as a percentage for categorical variables. Statistical significance was set at a P value <0.05, two-tailed. Analyses were performed using STATA (Version 11, StataCorp TX USA).

Results

Table 1 includes demographic and baseline outcome measure values for the CPAP and Sham groups (n=443 and 402 respectively) with SAQLI data. The two groups were generally similar in mean age, sex ratio, proportion of white participants and average BMI. Similar proportions of the two groups had severe OSA (57%), with an average AHI of 40/hour. The average CPAP adherence at 2 and 6 months was 3.43 ± 2.8 and 2.92 ± 2.9 hours/night for the Sham group vs. 4.31 ± 2.9 and 3.69 ± 3.1 hours per night in the CPAP group. BDI scores in both groups averaged approximately 6. Interestingly, the participants in the CPAP arm reported higher baseline POMS scores. The participants in both randomized groups had

similar SAQLI scores at baseline. At the 2 and 6 month visits (data not shown) no significant change was noted in total sleep time and sleep efficiency. However, a significant decrease in arousal index was noted at 6 months in the CPAP group (29/hour vs. 16/hour $P<0.001$). There was also a trend for the CPAP group to have a lower POMS score at 6 months, however the results were not statistically significant (12 vs. 6.6, $P=0.07$).

To assess QoL between treatment arms over time, we compared overall SAQLI total score at the three study visits and found no significant differences in means (Table 2a and Table 2b). Analyses were also stratified by OSA severity (mild, moderate, and severe), but no significant differences were detected. Additional focused analyses indicated a significant decline in SAQLI at 2 months among participants with mild OSA (4.6 to 4.2, $p=0.04$. This decline in SAQLI primarily occurred among participants with less than 4-hour use of CPAP. In contrast compared to Sham CPAP, participants in the CPAP arm with severe OSA and CPAP usage >4 hours/night had a small, but significant improvement in their SAQLI scores (4.7 to 5.0, $P<0.05$) at 6 months (Table 2b).

A multivariate logistic regression analysis was performed to identify factors predicting a change in the SAQLI of at least 1 total score (Table 3). Compared to the Sham CPAP arm, the participants in CPAP arm demonstrated increased odds of having a change in SAQLI total score of at least 1 (OR: 1.66, 95% CI: 1.1–2.6, $P<0.03$. Of note, severity of OSA (moderate to severe vs. mild) and CPAP compliance were not predictive of SAQLI change. Similarly, a one unit change in ESS total score also predicted significant change in SAQLI total score of at least 1 (OR: 1.76, 95% CI: 1.1–2.7, $P<0.01$).

Finally, as shown in Table 4, compared to the SHAM group significant improvement in ESS was noted amongst the CPAP group ($P<0.05$) for participants with moderate or severe OSA and the results were more prominent among women. No significant change in ESS was noted in mild OSA group in either treatment arm.

Discussion

Our results demonstrate that CPAP use of ≥4 hours per night among patients with severe OSA improves QoL as measured by the SAQLI. Clinically important changes in QoL occurred primarily in those who were subjectively sleepy. Our findings emphasize the importance of treatment adherence in predicting QoL improvements in patients with OSA. These results are in accordance with previous studies underscoring the importance of CPAP compliance. Using the functional outcomes of sleep questionnaire (FOSQ) as the QoL measure, Weaver *et al.* demonstrated improvement in FOSQ total score after CPAP use. Almost 67% of participants with CPAP, use of more than 5 hours achieved a score of 17.9 or above. In contrast, only 33% of participants with CPAP use of less than 2 hours had similar improvement in QoL(Weaver et al., 2007). Likewise, a large retrospective study of the French population using the Nottingham Health Profile (NHP) demonstrated that OSA patients with intermediate CPAP compliance (4–7 hours/night) had a better perception of their health than the poorly compliant patients (<4 hours/night)(Meslier et al., 1998). In another small study of 29 patients, 8 weeks of CPAP therapy (6.0 ± 1.6 hours/night) demonstrated significant improvement in vitality, social functioning, and mental health (*p*

<0.05) compared to baseline values(D'Ambrosio et al., 1999). Similarly a meta-analysis (*n* =1256) found improvement in physical function, energy/vitality, and the physical component summary (PCS) domain of the SF-36 after CPAP use(Jing et al., 2008). However, QoL was not measured among the non-compliant patients in these studies. Thus, there is limited research on the effect of CPAP on QoL in randomized controlled trials, and our study is one such study demonstrating improvement in the SAQLI after CPAP use.

The current study also indicates increased odds of a SAQLI total score change of >1.0 for participants with moderate to severe OSA and those adhering to CPAP (≥4 hours/night). It has been suggested that the minimal important difference in SAQLI score is approximately 1, and a score of this magnitude is associated with a clinically meaningful improvement in QoL for patients with sleep apnea(Flemons and Reimer, 2002). Our findings indicate that in addition to those with severe OSA, patients with moderately severe OSA also may experience some improvement in QoL with CPAP.

Impairment in physical health domains of health-related QoL has been reported among patients with OSA(Lacasse et al., 2002). Although CPAP treatment leads to improvement, very few studies have shown correlation between OSA severity and the QoL measures(Avlonitou et al., Engleman et al., 1997, Barnes et al., 2002, Tousignant et al., 1994, Sanner et al., 2000). In a retrospective study of 19 participants, positive correlation was demonstrated between OSA severity and health state(Tousignant et al., 1994). Similarly, in another study examining the long term effects of CPAP, a very weak correlation was observed between mean oxygen saturation at night and QoL as measured by the complaint list(Sanner et al., 2000). In contrast, for our study, severity of OSA played a vital role in predicting change in SAQLI total score for those randomized to the therapeutic CPAP treatment arm. Participants in the CPAP arm with severe OSA demonstrated improvement in SAQLI total score. No significant change in SAQLI was noted for participants with mild OSA.

In contradistinction to our results, others have reported improvement in QoL independent of OSA severity. Avlonitou *et al.* demonstrated significant improvement in SAQLI scores after CPAP treatment in the domains of social interactions and daily and emotional functioning irrespective of OSA severity(Avlonitou et al.). Prior to CPAP treatment, patients in the study by Avionitou *et al.* (*n*=50) reported a higher ESS total score, and the symptoms that showed the greatest improvement were those associated with daytime sleepiness. Similarly, significant increases in SF-36 scores after CPAP therapy has been reported in patients with mild sleep apnea with severely impaired QoL measures(Engleman et al., 1997, D'Ambrosio et al., 1999). Excessive sleepiness, not the severity of OSA, was thought to be responsible for low QoL scores in these studies. Our finding of an association between a change in SAQLI >1 and sleepiness is consistent with these previous studies and emphasizes the importance of sleepiness in determining QoL in patients with OSA.

Daytime sleepiness is one of the main reasons patient seek medical attention, and commonly, subjective sleepiness is assessed using the ESS. Although subjective sleepiness as measured by the ESS improved in both groups, the change in ESS total score was significantly greater for participants randomized to the CPAP treatment arm and was

predominantly seen among patients with moderate to severe OSA. Thus, our data provide additional evidence that CPAP is an effective treatment for OSA-related sleepiness over the long-term.

Quality of life is becoming an increasingly important construct in evaluating the benefits of treatment for many conditions. With respect to OSA, QoL has been selected as a quality metric to evaluate the standard of care rendered to patients(Aurora et al.). Research suggests that QoL among patients with OSA is not only limited to daytime sleepiness, but rather encompasses a wider perception of performance in domains such as physical function, emotional state, and social interaction. The SAQLI was developed to identify symptoms more relevant to patients, and thus should be an appropriate tool to measure treatment success in those with OSA. Our data demonstrating that the SAQLI is responsive to CPAP intervention supports its use in this context.

While our initial overall comparisons of total SAQLI score by treatment arm across study visits demonstrate a significant decrease in SAQLI scores in the mild OSA group who were treated with Sham CPAP, we found that long-term improvement in QoL occurs with the use of CPAP in persons with OSA who have severe, and possibly moderate OSA, and who are moderately compliant with CPAP. The decline in SAQLI in participants with mild OSA could be explained by the fact that the mild OSA patients with minimal symptoms found Sham CPAP to be uncomfortable as reflected in SAQLI score.

Strengths of this study include a large number of participants across multiple sites, randomized CPAP and Sham CPAP control groups, documentation of CPAP compliance at 6 months, and adjustment for multiple confounders that can affect QoL. Despite its strengths, the current study has some limitations. First, since the study was randomized to groups (CPAP and Sham CPAP) with no control arm, the possibility of placebo effect cannot be excluded even in the Sham CPAP arm. Second, the change in QoL after 6 months of CPAP treatment does not necessarily predict maintenance of this long-term clinical improvement indefinitely. Third, participants with very severe OSA were excluded from this study based on the exclusion criteria related to low oxygen saturation (saturation on baseline PSG <75% for >10% of the recording time). Lastly, our results are not necessarily applicable to other treatment modalities for OSA, such as oral appliances or upper airway surgery.

In conclusion, the findings of this study demonstrate that QoL improves in patients with severe and possibly moderate OSA who are adequately treated with CPAP, and this improvement is maintained over an extended time period. Future studies are needed with longer follow-up on OSA patients, treated with more diverse treatment modalities, with and without subjective sleepiness, to more thoroughly assess long-term effects of OSA treatment on overall QoL.

Acknowledgments

APPLES was funded by contract 5UO1-HL-068060 from the National Heart, Lung and Blood Institute. The APPLES pilot studies were supported by grants from the American Academy of Sleep Medicine and the Sleep Medicine Education and Research Foundation to Stanford University and by the National Institute of Neurological Disorders and Stroke (N44-NS-002394) to SAM Technology. In addition, APPLES investigators gratefully

recognize the vital input and support of Dr. Sylvan Green who died before the results of this trial were analyzed, but was instrumental in its design and conduct.

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*Sleep HealthCenters for the use of their clinical facilities to conduct this research

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Table 1

Baseline characteristics of APPLES participants with SAQLI data

	All Subjects	After Randomization	
	With SAQLI data	SHAM	CPAP
N	**845**	402	443
Age, *mean year* (SD)	52 ± 12	51 ± 12	52 ± 12
Gender, *n* (% men)	549 (65)	259 (64)	290 (65)
Ethnicity, *n*, (% White)	644 (76)	304 (76)	340 (77)
BMI (*Kg/m2*, SD)	32.2 ± 7.1	32 ± 6.7	32.5 ± 7.5
OSA Severity, *n* (%)			
Mild	113 (14)	50 (12)	63 (14)
Moderate	249 (29)	121 (30)	128 (29)
Severe	483 (57)	231 (57)	252 (57)
AHI at baseline *mean* (SD)	40 ± 25	41 ± 25	40 ± 24
ESS *mean* (SD)	10.4 ± 4.5	10.4 ± 4.4	10.3 ± 4.5
SAQLI at baseline	4.7 ± 0.8	4.7 ± 0.8	4.7 ± 0.8
BDI Score	6.1 ± 4.9	6.3 ± 5.0	5.9 ± 4.9
HMD Score	4.3 ± 4.1	4.1 ± 3.8	4.5 ± 4.3
POMS	8.6 ± 96	5.1 ± 113	11.8 ± 79
Total Sleep Time (min)	376 ± 65	377 ± 63	376 ± 66
Sleep Efficiency (%)	78 ± 13	78.3 ± 12	78 ± 13
Arousal Index	29 ± 20	30 ± 22	29 ± 19
Compliance at 2 Months	3.89 ± 2.9	3.43 ± 2.8	4.31 ± 2.9
Compliance at 6 Months	3.33 ± 3.1	2.92 ± 2.92	3.69 ± 3.1

SD: Standard Deviation, BMI: Body Mass Index, OSA: Obstructive Sleep Apnea, AHI: Apnea Hypopnea Index, ESS: Epworth Sleepiness Scale, BDI: Beck Depression Inventory, HMD: Hamilton Rating Scale for Depression, POMS: Profile of Mood States, SAQLI: Sleep Apnea Quality of Life Index.

Table 2a

Change in SAQLI at 2 Months based on treatment groups and OSA severity

	Compliance < 4 hours				Compliance > 4 hours			
	SHAM		CPAP		SHAM		CPAP	
	Baseline	2 M	Baseline	2M	Baseline	2 M	Baseline	2M
N	193	193	157	157	199	199	274	274
OSA	4.6 (0.8)	4.4 (1.3)*	4.6 (0.8)	4.5 (0.8)	4.7 (0.8)	4.7 (1.2)	4.8 (0.8)	4.8 (0.8)
N	25	25	23	23	21	21	38	38
Mild	4.6 (0.6)	4.2 (1.1)*	4.4 (0.8)	4.6 (0.7)	4.9 (0.7)	4.9 (0.7)	4.7 (0.6)	4.6 (0.8)
N	64	64	52	52	55	55	75	75
Moderate	4.7 (0.9)	4.5 (0.9)	4.6 (0.9)	4.3 (0.8)	4.8 (0.7)	4.8 (0.7)	4.8 (0.8)	4.6 (0.8)
N	104	104	82	82	123	123	161	161
Severe	4.6 (0.7)	4.4 (1.6)	4.7 (0.7)	4.6 (0.8)	4.7 (0.8)	4.5 (1.4)	4.9 (0.8)	4.9 (0.7)

Table 2b

Change in SAQLI at 6 Months based on treatment groups and OSA severity

	Compliance < 4 hours				Compliance > 4 hours			
	SHAM		CPAP		SHAM		CPAP	
	Baseline	6 M	Baseline	6M	Baseline	6 M	Baseline	6M
N	242	242	193	193	160	160	249	249
OSA	4.6 (0.8)	4.6 (1.0)	4.7 (0.8)	4.7 (0.8)	4.8 (0.8)	4.9 (0.7)	4.7 (0.8)	5.0 (0.7) *
N	34	34	29	29	16	16	34	34
Mild	4.6 (0.7)	4.6 (1.0)	4.5 (0.7)	4.8 (0.8)	4.7 (0.7)	4.9 (0.7)	4.6 (0.6)	4.8 (0.8)
N	75	75	59	59	46	46	69	69
Moderate	4.6 (0.9)	4.7 (1.0)	4.6 (0.8)	4.6 (0.9)	4.9 (0.7)	4.9 (0.6)	4.8 (0.8)	4.9 (0.7)
N	133	133	105	105	98	98	146	146
Severe	4.6 (0.8)	4.6 (0.9)	4.8 (0.8)	4.8 (0.8)	4.7 (0.8)	4.8 (0.8)	4.7 (0.8)	5.0 (0.7) *

Paired ttest for saqli at baseline and at 2 and 6 months stratified by severity and treatment groups

* P <0.05

Table 3

Odds ratios for change in SAQLI >1

	Odds Ratio	95% CI	P value
OSA	0.84	0.4–1.6	0.59
CPAP	1.66	1.1–2.6	0.03*
Compliance	0.86	0.54–1.4	0.53
Obesity	0.79	0.49–1.2	0.23
Depression	0.64	0.33–1.3	0.19
ESS	1.76	1.1–2.7	0.01*
Gender	1.2	0.76–1.9	0.44

Multiple Logistic Regression Model: SAQLI: Sleep Apnea Quality of Life Index, OSA: Obstructive Sleep Apnea, CPAP: Continuous Positive Airway pressure, ESS: Epworth Sleepiness Scale

* P< 0.05

Table 4

Change in ESS according to treatment group and stratified by gender

Δ ESS	**SHAM**			**CPAP**		
	Mild	**Mod**	**Severe**	**Mild**	**Mod**	**Severe**
Males	2.4±3.6	1.7 ±3.3	2.1 ± 3.4	2.9±4.8	1.9 ±4.1	**3.1 ±4.5** *
Females	2.3 ± 3.4	1.5 ±3.7	2.1 ± 4.1	3.2 ±4.0	**3.1 ± 4.3** *	**3.5 ± 3.9** *

ESS: Epworth Sleepiness Scale,

* $p < 0.05$