

# IMPROVING CPAP COMPLIANCE BY A BASIC EDUCATIONAL PROGRAM WITH NURSE SUPPORT FOR OBSTRUCTIVE SLEEP APNEA SYNDROME PATIENTS

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## ABSTRACT

**Background and objective:** Continuous Positive Airway Pressure (CPAP) is the treatment of choice for moderate to severe obstructive sleep apnea (OSA). However, the compliance to CPAP is variable. We evaluated the impact of a simple educational program administered by one nurse.

**Methods:** We evaluated CPAP compliance in 95 OSA patients that participated in the educational program and in 93 patients that did not. The program provided information and training, supported by video sessions and outpatient visits with the nurse at 7, 15, 30, 60 and 90 days after CPAP initiation. The control group did not receive any information or training. Both groups were evaluated at each visit, using the general sleep and Epworth Sleepiness Scale (ESS) questionnaire, for adherence and side effects of CPAP.

**Results:** Control and experimental groups had similar age ( $53 \pm 11$  vs.  $53 \pm 11$  y), body mass index ( $32 \pm 6$  vs.  $33 \pm 7$  kg/m<sup>2</sup>), apnea-hypopnea index ( $43 \pm 25$  vs.  $46 \pm 28$ ), and CPAP pressure ( $17 \pm 5$  vs.  $16 \pm 6$  cmH<sub>2</sub>O). CPAP compliance was significantly higher in the educational program group compared with the control group (71 vs. 56%,  $p=0.02$ ; and  $6.3 \pm 1.9$  vs.  $5.1 \pm 1.7$  hrs/night, respectively,  $p=0.01$ ) at the 90th day. In the educational program group, regular CPAP users had lower ESS scores after 90 days of CPAP therapy compared with irregular users ( $7.1 \pm 4.9$  vs.  $10.2 \pm 5.3$ , respectively;  $p=0.007$ ).

**Conclusions:** Our study supports the concept that an orientation program is effective in improving CPAP compliance.

**Keywords:** CPAP, compliance, educational program, OSAS.

## INTRODUCTION

Obstructive Sleep Apnea Syndrome (OSAS) is characterized by partial (hypopnea) or total (apnea) airway obstruction during sleep. These respiratory events usually cause hypoxemia and sleep fragmentation (1). Patients with OSAS complain of hypersomnolence and loud snoring, and their bed partners report witnessing sleep apneas (2).

Continuous Positive Airway Pressure (CPAP) is considered the standard of care for treating moderate to severe OSAS (3). CPAP

has been reported to abolish obstructive respiratory events, correct nocturnal oxyhemoglobin desaturation (4,5), and improve self-reported sleepiness (3,6). CPAP therapy could decrease blood pressure in OSA hypertensive patients (3,5,7,8). In addition, some studies suggested that CPAP may improve quality of life (3,9,10), mood, and cognitive function (3,11,12). CPAP therapy is safe, and the most common side effects are related to the nasal mask itself, such as air leaks or ulceration of the bridge of the nose (13). Nasal congestion, rhinorrhea, and sneezing have also been noted in many cases. Zierska and coworkers (14) reported that in patients under

CPAP treatment, 38% complained of rhinitis, 34% had discomfort due to the mask, 26% reported air leaks, 33% had nasal and oropharynx dryness, and 31% complained of sleep fragmentation. Despite the fact that CPAP is effective and the side effects are mainly minor, patients have difficulty adhering to this treatment regimen (15).

The adoption of the CPAP should be objectively monitored to help assure its utilization. Recent studies indicated that objectively-measured nightly CPAP “time on” ranges from 3.5 hrs/night in minimally symptomatic new patients to 7.1 hrs/night in established users (3,16,17). Ideally, to reduce hypersomnolence, CPAP should be used for over 4 hours per night and at least 70% of nights (18,19). This compliance, when assessed subjectively in patients’ reports, varies from 60 to 90% (20,21). However, when objectively gauged, compliance varies from 40 to 46% (17,22). Close follow-up of CPAP usage and the presence of an appropriately trained health care provider is indicated to establish effective CPAP utilization (9,15,23). There is evidence that the use of heated humidification and systematic educational program may improve CPAP compliance (3,23-28).

Several different CPAP educational programs have been proposed, including information sessions (29), telephone calls (30-32), delivery of audio-visual material (33), CPAP-user group meetings (32,34), and training for patients’ family members (35,36). Although these efforts do improve treatment compliance, the cost of intervention, the time, the number of specialists involved, and the rate of patients that finish those programs are not well established.

The aim of the study was to evaluate the impact of a simple orientation program with nurse support on CPAP compliance in OSAS patients.

## METHOD

OSAS patients recently diagnosed from the Instituto do Sono - Universidade Federal de Sao Paulo/ UNIFESP, were recruited by telephone. The protocol received the approval from the Ethics and Research Committee of Sao Paulo Hospital. All patients signed a consent form in order to take part in the trial.

Patients were included if they were aged 21 to 65 years old and presented moderate to severe OSAS, defined by either clinical diagnosis confirmed by polysomnography showing apnea-hypopnea index (AHI) higher than 15 obstructive events per hour of sleep, or mild OSAS (AHI lower or equal of 15) with excessive daytime sleepiness defined by an Epworth Sleepiness Scale (ESS) score over 10. All patients had already been submitted to a full night polysomnography for CPAP pressure titration. Further, and to avoid compromising results by poor attendance at the clinic, patients had to prove availability to participate in the study protocol. Patients could be either CPAP naïve or not CPAP naïve at the beginning of our study, but neither type of patients had previously followed any training program for CPAP users or used humidifiers. The exclusion criteria included patients whose CPAP device had no built-in compliance meter; patients unable to ensure regular attendance at the clinic; patients with severe otorhinolar-

ingological diseases that could find CPAP use difficult (e.g., those with deviated septum degrees III and IV, turbinate hypertrophy degrees III and IV (37) and tonsil hypertrophy degrees III and IV) (38); chronic alcoholics, and substance abusers.

Patients included in the experimental group were scheduled for visits on days 1, 7, 15, 30, 60 and 90 after the beginning of the protocol. On day 1, patients of the experimental group followed an educational program that consisted of a detailed explanation about OSAS and CPAP use lasting one hour, followed by a fifteen-minute video session showing features and consequences of OSAS as well as benefits and side effects of CPAP. Questionnaires and measurements were administered at every visit, and they included detailed clinical evaluation, characteristics of sleep related complaints, ESS, CPAP side effects, and adherence. Subjective sleep quality was evaluated through an analog visual scale (considerably worse = 0 and considerably better = 100), as was the extent of patients’ awareness of benefits of using the CPAP (response to an analog visual scale: totally unconvinced = 0 and fully convinced = 100). Objective compliance was checked out through verification of the CPAP built-in compliance meter. On each visit, the patient received reinforcement about the OSAS and CPAP treatment.

The control group was contacted by telephone, and this group consisted of patients that met the same inclusion and exclusion criteria but were unable to follow the entire training program. The control group was asked to attend the clinic at day 1, day 7, and day 90 (the end of the protocol) for follow-up, including the same clinically evaluation, questionnaire and measurements administered to the experimental group. Objective compliance was also checked on days 7 and 90 by verification of the CPAP built-in compliance meter. During the period of the protocol, patients included in the control group did not receive any information sessions or additional CPAP training.

We considered “regular users” as those patients who presented with 5 or more hours of CPAP use per night as evaluated by the CPAP built-in compliance meter.

All procedures were conducted by the same nurse. Patients of the experimental group were encouraged to call or to schedule extra appointments at the clinic wherever an issue or doubt arose over CPAP therapy and usage.

Descriptive statistical analyses of the numerical variables included mean and standard deviation for normal distributions or median, minimum, maximum values and inter quartile range (IQR) for variables with non-normal distributions. To compare groups, when variables were continuous, we used the Student’s *t* test for independent samples or the Mann-Whitney test. For intra-group comparisons we used the Student’s *t* test for dependent samples or the Wilcoxon test. To compare groups when the variables were categorical or nominal, we used the Chi-square ( $\chi^2$ ) test. The significance level was set at 0.05 (5%) or less. The statistical program used was Statistica, version 5 (Stat Soft Inc.).

## RESULTS

From a total of 355 contacted patients, 212 who had CPAP machines with built-in compliance meters were recruited. Of the

Table 1: General data for Control, Experimental, and Drop-out groups (Mean±SD)

	Control Group	Experimental Group	Drop-out Group	P-value *
N	93	95	24	
Male:Female (%)	91:9	82:18	67:33	
Age (years)	53 ± 11	53 ± 11	50 ± 14	NS
BMI (Kg/m <sup>2</sup> )	32 ± 6	33 ± 7	31 ± 6	NS
AHI	43 ± 25	46 ± 28	37 ± 24	NS
CPAP pressure (cmH <sub>2</sub> O)	10 ± 2	11 ± 2	10 ± 3	NS
Baseline ESS	17 ± 5	16 ± 6	13 ± 6	0.02

BMI: body mass index; AHI: apnea-hypopnea index; ESS: Epworth Sleepiness Scale score; \* ANOVA/MANOVA.

Table 2: Data from the questionnaires, scales and polysomnography of groups A and B

	Experimental Group	Control Group	P-value
N	95	93	
Patients with subjective CPAP use > 4 hrs/night (90th day)	88	84	NS
Sleep improved after CPAP * (90th day)	85 ± 19	80 ± 28	NS
Convinced ought to use CPAP ** (90th day)	89.9 ± 18.8	82.3 ± 31.1	NS
ESS (1th day)	16.1 ± 6.0	17.0 ± 5.4	NS
ESS (90 th day)	8.0 ± 5.2	8.8 ± 5.6	NS
Baseline AHI	46.4 ± 28.3	42.7 ± 25.2	NS
AHI after using CPAP	7.2 ± 7.6	7.3 ± 8.2	NS
CPAP pressure (cm H <sub>2</sub> O)	10.9 ± 2.0	10.3 ± 2.3	NS
Regular users (≥5 hrs/night)	68	52	0.02
CPAP built-in compliance meter (hrs/night) (7th day)	5.7 ± 1.8 #	5.3 ± 1.8	NS
CPAP built-in compliance meter hrs/night) (90th day)	6.3 ± 1.9 #	5.1 ± 1.7	0.01

AHI: apnea-hypopnea index; ESS: Epworth Sleepiness Scale; \* = scale: much worse = 0 and much better = 100; \*\*: scale: not convinced = 0 and fully convinced = 100; #: p<0.001

212 patients, 95 patients (44.8%) were included in the experimental group, 93 patients (43.9%) were in the control group, and 24 patients (11.3%) either rejected or abandoned the CPAP treatment (drop-out group) at the beginning of the study protocol. Drop-out reasons, as self reported, were discomfort with the pressure (12.6%), noisy apparatus (25%), nasal symptoms such as obstruction and dryness (25%), insomnia caused by use of apparatus (12.5%), claustrophobia (12.4%) and undetermined causes (12.5%). No differences were found between the three groups in age, body mass index (BMI), and AHI. However, the ESS score of the drop-out group was significantly lower (table 1).

No differences were detected between experimental and control groups concerning subjective CPAP compliance and sleep quality, degree of sleepiness, optimal CPAP pressure, or AHI before and after CPAP treatment (Table 2). Analyses were carried out using the data collected from the initial visit (1st day), after 7 days, and after 90 days. On analyzing the first measurement from the CPAP built-in compliance meter (7th day), no difference between groups was detected. However, on the second measurement (90th day), the experimental group used their CPAPs for longer than the control group (6.3 ± 1.9 vs. 5.1 ± 1.7 hrs/night, respectively, p=0.01). There was a significant improvement in CPAP compliance between day 7 and day 90 in the experimental group but not in the control group (5.7 ± 1.8 to 6.3 ± 1.9 hrs/night, p<0.001, and 5.3 ± 1.8 to 5.1 ± 1.7 hrs/night, p=0.10, respectively) (Table 2).

The experimental group had higher frequencies of side effects

than the control group (Table 3).

Table 3: Side effects in the Experimental and Control Groups.

	Experimental Group (%)	Control Group (%)	P-value
Nasal sore	29	17	0.04*
Skin lesion	55	41	0.04*
Nasal obstruction	49	29	0.0031*
Dry mouth	72	57	0.03*
Bleeding	17	14	NS
Claustrophobia	22	16	NS
Mask leaking air	54	49	NS
Eye irritation	33	29	NS
Difficulty breathing	42	32	NS
Dry nose	53	39	NS

A patient may report more than one side effect; \* X2 test.

When comparing the objective (CPAP built-in compliance meter) with subjective (as reported by the patient) CPAP compliance in the experimental group, we found that patients who matched the CPAP built-in compliance meter record of approximately 5 hours per night had estimated the CPAP use of approximately 4 hours per night (p=0.007). For readings of the CPAP built-in compliance meter, in the control group, 52 patients (56%) used CPAP over 5 hours per night (regular users) and in the experimental group, 68 patients (71%) were regular

users ( $p=0.02$ ) (Table 2).

Regular CPAP users had less sleepiness when compared with irregular users on the 90th day (Table 4). These regular users also showed more side effects than irregular users (Table 5).

**Table 4: Regular compared with irregular users of the Experimental Group.**

	Regular users (Mean $\pm$ SD)	Irregular users (Mean $\pm$ SD)	P-value
N	68	27	
Age (years)	54.5 $\pm$ 10.5	51.1 $\pm$ 11.5	NS
Male/Female (n)	56/12	24/3	NS
BMI (Kg/m <sup>2</sup> )	33.2 $\pm$ 6.8	32.6 $\pm$ 11.5	NS
Baseline AHI	49.2 $\pm$ 28.5	38.3 $\pm$ 26.8	NS
AHI after using CPAP	7.9 $\pm$ 7.9	5.6 $\pm$ 6.8	NS
Baseline ESS	16.3 $\pm$ 6.2	15.6 $\pm$ 5.4	NS
ESS after using CPAP	7.1 $\pm$ 4.9	10.2 $\pm$ 5.3	0.007
CPAP pressure (cm H <sub>2</sub> O)	11.0 $\pm$ 2.1	10.6 $\pm$ 2.0	NS
Time used (months)	15.5 $\pm$ 16.6	14.4 $\pm$ 17.4	NS

BMI: Body Mass Index; AHI: apnea-hypopnea index; ESS: Epworth Sleepiness Scale.

**Table 5: Side effects in regular and irregular users of the Experimental Group**

	Regular users (%)	Irregular users (%)	P-value
Nasal sore	29	29	NS
Skin lesion	60	41	0.04
Nasal obstruction	47	22	0.03
Dry mouth	72	29	0.02
Bleeding	18	15	NS
Claustrophobia	19	30	0.04
Mask leaking air	57	44	NS
Eye irritation	31	37	NS
Difficulty breathing	44	37	NS
Dry nose	54	38	0.03

A patient may report more than one side effect.

## DISCUSSION

Our trial shows that a basic CPAP educational program and nurse support enhanced the rate of CPAP adherence, leading to improved hours of CPAP use at 90 days. It is likely that this could be due to the effect of our educational program, since OSAS severity (AHI and somnolence), age, and objective CPAP use at the beginning (7th day) of our study protocol were similar between both groups (experimental and control).

In our sample, 11% of the recruited patients had abandoned CPAP treatment (drop-out group). Some authors have reported that 25 to 50% of patients interrupt this treatment within the first two to four weeks (26). Other studies also referred to a rejection rate of CPAP varying from 5 to 50% with an average of 17.4% (15). These rates are lower in more recent studies, such as in ours, perhaps reflecting greater awareness of patients of the use of CPAP or due to technological improvement in new CPAP models. Besides, although patients of our drop-out group presented

the same age, BMI, AHI, and CPAP pressure when compared with experimental and control groups, subjective somnolence was significantly higher. These data confirm other studies that suggest that daytime sleepiness could be an important factor in the adherence to CPAP treatment (39).

Several studies have shown the influence of OSAS severity on CPAP adherence. The results are variable but the preponderance of evidence indicates a positive association between OSA severity and CPAP compliance (20,40). Our study showed that CPAP compliance was not influenced by OSA severity.

Our results point to a curious fact: the patients who followed the program (experimental group) used CPAP for longer periods than the controls, despite having to cope with the undesired effects and discomfort. Because the most common side effects that influence adherence to this treatment are related to nasal complaints, masks and pressures (15,26), such as were reported by our patients, we may speculate that our orientation program had a considerable impact in this sample, and that it mitigated or annulled the unfavorable factors of CPAP use.

In both experimental and control groups, the use of CPAP produced a similar reduction in subjective hypersomnolence. We did not use objective measures of sleepiness such as Multiple Sleep Latency Test or Maintenance of Wakefulness Test since our objective was to carry out a simple, feasible protocol with low cost.

Comparing regular and irregular users in the experimental group, we found that age, gender, body mass index and severity of OSAS (AHI and baseline somnolence) had no bearing on the observed pattern of use. It seemed that compared with the side effects in irregular users, the side effects of the regular users did not negatively influence the treatment. A desirable effect of CPAP is the control of sleepiness. As expected, we found more reduced subjective daytime hypersomnolence in regular users after CPAP use. This finding could be interpreted in 2 ways. One is that having used CPAP for longer, the regular users improved sleepiness levels compared with irregular users. The other is that due to improved daytime sleepiness, they started to use their own apparatus more frequently.

Limitations of our study included the fact that patients were not randomized to the groups (experimental and control) and were contacted by a phone call without previous orientation or training. It indicates that subjects were "self-selected" into either the experimental group or control, and we must take into consideration the motivation of the experimental group to participate in the study protocol as a possible bias. However, our results were similar to the results from randomized studies in terms of rates of CPAP compliance, which reached up to 70% (29,32,36,41).

Our study demonstrates that one simple and inexpensive program was effective in improving CPAP compliance. However, there was a lower impact in our study than would have been expected had we used a more advanced program that included home visits, cognitive and behavior therapy, collective meetings and participation of a multi-disciplinary team. Building on findings utilizing cognitive-based interventions, Aloia and coworkers (29) applied these theories to improve adherence in older OSA patients. The intervention group attended a pretreatment session that included a review of symptoms and results of the titration study along with

a discussion about the advantages and disadvantages of treatment. A second session was conducted in which nightly CPAP use data, changes in symptoms, problems related to use, and realistic expectations for treatment adherence were discussed. The control group also underwent two sessions, receiving the same contact, but was not provided with information regarding OSA or CPAP. Adherence assessed after the first week and then again at 4 weeks did not show a statistically significant difference. However, after 12 weeks of use, those in the intervention group used CPAP 7.8 h/night compared with 4.6 h/night in the other group. In addition to teaching and technical support, we should also consider that the nurse-patient relationship could help the treatment since this interaction fosters positive psychological aspects. Additionally, it is not possible to exclude the role of orientations given by the sleep physician and CPAP dealer as well as the new technology employed in masks and in the machines.

Based on the previous literature, we have conducted a study that focuses on clinical staffing, resources, and a specific population. Our findings provide exploratory evidence of the utility of such an intervention aimed at enhancing CPAP compliance.

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