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Original Article

Long-term prediction of adherence to continuous positive air pressure therapy for the treatment of moderate/severe obstructive sleep apnea syndrome

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ABSTRACT

Background: Continuous positive airway pressure (CPAP) therapy is a highly effective treatment for obstructive sleep apnea syndrome (OSAS). However, poor adherence is a limiting factor, and a significant proportion of patients are unable to tolerate CPAP. The aim of this study was to determine predictors of long-term non-compliance with CPAP.

Methods: CPAP treatment was prescribed to all consecutive patients with moderate or severe OSAS (AHI ≥15 events/h) (n = 295) who underwent a full-night CPAP titration study at home between February 1, 2002 and December 1, 2016. Adherence was defined as CPAP use for at least 4 h per night and five days per week. Subjects had periodical follow-up visits including clinical and biochemical evaluation and assessment of adherence to CPAP.

Results: Median follow-up observation was 74.8 (24.2/110.9) months. The percentage of OSAS patients adhering to CPAP was 41.4% (42.3% in males and 37.0% in females), and prevalence was significantly higher in severe OSAS than in moderate (51.8% vs. 22.1%; $p < 0.001$; respectively). At multivariate analysis, lower severity of OSAS (HR = 0.66; CI 95 0.46–0.94) $p < 0.023$), cigarette smoking (HR = 1.72; CI 95 1.13–2.61); $p = 0.011$), and previous cardiovascular events (HR = 1.95; CI 95 1.03–3.70; $p = 0.04$) were the only independent predictors of long-term non-adherence to CPAP after controlling for age, gender, and metabolic syndrome.

Conclusions: In our cohort of patients with moderate/severe OSAS who were prescribed CPAP therapy, long-term compliance to treatment was present in less than half of the patients. Adherence was positively associated with OSAS severity and negatively associated with cigarette smoking and previous cardiovascular events at baseline.

1. Introduction

Obstructive sleep apnea (OSAS) is a disorder characterized by daytime sleepiness and repeated breathing cessations during sleep, which can result in cycles of hypoxia, negative intrathoracic pressure, and arousals with potentially serious cardiovascular consequences [1–5].

Abbreviations: OSAS, obstructive sleep apnea syndrome; CPAP, continuous positive air pressure; AHI, apnea/hypopnea index; MACCE, major adverse cardiac and cerebrovascular events; CVD, cardiovascular disease.

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Continuous positive airway pressure therapy (CPAP) is a highly effective treatment for OSAS and should be considered both first-line and gold-standard treatment for patients with all stages of OSAS [6–8]. CPAP improves quality of life and excessive daytime sleepiness and decreases sympathetic neural activity and blood pressure. Moreover, the prescription of CPAP appears to reduce long-term cardiovascular disease (CVD) events [9] and total mortality, although negative results have been also reported, and not all patients benefit from CPAP treatment even if they have a severe OSAS [10,11].

Adequate CPAP compliance is essential for achieving cardiovascular and metabolic benefits in patients with OSAS. However, poor adherence to CPAP is a significant limiting factor in treating OSAS despite efforts to improve devices and educate patients, especially during the early stages of treatment. In fact, failure to comply with CPAP therapy may occur in up to 25%–50% patients with OSAS, and patient adherence to treatment frequently remains inadequate [12,13]. A significant proportion of patients are unable to tolerate CPAP therapy and frequently seek alternate treatment. A recent systematic literature review reported that the rate of CPAP adherence remained persistently low over 20 years of published data [14].

Various factors were evaluated while trying to predict compliance [15]. Some patients may refuse treatment without even initiating it, and some eventually abandon therapy. Poor mask fit and discomfort, complaints of noise, and interference with normal life and sexual functioning frequently induce low adherence. In fact, CPAP may induce nasal drying, congestion, rhinorrhea, sinusitis, and allergic reaction to the materials in the mask. Moreover, patient's age, gender, low socioeconomic status, overweight, obesity, comorbid conditions, and smoking have been associated with poor compliance. In contrast, patients with a more severe OSAS tend to be more compliant, and their apnea/hypopnea index (AHI) showed a relationship with improved compliance [16]. In particular, the balance between symptom severity pre-treatment and symptom relief with CPAP treatment is among the strongest predictors of CPAP compliance.

However, so far, no single factor has been consistently identified as predictive of adherence. Moreover, there are very few data on objectively assessed compliance with CPAP in large OSAS cohorts, and treatment adherence has been incompletely assessed in long-term follow-up studies.

The aim of this study was to determine predictors of long-term non-compliance with CPAP in a large cohort of moderate and severe newly diagnosed OSAS patients during a six-year follow-up.

2. Material and methods

2.1. Subjects

The initial population consisted of 483 patients who consecutively attended our outpatient metabolic clinic between February 1, 2002 and December 1, 2016 because of suspected metabolic disorders with heavy snoring and possible OSAS. Patients had a complete clinical and biochemical work-up including unattended overnight home polysomnography. The device recorded nasal and oral airflow, chest and abdominal movement, pulse oximetry, body position, and snoring noise. The sleep recordings were downloaded to a computer and scored by a principal investigator. OSAS severity was quantified as the number of apnea/hypopnea events/h during sleep study (AHI). Patients were categorized as follows: snorers without OSAS with AHI <5 events/h; with mild OSAS with AHI 5–14 events/h; and with moderate/severe OSAS with AHI ≥15 events/h.

Information on previous cardiovascular and cerebrovascular disease (major adverse cardiac or cerebrovascular event, MACCE), defined as history of physician-diagnosed heart failure, angina, myocardial infarction, stroke, and coronary revascularization, was obtained for each participant. Finally, all the therapies and the number of tablets consumed every day were recorded. A detailed description of screening procedures was previously reported [17,18].

CPAP treatment was prescribed to all consecutive patients with moderate or severe OSAS (AHI ≥15 events/h) (n = 301) who underwent a full-night CPAP titration study at home using an automated pressure setting device. Written consent was obtained from all subjects before the study, and the study conforms to the ethical guidelines of the 1975 declaration of Helsinki. The research protocol was approved by the University Department of Experimental Medicine and Pathology scientific board in 2002.

2.2. Assessment of compliance to CPAP

Adherence to CPAP was arbitrarily defined as CPAP use for at least 4 h per night and five days per week, although there is no definite agreement on frequency and duration of optimal CPAP treatment. The subjects had periodical follow-up visits including clinical and biochemical evaluation and assessment of adherence to CPAP. Moreover, patients were contacted by telephone by a single investigator who was not part of the clinical team between December 1, 2016 and May 31, 2017. First, they were questioned whether they started treatment and were still using their CPAP device. Those adhering to therapy were asked to estimate the number of nights per week and hours per night CPAP was being used. Those who abandoned therapy and those who never initiated treatment were questioned about their reasons for non-adherence.

2.3. Statistical analysis

Continuous variables are reported as mean ± standard deviation or median with interquartile range. Continuous variables were analyzed by Student's t-test or Mann–Whitney test depending on their distribution. Dichotomous variables are reported as numbers and percentages. Differences were tested using the $\chi 2$ test for categorical variables. All tests were two-tailed, and only *p* values <0.05 were considered statistically significant. Univariate and multivariate Cox regression analyses using a forward selection were used to calculate the unadjusted and adjusted relative hazard ratios (HR) of predictors for discontinuation of CPAP therapy. Analyses were carried out with SPSS V.18.0 (Armonk, USA).

3. Results

Complete information on CPAP compliance was available for 301 subjects with moderate or severe OSAS. Median follow-up observation was 74.8 (24.2/110.9) months. The percentage of OSAS patients adhering to CPAP was 41.4% (42.3% in males and 37.0% in females), and prevalence was significantly higher in severe OSAS than in moderate OSAS (51.8% vs. 22.1%; $p < 0.001$, respectively). Severe OSAS had a better compliance than moderate both in males (53.4% vs. 20.0%; $p < 0.001$, respectively) and females (43.3% vs. 29.2%; $p = 0.39$, respectively). Adherers and non-adherers had similar age at the time of diagnosis of OSAS (57.1 ± 10.5 years vs. 57.0 ± 10.9 years, respectively).

Clinical and biochemical characteristics of adherers and non-adherers are reported in Table 1. At baseline examination, the indices of OSAS severity, ie, AHI and ODI, were significantly increased, while $SatO_2$ was decreased in patients with good compliance. In the same group, the indices of central obesity and

Table 1
Clinical and biochemical characteristics of adherers and non-adherers to CPAP therapy.

	Non-adherers to CPAP (n = 178)	Adherers to CPAP (n = 123)	*p*
Age (years)	57.0 ± 10.5	57.1 ± 10.9	0.944
AHI (events/h)	37.6 ± 20.4	45.7 ± 17.6	0.001
ODI (events/h)	34.7 ± 22.4	45.6 ± 21.3	0.000
Average $SatO_2$ (%)	92.3 ± 3.6	90.3 ± 7.8	0.007
BMI (kg/m^2)	32.9 ± 6.0	34.4 ± 8.8	0.099
Waist circumference (cm)	113.0 ± 13.6	116.2 ± 12.9	0.052
Hip circumference (cm)	114.2 ± 12.1	117.7 ± 11.9	0.022
Systolic blood pressure (mmHg)	135 ± 15	135 ± 15	0.455
Diastolic blood pressure (mmHg)	84 ± 10	83 ± 10	0.562
Total Cholesterol (mg/dl)	206.2 ± 42.3	196.7 ± 42.5	0.067
HDL Cholesterol (mg/dl)	45.7 ± 12.0	42.2 ± 9.9	0.012
LDL Cholesterol (mg/dl)	129.0 ± 35.8	121.1 ± 40.5	0.088
Triglycerides (mg/dl)	130.0 (92.0/180.0)	148.0 (102.5/205.0)	0.107
Fasting blood glucose (mg/dl)	103.4 ± 27.0	104.0 ± 26.1	0.835
Insulin (μU/ml)	20.9 ± 17.5	21.7 ± 16.9	0.748
HOMA-IR	3.9 ± 4.8	4.0 ± 5.5	0.831
Diabetes (%)	18.1	20.3	0.648
Hypertension (%)	69.1	73.0	0.513
Metabolic syndrome (%)	61.3	71.2	0.099
Cigarette smoking (%)	20.8	10.7	0.026
Statin use (%)	38.6	45.7	0.262
Polypharmacy (number of pills/day)	2.5 (1.0/5.0)	4.0 (2.0/6.0)	0.001
Previous MACCE (%)	13.0	10.1	0.274

serum triglycerides tended to be higher. Prevalence of cigarette smokers was approximately double in non-adherers as compared to adherers (20.8% vs. 10.7%; p = 0.026, respectively). No statistically significant differences were observed for the prevalence of diabetes, arterial hypertension, metabolic syndrome, statin use, and previous MACCE at the basal examination.

Table 2 reports the results of univariate and multivariate Cox regression analyses of predictors of CPAP discontinuation. In the Cox analysis adjusted for possible confounders, lower severity of OSAS (HR = 0.66; CI 95 0.46–0.94; p < 0.023), cigarette smoking (HR = 1.72; CI 95 1.13–2.61; p = 0.011), and previous MACCE (HR = 1.95; CI 95 1.03–3.70; p = 0.04) were the only independent predictors of long-term non-adherence to CPAP after controlling for age, gender, and metabolic syndrome.

The main reasons for poor adherence were self-reported mask-related and pressure-related side effects, nasal symptoms, and psychological and social factors. Other frequent reasons for stopping treatment were surgical management or weight loss with consequent improvement of OSAS.

4. Discussion

There are few data on the long-term assessment of adherence to CPAP in OSAS patients, and no single factor so far has been

Table 2
Univariate and multivariate Cox regression analyses of predictors of CPAP discontinuation.

	Univariate analysis		Multivariate analysis	
	HR (C.I. for HR)	*p*	HR (C.I. for HR)	*p*
Age (years)	1.007 (0.993–1.021)	0.331	1.008 (0.992–1.025)	0.331
Female gender	1.123 (0.762–1.656)	0.558	1.050 (0.664–1.661)	0.835
AHI (events/h)	0.989 (0.981–0.997)	0.007		
ODI (events/h)	0.993 (0.986–1.001)	0.081		
Average $SatO_2$ (%)	1.014 (0.975–1.055)	0.480		
Severe OSAS (%)	0.630 (0.461–0.862)	0.004	0.661 (0.463–0.945)	0.023
BMI (kg/m^2)	0.989 (0.962–1.016)	0.428		
Waist circumference (cm)	0.994 (0.982–1.006)	0.322		
Hip circumference (cm)	0.995 (0.982–1.009)	0.501		
Systolic blood pressure (mmHg)	0.992 (0.982–1.002)	0.134		
Diastolic blood pressure (mmHg)	0.987 (0.971–1.002)	0.093		
Total cholesterol (mg/dl)	1.001 (0.997–1.004)	0.770		
HDL cholesterol (mg/dl)	1.016 (1.003–1.030)	0.019		
LDL cholesterol (mg/dl)	0.999 (0.995–1.003)	0.557		
Triglycerides (mg/dl)	1.000 (0.998–1.002)	0.991		
Fasting blood glucose (mg/dl)	1.001 (0.994–1.007)	0.868		
Insulin (μU/ml)	0.999 (0.990–1.007)	0.757		
Diabetes (%)	0.913 (0.610–1.367)	0.659		
Hypertension (%)	1.153 (0.801–1.659)	0.443		
Metabolic syndrome (%)	0.802 (0.581–1.109)	0.182	0.757 (0.531–1.080)	0.125
Cigarette smoking (%)	1.655 (1.119–2.447)	0.012	1.723 (1.133–2.619)	0.011
Statin use (%)	0.979 (0.698–1.372)	0.901		
Polypharmacy (number of pills/day)	1.000 (0.938–1.066)	0.995		
Previous MACCE (%)	1.889 (1.114–3.204)	0.018	1.954 (1.030–3.705)	0.040

consistently identified as predictive of long-term adherence. Moreover, studies on CPAP adherence in Mediterranean countries are limited.

In this study, about 40% of patients with moderate or severe OSAS, who were prescribed CPAP therapy, were still on treatment after an average six-year follow-up observation when non-adherence was defined as a mean of ≤4 h of use per night and five days per week. This is in agreement with previous studies, showing a compliance with treatment in about 30%–80% of patients depending on the definition criteria for adherence and the duration of follow-up [12,13].

Compliance was higher in patients with more severe OSAS, where half of those with AHI >30 events/h were good adherers to CPAP treatment. Those with a higher AHI tended to be more compliant both in males and females and in all ages.

Our findings are in keeping with the results of some studies, reporting a strong relationship between adherence to CPAP and the severity of sleep-disordered breathing. Hence, in a large prospective study performed in the US, disease severity rather than patient symptoms or complaints, seemed to play a role in the quality of compliance to treatment [19]. Moreover, in a large cohort of OSAS patients, severity of sleep-disorder breathing assessed as number of oxygen desaturation events, was the only clinical condition associated with long-term adherence [20]. Similar findings were reported in a retrospective chart review of 369 patients with moderate or severe OSAS who were recommended to receive CPAP: at one year, older male patients with higher AHI values were more adherent to CPAP [21]. In addition, a highly significant correlation of compliance with the initial AHI was found in a small study of OSAS patients at 14 months on the average after starting treatment with CPAP [22]. Moreover, an association between compliance to treatment and severity of OSAS was also reported in a retrospective study evaluating 156 patients with OSAS: patients with a higher AHI were those who better adhered to long-term treatment with CPAP [23]. Finally, in a cross-sectional study of 138 OSAS patients performed in Lebanon, higher oxygen desaturation index at baseline was associated with a better short-term CPAP adherence [24].

According to these data, it could be speculated that patients with more severe OSAS have a better compliance. However, other studies showed that measures of OSAS severity *per se* appear poorly associated with CPAP. In fact, in a short-term study of 59 patients (42 men) with metabolic syndrome and OSAS, mask leak was the only independent predictor of CPAP compliance at the eight-week follow-up visit [25]. Moreover, in another study of 60 patients who were recommended CPAP therapy, one-year compliance was associated with higher body mass index, higher Epworth sleepiness scale score, history of witnessed apnea, and reduction in daytime sleepiness with CPAP therapy, while OSAS severity was not associated [26]. In conclusion, on the basis of the above data, it is difficult to conclude that the severity of OSAS at the initial sleep study always predicts long-term use of CPAP.

In our study, cigarette smoking was an independent predictor of non-compliance to CPAP. This is in keeping with the results of an eight-year retrospective chart review of older male patients prescribed CPAP therapy for OSAS, where cigarette smoking was associated with non-compliance [27]. However, these findings are in contrast with data from a small prospective cohort study where cigarette smoking, alcohol intake, concurrent medication use, and work patterns were not important predictors of short-term CPAP use [28].

Previous MACCE in our study were independent predictors of worse adherence to CPAP. Similar findings have been reported in previous studies on the compliance to CPAP in patients with concomitant OSAS and CVD, where adherence decreased progressively over time [29,30]. These findings raise the possibility that patients with OSAS and CVD may benefit less from CPAP therapy as they are more concerned with CVD.

There are several strengths and limitations of this study that merit to be discussed. The major strength of this study is the duration of follow-up that is greater than that of most published studies. Unattended home polysomnography should be considered as a major limitation of this study, although an excellent correlation with the results of attended polysomnography has been reported [31]. A further limitation is that we used telephone survey to assess the compliance to CPAP therapy in half of the patients because almost all of the patients used CPAP units that were not capable of keeping record of night use. This may have ended with a possible selection bias because patients often lie when asked about compliance, and there may be discrepancies between what patients think they do at night and what they really do [32]. Moreover, the studied population was taken only from an outpatient metabolic clinic and non-snorers, and patients without metabolic disorders were probably not included in the study. Finally, CPAP compliance was not assessed in patients with mild OSAS.

In summary, in our cohort of patients with moderate or severe OSAS who were prescribed CPAP therapy, long-term compliance to treatment was present in less than half of the patients. Adherence was positively associated with severity of OSAS and negatively associated with cigarette smoking and previous MACCE at the initial examination.

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Author contributions

F Angelico, M Del Ben, and M Fabiani: Study concept and design; interpretation of data; drafting of the manuscript; and critical revision of the manuscript.

F Baratta, T Bucci, and D Pastori: Analysis and interpretation of data; drafting of the manuscript; and critical revision of the manuscript.

V Fabiani, M Brunori, G Pannitteri, R Lillo and L Loffredo: Acquisition and interpretation of data; and critical revision of the manuscript.

F Angelico is the guarantor of the paper. All authors read and approved the final version of the manuscript.

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Conflict of interest

All the authors have seen and approved the manuscript. All the authors did not receive financial support and have no conflict of interest in relation to the manuscript.

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: https://doi.org/10.1016/j.sleep.2017.09.032.

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