ELSEVIER

Sleep Medicine 2 (2001) 225–232

SLEEP MEDICINE

www.elsevier.com/locate/sleep

Original article

The age and other factors in the evaluation of compliance with nasal continuous positive airway pressure for obstructive sleep apnea syndrome. A Cox's proportional hazard analysis

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Received 4 May 2000; received in revised form 13 July 2000; accepted 13 July 2000

Abstract

Objective: To elucidate the predictive role of age and other pre-treatment, putative confounding factors on compliance with nasal continuous positive airway pressure (nCPAP) therapy.

Patients and methods: This study was designed as a prospective cohort study in the setting of a sleep laboratory in a teaching hospital at Saint Antoine, Paris. One hundred and sixty-three patients referred to the sleep laboratory with complaints of snoring and excessive daytime sleepiness for whom nCPAP had been prescribed for obstructive sleep apnea syndrome (OSAS; defined as an apnea–hypopnea index (AHI) of >15/h of sleep during a polysomnographic recording) were followed for a median period of 887 days. The main outcome measure was the risk ratio for elderly patients associated with nCPAP compliance.

Results: Four patients, who remained under treatment, died before the end of the study, and 50 patients stopped their nCPAP therapy for reasons other than death (insomnia, equipment too noisy, etc.). When compliance curves were compared by univariate analysis (log-rank test), the oldest group (57/163 patients, >60 years old) was significantly less compliant with nCPAP than the youngest ($P = 0.01$). However, in the Cox's proportional hazards model, age did not exert any independent effect on compliance with nCPAP after controlling for confounding factors (adjusted relative risk, 1.09, 0.5–2; $P = 0.70$). On the other hand, female sex (adjusted relative risk, 2.8, 1.4–5.4; $P = 0.002$), a body mass index (BMI) of ≤30 kg/m^2 (adjusted relative risk, 2.2, 1.2–4; $P = 0.006$), an Epworth sleepiness scale (ESS) score of ≤15 (adjusted relative risk, 3.2, 1.1–8.9; $P = 0.025$), an AHI of ≤30/h (adjusted relative risk, 2.2, 1.2–4; $P = 0.01$) and a nCPAP of ≥12 cmH_2O (adjusted relative risk, 2.3, 1.2–4.4; $P = 0.011$) were predictive factors for non-compliance.

Conclusion: This study suggests that there is no independent effect of age on compliance with nCPAP therapy. © 2001 Elsevier Science B.V. All rights reserved.

Keywords: Long-term compliance; nCPAP therapy; Obstructive sleep apnea syndrome; Elderly

1. Introduction

Sleep–wake patterns in older adults are modified and a difficulty in sleep maintenance is commonly reported with increasing age [1]. The number and duration of nocturnal awakenings increase in the elderly, and the duration of rapid eye movement (REM) episodes declines. New data, however, have shown that daytime complaints, such as excessive daytime napping, which are very incapacitating in the daily life of the elderly, may be secondary to specific sleep disorders, i.e. sleep apnea [2]. Obstructive sleep apnea syndrome (OSAS) is highly prevalent in the elderly population [3–6].

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PII: S1389-9457(00)00063-0

Mant et al. [7] reported a prevalence rate of 15%, when a criterion as severe as 15 apneas or more/h of sleep was used. Among elderly subjects, almost 3% suffer from a symptomatic sleep apnea syndrome [8]. Nasal continuous positive airway pressure (nCPAP) therapy is the treatment of first choice for OSAS [9]. While its role in improving survival is still being debated [10], clear-cut objective benefits, in terms of reduced daytime sleepiness and improved cognitive functions, have been demonstrated [11,12]. However, this is a palliative treatment, which is both constraining for the patient and expensive. Presently, the social security funds in France reimburse such treatment at the rate of FF9000 (Euro1500)/patient per year [13]. More than 20 000 patients were on nCPAP in 1996, and a recent French study reported that of 547 patients treated, 30% were aged 60–69 years old, and 13% were more than 70 [14].

Many reasons might negatively influence the compliance with nCPAP in the elderly: social discomfort due to excessive daytime somnolence, physical problems to adapting the mask, e.g. loss of vision, greater physical impairment, associated chronic diseases and treatments.

At the same time, some authors do not consider OSAS to be a mortality risk factor in the elderly, and several retrospective case series imply that sleep apnea in this population does not warrant treatment [15,16]. Actually, under the present financial constraints affecting health care, age is increasingly put forward as a criterion for access to care, considering that aged people consume more healthcare resources, but less benefit, than younger patients [17–19].

All these considerations make an objective evaluation of the long-term compliance with nCPAP therapy in the elderly population pertinent. Using Cox' proportional hazards model, our prospective study, lasting about 4 years, was conducted to elucidate the predictive role of age and other putative, pre-treatment, confounding factors on compliance with nCPAP therapy, in a cohort of 163 OSAS patients.

2. Patients and methods

2.1. Patients

The study population was based on all 199 patients for whom nCPAP had been prescribed for OSAS (defined as an apnea–hypopnea index (AHI) of greater than 15/h of sleep over a 26-month period. These patients had been referred to the sleep laboratory with complaints of snoring and excessive daytime sleepiness. We excluded 36 patients; five had an AHI < 15 before nCPAP therapy, 13 only had their respiratory measures recorded during the diagnostic study (i.e. sleep characteristics were not available), nine remained with an AHI of between 15 and 20 under nCPAP therapy during the titration night (despite a 50% reduction of its initial value) and nine patients' files were lost. This left 163 patients who fulfilled the inclusion criteria of having: (1), a recording of respiratory and sleep characteristics to diagnose OSAS and to titrate the nCPAP; (2), an AHI of greater than 15 during the diagnostic recording; and (3), an effective positive airway pressure suppressing apneas and hypopneas.

The nCPAP was started at 3 cmH_2O. With the occurrence of abnormal respiratory events, this pressure was increased by increments of 1 cmH_2O every 10 min. Effective nCPAP was defined as a reduction of AHI to less than 10/h of sleep in all sleep stages, including REM sleep on the back.

Compliance with the treatment was evaluated at home after 1 month and then every 3 months, by a nurse who read the built-in time counter. If a patient had died before the end of the follow-up period, the date of death and information on the cause of death were recorded. The reasons for stopping treatment were also recorded.

The follow-up period was defined as the number of days from the date of the beginning of nCPAP therapy to the date of stopping treatment for patients who gave up treatment, the date of their death, or to the last date of the follow-up period for those who were still under mechanical treatment.

At the beginning of the study, 'spy' chips and pressure monitoring devices were uncommon, but time counters were present in all the CPAP machines used. Then, we calculated the daily rate of use by dividing the time, in hours (built-in time counter), that the nCPAP unit had been used since the beginning of treatment to either the cessation of therapy or the last date of the study by the corresponding time interval in days. The close relationship between the mean effective daily rate of use and the rate of use indicated by the built-in time counter of the machine has been already reported [20].

Patients were considered 'compliant' if they were still under nCPAP and used their device for more than 3 h/day at the end of the study. Compliance data for these patients were considered as right-censored data (see Section 2.4). Patients were considered 'non-compliant' if they stopped their treatment before the last date of the study or used their device for less than 3 h/day. The arbitrary cut-off of at least 3 h/day corresponds to the legal minimum required in France, by the French National Health Insurance to ensure the patient's reimbursement for treatment with nCPAP, which must be objectively demonstrated (hourly counter records must be regularly provided). Even if this threshold is a somewhat arbitrary value, we decided to use it as there is no known lower limit of average nightly use below which CPAP is ineffective [21].

2.2. Sleep studies

Before beginning nCPAP therapy, all 163 patients underwent either two consecutive overnight polysomnographies (PSG; 104 patients), one to diagnose the OSAS and the other to titrate nCPAP, or a split-night study, i.e. half a night to evaluate OSAS, and half a night to establish an effective nCPAP level (59 patients) [20]. The variables were recorded on an eight-channel polygraph (Respisomnograph®, Sefam, France). Two channels of electroencephalography, one channel of electrooculography and one channel of submental electromyography were used to monitor sleep. To analyze the sleep architecture, stages 1 and 2 were combined (light sleep), as were stages 3 and 4 (deep sleep). The air flow was detected with a pneumotachograph and the arterial oxygen saturation (SaO_2) was measured with a finger oximeter (Biox 3700®, Ohmeda, Louiseville). Rib-cage and abdominal-wall motions were recorded with a respiratory inductive plethysmograph. Apnea was defined as a cessation of airflow for 10 s or longer. Hypopnea was defined as a 50% reduction in airflow associated with a decrease in oxygen saturation of more than 3%.

2.3. Data collection

At the beginning of treatment, age (years), sex, body mass index (BMI; kg/m^2), drugs for insomnia or depression, the presence of severe disease(s) other than OSAS (cardio-vascular disease, cancer, diabetes, etc.), educational background (years) and Epworth sleepiness scale (ESS) scores were registered. The following polysomnographic characteristics before treatment were also collected: AHI, the percentage of total sleep time spent below an SaO_2 of 90%, and the percentages of total sleep time spent in light sleep, deep sleep and REM sleep. The effective level of positive airway pressure was also registered.

2.4. Statistical analysis

The statistical analysis was performed using the SAS program [22].

2.4.1. Description of the population

Values are given as means (SDs) and medians (range). We used the unpaired *t*-test to compare cross-classified continuous variables, and the Chi-square test to evaluate proportions when we compared data in the group of patients who were 60 years old or less at the beginning of nCPAP therapy with the group of patients who were more than 60. Pearson's correlation analysis between the illness severity measures, nCPAP level and anthropometric parameters were also conducted.

2.4.2. Patients' compliance

We estimated the compliance function with the Kaplan–Meier cumulative incidence method [23]. This compliance distribution function permitted to describe the compliance of the population studied, taking into account right-censored observations due to patient death or termination of the study.

We used the log-rank test to compare compliance curves in univariate analyses. For the variables that were not already divided into classes (such as sex and the type of recording, i.e. split-night vs. full-night PSG), the relative importance of each of them on the cumulative incidence of compliance was calculated according to the following strata for age ($\leq 60/ > 60$), according to their quartiles for the ESS score, AHI and nCPAP level, and according to their median for the BMI, oxygen saturation and sleep parameters; for the educational background, less than 7 years of education was compared to a higher educational level.

Cox's proportional hazards multiple regression analysis [24] was used to examine whether age exerted an independent effect on compliance with nCPAP therapy, controlling for the remaining variables. In addition to age, a variable was eligible for entry into Cox's model if it verified the proportional hazards assumption and if it was associated with compliance with a P value of <0.3. Then, a stepwise regression analysis was performed. Only the variables which met a P value level of 0.05 remained in the model and these were regarded as significantly influent on compliance with nCPAP therapy. The results are described as adjusted relative risk (95% confidence intervals).

3. Results

3.1. Description of the population

3.1.1. The 163 OSAS patients

We followed up the 163 patients for a median of 887 (range, 14–1549) days. There were 27 females (17%) and 136 males (83%), on average they were 55 years old (11.5), 35% being more than 60, and 8% more than 70, with a BMI equal to 30.80 (5.5) kg/m^2 and an AHI equal to 52 (27). The effective nCPAP was 10.36 cmH_2O (2.1). A positive correlation was found between the AHI and the nCPAP level ($r = 0.21$; $P = 0.008$), and also between the BMI and the effective level of pressure ($r = 0.20$; $P = 0.01$).

No patients were lost in the follow-up. Four patients, who remained under treatment, had died; one from myocardial infarction, one from prostate adenocarcinoma, one from suicide, and the last one in a car accident. Compliance data for these four patients were considered as right-censored data. Fifty patients stopped their treatment for reasons other than death. The reasons for intolerance to the therapy included insomnia, equipment too noisy, claustrophobia, skin lesions with the mask and nasal side effects. The cumulative incidence of compliance was estimated to be 85.82% after 6 months, 83.95% after the 1st year, 71.47% after the 2nd year, and 67.34% after the 3rd year and thereafter (Fig. 1). The mean daily rate of use was 1.46 (1.82) h for the patients who gave up treatment before the end of the study, and 6.09 (2.17) h for the patients still under treatment.

3.1.2. Patients of 60 or less compared with patients of more than 60

Table 1 shows the clinical characteristics of the patients who were 60 years old or less at the beginning of treatment and those who were more than 60. In the oldest group, women were over-represented ($P = 0.001$) and a higher prevalence of other chronic disease(s) was observed ($P = 0.008$). Older patients had also a less severe OSAS both in terms of ESS score ($P = 0.03$) and AHI ($P = 0.003$), a higher percentage of light sleep ($P = 0.04$) and a lower percentage of REM sleep before nCPAP ($P = 0.006$). Age was negatively correlated with ESS score ($r = -0.18$, $P = 0.01$).

3.2. Comparison of compliance curves

In the univariate analysis, the age at the beginning

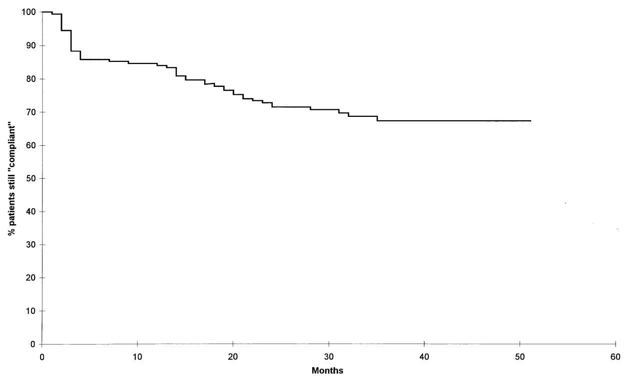

Fig. 1. Compliance curve of the 163 patients with OSAS under nCPAP included into the study (Kaplan–Meier method).

Table 1
Baseline variables and sleep parameters of 163 patients with OSAS under nCPAP therapy according to age[a]

Variable	$\leq$ 60 years old ($n = 106$)	$>$ 60 years old ($n = 57$)	P value
Sex, M/F (%)	90.5/9.4	70.1/29.8	0.001
BMI (kg/m^2)	31.1 (29.9–32.2)	30.7 (29.3–32.1)	0.70
ESS score	10.9 (9.7–12)	8.9 (7.4–10.3)	0.03
Educational level, <7; 7–16; >16 years (%)	27.7/40.5/31.6	36.3/43.6/20	0.25
Other chronic diseases, 0/≥1 (%)	37.7/62.2	17.5/82.4	0.008
Neuro-medications, 0/≥1 (%)	77.6/22.3	61.8/38.1	0.03
AHI (n/h)	58 (52.9–63.4)	45.3 (38.7–52)	0.003
SaO_2 below 90% (% TST[b])	22 (17.5–26.6)	17.2 (12.1–22.3)	0.16
Stages 1 and 2 (% TST[b])	81.5 (79.2–83.9)	85.6 (82.5–88.8)	0.04
Stages 3 and 4 (% TST[b])	11.2 (9.1–13.2)	9.7 (7–12.3)	0.38
REM sleep (% TST[b])	7 (5.7–8.4)	4.5 (3.2–5.8)	0.006
nCPAP (cmH_2O)	10.4 (10–10.7)	10.2 (9.5–10.9)	0.61

[a] Values are means (95% confidence interval) unless stated otherwise.
[b] TST, total sleep time.

of nCPAP therapy significantly influenced OSAS patients' compliance with treatment: the 3-month compliance was estimated to be 80.70% in the oldest group (>60 years old) vs. 92.39% in the group of patients of age 60 or less; the 6-month compliance was estimated to be 77.19 vs. 90.48%; the 1-year compliance was estimated to be 71.93 vs. 89.52%; and the 3-year compliance and over was estimated to be 55.92 vs. 73.52% ($P = 0.01$).

In addition to age, female sex ($P = 2.10^{-3}$), a BMI of ≤30 kg/m^2 ($P = 0.03$), an ESS score of ≤15 ($P = 0.01$), an AHI of ≤30/h ($P = 4.10^{-3}$) and a percentage of the total sleep time of <11% spent with an oxygen saturation below 90% ($P = 0.04$) - putative confounding factors - were also significantly associated with non-compliance with nCPAP therapy in the univariate analysis.

3.3. Multivariate analysis

Cox's multiple regression analysis indicated that female sex, a BMI of ≤30 kg/m^2, an ESS score of ≤15, an AHI of ≤30/h, and a level of nCPAP of ≥12 cmH_2O were independent predictors of poor compliance with nCPAP therapy (Table 2). Age was removed from the model because it did not meet the 0.05 level to remain included after controlling for the other covariates (adjusted relative risk, 1.09, 0.5–2; $P = 0.70$). The effect of age was also tested as a continuous variable without finding any independent association with compliance. Deviance residual plot did not indicate a lack of fit of the model to individual observations.

4. Discussion

The development of new technologies will keep driving healthcare costs up, and it is likely that a next step will be some form of systematic rationing of healthcare [19,25]. Berry et al. [26], Ancoli-Israel et al. [6], and more recently, Bixler et al. [8] stated that sleep apnea syndromes in any age group, if severe and accompanied by symptoms, should be adequately treated on a long-term basis. In our opinion, compliance with nCPAP should constitute one of the major criteria for allocating resources. Although there have been many other studies of compliance with nCPAP therapy [27–35], it is the first time, to our knowledge, that the association between age and compliance is specifically studied. In most of the previously

Table 2
Predictive factors for non-compliance with nCPAP therapy in 163 patients with OSAS by means of Cox's multiple regression analysis

Variables	Adjusted relative risk (95% CI)	P value
ESS score (≤15)	3.2 (1.1–8.9)	0.025
Female sex	2.8 (1.4–5.4)	0.002
CPAP level (≥12 cmH_2O)	2.3 (1.2–4.4)	0.011
AHI (≤30/h)	2.2 (1.2–4.0)	0.010
BMI (≤30 kg/m^2)	2.2 (1.2–4.0)	0.006

published compliance series, the analysis was limited to the comparison of the mean ages of the 'compliant' and 'non-compliant' patients that were not statistically different [27–30]. Recently, however, Pieter et al. [32] observed a negative correlation between age and the daily rate of use of the CPAP machine; they chose a different definition for this entity than ours. Our study, using an appropriate multivariate analysis, suggests that age may have no independent effect on compliance with nCPAP therapy, but that other factors correlated with age may make elderly patients appear less 'compliant'.

In the literature, the determinants of compliance with nCPAP therapy are highly variable among the studies, depending on patient selection, sample size or statistical analysis of the data (mostly limited to univariate analyses). Thus, the results reported are contradictory, with nCPAP compliance predicted by polysomnographic severity in some [29–31], and not in other studies [27,28,30], by prior sleepiness in some [29,31,33], but not in others [28,30]. In order to limit the methodological bias, as Mac Ardle et al. [21], we carried out the statistical analysis using Cox's proportional hazards models which allow analysis of the independent effect of age, or other variables, after controlling for all covariates, such as sex, severity of the disease and sleep architecture. This analysis can also handle data from a cohort in which patients entered the study at different dates, but had the same end date of observation [24].

In the present study, one can hypothesize that the apparent discrepancy between the conclusions of the univariate and multivariate analyses on the putative role of age is due to the over-representation of female sex and a less severe OSAS among elderly patients. Actually, in our elderly sub-population, 30% of the patients under mechanical treatment were women vs. 9% in the youngest group ($P = 0.001$). This proportion of elderly women is closest to the one reported (26%) in a large population representative of OSAS patients under nCPAP in France [14]. The proportion of women increases sharply among the elderly, and all the studies agree that the prevalence of sleep-disordered breathing is higher in postmenopausal women than in premenopausal women [36]. The perceptions of health and quality of life were recently reported as being lower in women with OSAS than in men, this difference lasting even after long-term correction of the sleep respiratory disturbances by nCPAP therapy [37]. Whatever the unknown causes for this dissatisfaction found in women, it might partly explain the non-compliance with such a constraining treatment, the adjusted risk ratio associated with the female sex being 2.8 ($P = 0.002$) in our cohort.

An AHI of $\leq$30/h (the lowest quartile in our sample), another factor for non-compliance with nCPAP therapy, was also found in a higher proportion of elderly patients compared with patients under 60 (37 vs. 20%; $P = 0.01$). There is uncertainty as to the determination of abnormality of breathing during sleep in the elderly, but a loud snoring and a daytime somnolence even associated with a low AHI, if greater than 15, justified a treatment in our elderly sub-population [38]. Although we found that a low AHI significantly predicted non-compliance with nCPAP therapy (adjusted risk ratio of 2.2; $P = 0.01$) similar to that reported by Mc Ardle et al. [21], the association between nCPAP use and AHI is still debated. Waldhorn et al. [27], using the same definition of compliance as ours, did not find any significant difference when they compared the mean AHI between groups of 'compliant' and 'non-compliant' patients. Similar results have been reported by Hoffstein et al. [28]. When the compliance definition is based on the daily rate of use of the machine, similar controversies are observed. Rauscher et al. [29] and Meurice et al. [31] have reported a significant positive correlation between nCPAP use and the initial AHI. This association, however, was not found among the patients studied by Engleman et al. [33] and Pieters et al. [32]. The variability in the definitions of OSAS and compliance with nCPAP therapy, and the use of different statistical methods to analyze the data may contribute to these conflicting findings in the literature.

The predictive role of excessive daytime sleepiness is less controversial. Several studies have already reported a positive association between this variable and nCPAP compliance, although various sleepiness scales were used [21,29,31,33]. In our population, the patients with an ESS score of $\leq$15 were 3.2 times less likely to be 'compliant' than sleepier patients ($P = 0.02$), confirming that sleepiness is a major determinant of nCPAP compliance. In the elderly, excessive daytime sleepiness has been reported to reliably predict perceptions of declining health and quality of life [39]. In the present study, age was weakly, but significantly, correlated with ESS score ($r = -0.18$; $P = 0.01$). This negative correlation could reflect either less severe disease observed in the elderly or an underestimation of the symptom of daytime sleepiness. A low ESS score could act as a confounding factor in addition to female sex and a low AHI, to explain the negative influence of age on compliance found in the univariate analysis.

We did not find any association between nCPAP level and compliance in the univariate analysis similar to other studies [27,28]. However, the clinical practice leads us to think that a high level of pressure could play a negative role on compliance, and that was confirmed by the Cox's proportional hazards analysis. Actually, the patients treated with a pressure of 12 cmH_2O or greater (fourth quartile in our population) were 2.3 times ($P = 0.01$) less 'compliant' than the patients treated with a lower pressure. The effect of a high CPAP on compliance was probably hidden in univariate analysis because the pressure is correlated [40,41] with the AHI ($r = 0.21$; $P = 0.008$) and the BMI ($r = 0.20$; $P = 0.01$); these latter characteristics exert an opposite independent effect on compliance. Using a low threshold (8 cmH_2O), McArdle et al. [21] did not find any independent effect of CPAP pressure, but they did not comment on compliance at high pressure. Even if the absolute value of the cut-off, 12 cmH_2O, is debatable, it suggests that compliance might be enhanced by lowering the pressure. The ability to deliver a variable CPAP level sufficient to prevent an abnormal respiratory event at the lowest possible pressure could improve the tolerance and the compliance [42]. Further studies using large numbers of patients are necessary to evaluate the effects of the use of the new 'intelligent CPAP' on compliance, which may deliver a wide range of pressures in a single night, according to the respiratory needs of the patient [43].

Acknowledgements

The authors would like to thank Mrs Olga Razanadramasy-Chapelle for her support in extracting the data from the sleep laboratory register.

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