

Acceptance and long-term compliance with nCPAP in patients with obstructive sleep apnoea syndrome

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ABSTRACT: Previous studies have generally shown poor effective long-term compliance with nasal continuous positive airway pressure (nCPAP) in patients with obstructive sleep apnoea syndrome (OSAS).

We performed a retrospective study of patients treated with nCPAP for more than one year. Compliance was defined as the average number of hours of nCPAP use per day, where hours of use were obtained from the built-in time counter of the nCPAP device, after deduction of the 10% difference between effective use and time counters previously shown by others. We present data on the first 95 patients for whom results were available.

The follow-up period was 784 ± 366 (mean \pm SD) days for the whole group. Compliance was 5 ± 1.8 h. For a subgroup of 36 patients, we had data on two consecutive follow-up periods (673 ± 235 and 390 ± 147 days for the first and second period, respectively). Compliance remained stable (5.2 ± 1.5 and 5 ± 2.3 h, respectively). For the whole group, a significant correlation was found between compliance and sleep fragmentation expressed as the movement arousal index ($r=0.226$).

During a similar 3 year period, 155 patients with a confirmed diagnosis of OSAS were offered a nCPAP trial. CPAP was actually delivered for home use to 117 patients (76%). During this same 3 year period, only 21 patients out of a total of 192 followed-up in our institution quit treatment, mainly due to intolerance or cure.

These results indicate that in a nonselected group of obstructive sleep apnoea syndrome patients a high and stable compliance with nasal continuous positive pressure can be achieved, contradicting recent results of other series.

Eur Respir J., 1996, 9, 939-944.

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Keywords: Compliance
obstructive sleep apnoea syndrome
nasal continuous positive airway pressure
therapy
treatment

Received: August 7 1995
Accepted after revision January 10 1996

Partly supported by grant No. 9.4547.93
from the Belgian Fonds de la Recherche
Scientifique Médicale.

First described in 1981, nasal continuous positive airway pressure (nCPAP) is recognized as the best treatment of the obstructive sleep apnoea syndrome (OSAS) [1, 2]. It is a safe therapeutic option with few contraindications or serious side-effects [3].

Unlike procedures such as maxillofacial surgery, which could theoretically result in the disappearance of the condition (cure), nCPAP is a "symptomatic" therapy generally proposed for an undetermined period of time. Indeed, cure is rare [4]. The question, thus, arises on the long-term compliance with this treatment. Short- and long-term compliance is known to be linked to the improvement of symptoms, such as daytime sleepiness [5, 6]. Until very recently, long-term compliance was believed to be high, exceeding 70% [7]. However, in the last 2 yrs, studies based on the monitoring of the pressure in the nasal mask, have shown that effective use of CPAP during periods of up to 3 months was poor, approaching 50% [2].

In Belgium, the CPAP devices are currently reimbursed by the social security system, provided that polysomnographic data disclose on the one hand a diagnosis of OSAS with an apnoea/hypopnoea index (AHI; number

of apnoeas + hypopnoeas per hour of sleep) ≥ 20 and confirm on the other hand the beneficial effect of nCPAP on OSAS. Moreover, the compliance, assessed through measurements of running-time with built-in time counters should be "sufficient". Accordingly, we have acquired data on long-term compliance in a large number of patients, many of whom have been followed in our sleep laboratory for quite lengthy periods of time. We report here the results of this follow-up, as well as the analysis of several parameters that may explain the compliance level in our group of patients.

Methods

We present data on the first 95 patients with confirmed OSAS (see below) treated with nCPAP in whom compliance data were acquired for at least 1 yr. In 36 patients, data on two consecutive follow-up periods were available. Running time of nCPAP is read at home on the built-in clock on the occasion of the annual maintenance. We define compliance as the average number of hours of daily use. Compliance is calculated as the number of

hours separating two readings of the built-in time counter, divided by the number of days separating the two readings. Ten percent of this value is subtracted to give the final daily compliance in hours (see Discussion for the explanation of this procedure).

Patients were referred to our unit for snoring and/or daytime sleepiness. Each patient was diagnosed after a full night polysomnography. Details of our method have been described previously [8]. Electroencephalogram (EEG), electro-oculogram (EOG), and submental electromyogram (EMG) were obtained from surface electrodes using standard techniques. Airflow was monitored by three thermocouples placed in front of the mouth and nostrils. Respiratory movements were assessed by a thoracic strain gauge. A microphone glued on the neck recorded snoring. Electrocardiogram (ECG) was obtained from two electrodes placed on the chest. All these data were recorded simultaneously on a polygraph system (Nihon Kohden ink recorder; Tokyo, Japan) at a paper speed of 10 mm·s⁻¹. Transcutaneous oxygen saturation (S_{tc,O_2}) was simultaneously recorded by pulse oximeter (Nellcor N-100; Hayward, CA, USA) using a finger probe. Sleep variables were scored according to standard recommendations [9], and compared with normal values published by WILLIAMS *et al.* [10]. A movement arousal (MA) was defined as the reappearance of an alpha rhythm in the EEG during a sleep epoch, accompanied by an increase in EMG activity lasting for at least 2 s. This definition is derived from that of RECHTSCHAFFEN and KALES [9], and is the usual one used in our laboratory [8, 11]. The movement arousal index (MAI) designates the number of MA per hour of sleep. An apnoea was defined as airflow cessation for a period of 10 s or longer. Apnoeas were classified as central, obstructive or mixed according to the absence or presence of breathing efforts. Hypopnoeas were defined as any decrease in S_{tc,O_2} greater than 4% associated with a reduction, but without complete cessation, of oronasal flow. The apnoea-hypopnoea index (AHI) was scored as the desaturation index (DI) (number of desaturations >4% per hour of sleep). OSAS was retained as a diagnosis when the DI exceeded 15.

Patients with a DI ≥ 20 and excessive sleep fragmentation (MAI ≥ 22 , the highest limit of normality in our laboratory) were offered a therapeutic trial with nCPAP. Patients were admitted for 3–4 nights as described previously [12]. They were instructed in the use of nCPAP, and slept with the device at a low pressure (about 5 cmH₂O) during naps and nights. They were encouraged to try different masks and to get acquainted with the apparatus. On the third or fourth night, a full polysomnography was repeated. During the first part of the night, pressure was gradually increased to suppress apnoeas, hypopnoeas, snoring and sleep fragmentation. If the treatment proved effective, and the patient seems willing to use it, home therapy was started. The device was delivered at home by a commercial delegate not belonging to our unit. He would, thereafter, solve all the technical problems, including nasal mask discomfort. During follow-up, there was no reinforcement for treatment either by means of home visit or phone calls by any member of our unit (physicians, nurses or physiotherapist) but the patients were aware that they could contact our team in case of problems not otherwise solved. The patient's family physician took part in the solution of minor side-effects

(nasal congestion, rhinitis, *etc.*). We normally saw the patient again after 1 year of treatment on routine visit. The patient was not expressly aware of the reading of the counter.

This was a retrospective study based, by inclusion criteria, only on compliant patients, since the existence of two consecutive readings of the time counter was the basis of the choice of the patients. To get a better idea on acceptance of therapy, and on the number of patients that quit therapy, we checked the number of patients with OSAS in whom nCPAP was tested, the number of nCPAP machines that were delivered after the three to four nights habituation period, and the number of patients that abandoned their treatment afterwards. Acceptance rate was defined as the number of patients offered a nCPAP trial and accepting home treatment divided by the total number of patients offered the nCPAP trial. We looked systematically at each patient admitted to our sleep laboratory between 1992 and 1994.

Statistical methods

Correlations between compliance and other indices (age, body mass index (BMI) and polysomnographic data) were examined using least-squares regressions. The null hypothesis was rejected at $p < 0.05$. A stepwise multiple linear regression was used to detect the best polysomnographic data able to predict compliance. The parameters analysed were age, MAI, BMI, apnoea index, DI, percentage of stage 3–4 non-REM sleep, mean S_{tc,O_2} during non-REM and REM sleep, the lowest S_{tc,O_2} and the difference between the last seven parameters during the diagnostic and the CPAP polysomnography. Paired t-test was used to compare compliance on two successive periods. Unpaired t-test was used to compare the entire group with the subgroup of 36 patients with two consecutive follow-up periods. A p-value of less than 0.05 was considered to be significant.

Results

Ninety five patients were included in the study. In all patients, at least two time-counter readings were available. Among them, 36 patients had three readings, encompassing two consecutive time periods. Tables 1 and 2 summarize the baseline values and the polysomnographic data under nCPAP in the entire group, as well as in the subgroup of patients with two follow-up periods. Patients were generally obese, (mean \pm SD) BMI 36 ± 6 kg·m⁻²). Only three patients had a BMI below 25 kg·m⁻². MAI was high (58 ± 23) as was the DI (66 ± 23). Percentage of stage 3–4 non-REM sleep and REM sleep during the diagnostic polysomnography were, respectively, 7 ± 10 and $16 \pm 7\%$ of total sleep time (TST). During the polysomnography with nCPAP, both increased to 22 ± 14 and $23 \pm 10\%$ of TST, respectively ($p < 0.05$), whereas the DI and the MAI decreased significantly. Mask pressure was 10 ± 2 cmH₂O.

The mean follow-up period was 784 days (range 341–2080 days) for the whole group with a mean compliance of 5 ± 1.8 h. Lowest and highest compliance were, respectively, 1.4 and 9.7 h with a median compliance of 5.2 h.

Table 1. – Baseline characteristics of patients

Characteristic	Entire study group (n=95)	Subjects with two follow-up periods (n=36)
Sex M/F	88/7	34/2
Age yrs	53±12	51±12
Body Mass Index kg·m ⁻²	36±8	36±7
Apnoea index n·h ⁻¹ of sleep	25±21	26±20
Desaturation index n·h ⁻¹ of sleep	66±23	70±20
REM sleep % of TST	16±7	17±6
Stage 3–4 non-REM sleep % of TST	7±10	7±9
MAI n·h ⁻¹ of sleep	58±23	60±18
Mean Stc,O ₂ non-REM sleep %	86±9	84±10
Mean Stc,O ₂ REM sleep %	79±14	78±15
Lowest Stc,O ₂ %	56±19	54±20

Values are presented as mean±SD. M: male; F: female; REM: rapid eye movement; MAI: movement arousal index; TST: total sleep time; Stc,O₂: transcutaneous oxygen saturation.

Table 2. – Polysomnographic data under nasal continuous positive airway pressure

Characteristic	Entire study group*	Subjects with two follow-up periods*
Apnoea index n·h ⁻¹ of sleep	2±7	2±9
Desaturation index n·h ⁻¹ of sleep	20±20	23±24
REM sleep % of TST	23±10	26±10
Stage 3–4 non-REM sleep % of TST	22±14	24±14
MAI n·h ⁻¹ of sleep	12±11	15±15
Mean Stc,O ₂ non-REM sleep %	91±17	91±16
Mean Stc,O ₂ REM sleep %	90±17	90±16
Lowest Stc,O ₂ %	78±20	77±22

Values are presented as mean±SD. *: all values significantly different from diagnostic night (see table 1), p<0.05. For abbreviations see legend to table 1.

Seventy four percent of patients used their CPAP device for more than 4 h·day⁻¹. There was a significant positive correlation between compliance and the MAI (r=0.226; p<0.05) (fig. 1). There was no significant correlation with age (r=-0.202; p=0.05) (fig. 2). On multiple linear regression, in addition to MAI and age, the mean non-REM sleep Stc,O₂ during the diagnostic polysomnography also contributed to the regression model (overall r=0.324; p<0.01). MAI was positively, whereas age and Stc,O₂ were negatively, correlated to the compliance. There was no significant relationship between DI and compliance.

For 36 patients, there were two consecutive follow-up periods of, respectively, 673±235 and 390±147 days. The characteristics of this group were not different from those of the entire study group (tables 1 and 2). Median compliance was 5 h. Compliance was 5.2±1.5 h during the first period and 5.0±2.3 h during the second period. The difference was not significant (fig. 3). In this group, six patients showed low levels of average daily use of nCPAP (<4 h·day⁻¹). After one year, compliance remained low for these six patients. Four patients who were good compliers during the first follow-up period became poor

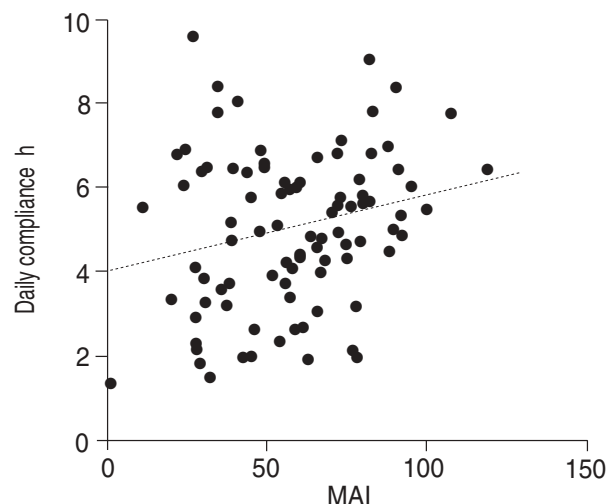


Fig. 1. – Relationship between movement arousal index (MAI) and average daily compliance long-term follow-up (r=0.226; p<0.05).

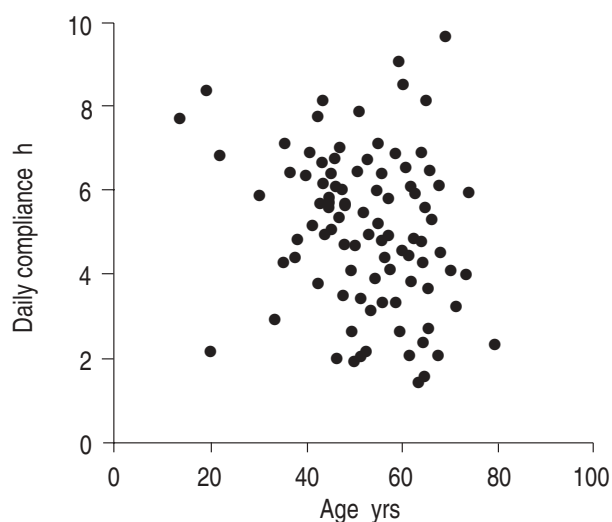


Fig. 2. – Relationship between age and average daily compliance on long-term follow-up (r=-0.202; p=0.05).

compliers during the second follow-up period. They were contacted as they reported good acceptance of treatment during the annual routine visits. Only two of them acknowledged a low compliance.

During the years 1992, 1993 and 1994, respectively, 39, 64 and 52 full night polysomnographic studies under nCPAP were performed after the habituation period in patients with a diagnosis of OSAS. The number of CPAP devices that were subsequently delivered at home reached 29 (74%), 47 (73%), and 41 (79%), respectively. The reasons why nCPAP therapy was not offered to a quarter of our patients were: intolerance (10 patients; 27%); inability to fully and satisfactorily correct apnoeas, hypopnoeas, snoring and/or movement arousals (14 patients; 38%) or both (5 patients; 14 %); three patients (8%) were never seen afterwards though nCPAP was well-tolerated and efficient; two patients (5%) were offered septoplasty first but were lost to follow-up; two others (5%) received nCPAP only during the time of hospitalization for coronary bypass surgery [12]; and, finally, in one patient weight loss was advocated and nCPAP deferred until further evaluation.

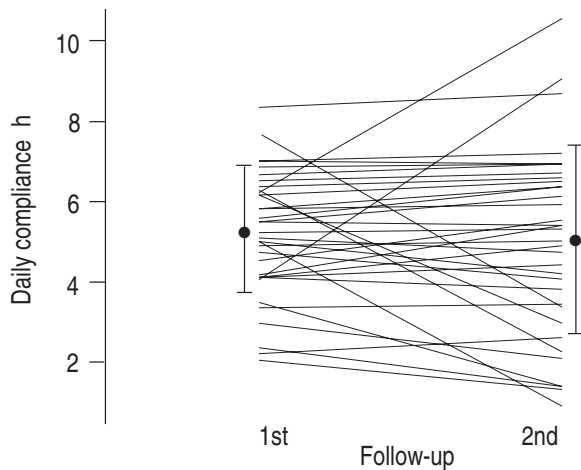


Fig. 3. — Evolution of long-term average daily compliance on two consecutive follow-up periods (first and second follow-up) in a subgroup of 36 patients. Thin lines represent individual data; thick lines show mean \pm SD. Difference in compliance between periods is not significant (see text for details).

During this 3 year period, a total of 192 patients with home nCPAP therapy were followed-up in our institution. Of these, 21 patients quit nCPAP treatment during this 3 year period (three in 1992; seven in 1993; and eleven in 1994). The reasons were as follows: six patients were cured (with polysomnographic confirmation of near or complete normalization of sleep and breathing); 13 could no longer tolerate the nasal mask, despite trying different models; two died (one from a cervical cancer that was the origin of the obstructive events; one from undetermined cause, he had a diabetic micro- and macro-angiopathy). Of the six patients cured, four had lost significant amounts of weight. In two, weight was unchanged.

Discussion

This retrospective study performed in a nonselected group of patients with OSAS shows that compliance to nCPAP treatment was reasonably good during a relatively long follow-up period of more than 2 yrs on average, and that there was little change in compliance among individual patients over successive follow-up periods of 3 yrs on average. Moreover, a multiple linear regression model showed compliance to be significantly related to age, sleep fragmentation and mean nocturnal saturation during non-REM sleep at the time of diagnosis, so that younger patients with more sleep fragmentation and less severe desaturation during non-REM sleep were likely to use their nCPAP machines the most. Finally, acceptance was found to be relatively good for this demanding treatment and the number of drop-outs was quite small.

Before analysing our results, a technical point merits consideration. We decided to take into account 90% of the running-time as a measure of effective use. This was based on results of three different studies where effective use (*i.e.* hours of effective pressure in the mask) was compared to running-time of the nCPAP devices. All three studies gave an effective time that corresponded to about 90% of the running-time (91, 89 and 91%, respectively, in [13–15]). We can, therefore, be confident that

effective time of use by the patients does not deviate by more than about 10% from the running-time of the device.

We decided not to rely on subjective patient's reports, since it is known that these deviate quite substantially from real use [16].

Initial studies of compliance with nCPAP based on questionnaires showed quite high levels of use, greater than 70% [17, 18]. Most, though not all, of later reports relying on the time counter-based running-time showed that subjective use of nCPAP largely overestimated real running-time [19, 20]. More recently, effective use of nCPAP has been measured as the time during which the pressure needed to control sleep apnoea is effectively applied on the nasal mask. This showed that, on the one hand, effective time is about 10% less than running-time, and that, on the other hand, compliance is much less than previously thought. Indeed, KRIBBS *et al.* [13] in a study of 35 patients followed for 3 months reported that patients used their devices only 66% of days, for a mean time of 4.9 h. Converting these data to our way of calculating compliance gives a mean daily compliance of 2.9 h. ENGLEMAN and co-workers [14], using a similar methodology, found in 54 patients followed up for 3 months a compliance of 4.1 h (taking into account the 10% difference with respect to running-time) [14]. Finally, REEVES-HOCHE *et al.* [15] found in a group of 38 patients followed up for 6 months an effective compliance of 4.3 h-day⁻¹. Our data show quite high values, of more than 5 h-day⁻¹, in a larger group of patients with a much longer follow-up. This is similar to the results reported by KRIEGER [7], with the difference that we subtracted 10% of the running-time to calculate compliance. Moreover, this high rate of use of nCPAP is maintained over time as previously reported by others [19]. Indeed, in the group of 36 patients with two consecutive follow-up periods, only four patients decreased their rate of use of nCPAP over time (fig. 3).

The success rate of nCPAP therapy in the current study group could be artifactually high because the study was based only on patients for whom data about compliance could be recorded. It is also important to know the number of patients refusing or abandoning therapy. After looking at all the patients seen in our sleep laboratory during a period of 3 yrs, approximately equal to the mean follow-up period of the study group, we observed a relatively small number of treatment arrests or refusals. Refusals concerned less than 25% of patients to whom a nCPAP trial was offered and included a number of patients lost for follow-up, which is not unusual in clinical practice. This leads to an acceptance rate of 74%. The major reasons of treatment arrest were cure of OSAS or intolerance to the nasal mask. Cure seems to represent one third of the causes of treatment interruption [4].

Why are our results better than those of others? We might have followed a group of more severe OSAS. This is unlikely. The BMI in our group (36 kg·m⁻²) is comparable to that of the group of ENGLEMAN and co-workers [14] (33 kg·m⁻²), KRIBBS *et al.* [13] (39.5 kg·m⁻²) and REEVES-HOCHE *et al.* [15] (40.2 kg·m⁻²). The DI is also comparable (65 in our group *versus* an AHI of 36 in [14], 65 in [13] and 56 in [15]). Finally, the age of the group is also comparable (53 yrs *versus* 51, 46 and 50 yrs, respectively).

Neither does reinforcement seem to explain our better results. Indeed, we have no formal policy of reinforcement. We do not contact patients by mail or phone except for the annual out-patient clinic visit. Moreover, it has been shown that, over a short period of 3 months, positive reinforcement by telephone for new users of CPAP does not improve compliance in comparison with a group of new or chronic users without reinforcement [21].

"Economic" reasons cannot explain our good results. In Belgium, as in the UK, CPAP units are free of charge for the patients. This, as ENGLEMAN *et al.* [14] suggested, would reduce rather than stimulate the motivation.

We must, therefore, look for other reasons to explain the high level of daily use that we observed. The only difference between our methodology and that of most other sleep units is that our patients are admitted to the hospital for 3–4 days before nCPAP polysomnography is performed. During this period, the patient has the opportunity to obtain experience with the device, to test different masks and to slowly adapt to the positive pressure. Only then is the pressure increased under polysomnographic control to eliminate apnoeas, hypopnoeas, snoring and sleep fragmentation. We cannot be sure that our good compliance results from this method of implementing nCPAP, but we suggest that this could well be the case. Patients are likely to get more information from our team *via* nurses, technicians, respiratory therapists and physicians. They can choose the most comfortable type of mask and straps and feel more at ease with respect to the machine. In this respect, home treatment is more a continuation of the in-hospital experience and may result in better use of the devices.

Previous studies have found correlations between compliance and some indicators of sleep-disordered breathing, such as AHI or the mean S_{tc,O_2} during sleep [7, 19]. Others have reported a correlation between compliance and some estimation of daytime somnolence [15, 19]. However, other authors have found no correlation between compliance and sleep, breathing and somnolence data [14]. Sleep fragmentation is a major determinant of daytime sleepiness but has never been taken into account in previous studies [22, 23]. We examined the relationship between compliance and the MAI, as an objective measure of sleep fragmentation, and found a weak but significant positive correlation suggesting that, indeed, patients with more sleep fragmentation (and therefore probably more daytime sleepiness) can be expected to adhere more to treatment. Negative correlations were also found between compliance and age or mean S_{tc,O_2} during non-REM sleep in a multiple linear regression analysis. It is difficult to understand the relationship with S_{tc,O_2} , but others have reported the same finding [7]. It is easier to explain the role of age and sleep fragmentation: younger patients with more sleep fragmentation are more likely to get better symptomatic relief with the use of nCPAP, and therefore be more compliant. In any case, long-term compliance to nCPAP is probably determined by many factors, and it is therefore not surprising that the correlations we found were, though significant, weak.

Even if we observed very good and stable compliance, the question remains "What is the optimal compliance for one given patient?". For MEURICE *et al.* [19], 5 h-night⁻¹ running-time is the limit to define a good compliance.

This criterion is based on the necessity to prevent oxygen desaturation during sleep. However, ENGLEMAN and co-workers [24] demonstrated improvement of daytime sleepiness and cognitive performance even at lower levels of CPAP use (3.4 ± 0.4 h of effective pressure mask time in 32 patients). In another study comparing CPAP and conservative treatment, the same group showed no difference in cognitive performance but a significant effect on mood and daytime sleepiness assessed by multiple sleep latency test [25]. These authors defined as good compliers those who used CPAP for at least 4.5 h running-time per night. For others, the criterion for regular use is defined by at least 4 h of CPAP administered on 70% of the days [13].

On the other hand, we can look at compliance in other chronic respiratory diseases. Recently, a compliance rate of only 57% in asthmatic patients treated with inhaled corticosteroids has been reported: for 10 prescriptions, only six are effectively delivered at the pharmacy [26]. Similarly, COCHRANE [27] reviewing studies on asthmatic patients showed poor compliance levels of 48–67% in out-patients [27]. Similarly, compliance with long-term oxygen therapy by concentrators is below the level at which clinical benefit is to be expected in at least 50% of patients [28].

Figure 3 shows several patients with what could be considered as very poor levels of compliance (1.2–3.3 h). These patients remained at these low levels for more than 3 yrs, and did not give up treatment. We do not know whether they used their nCPAP machines for short periods of time every night, or for longer periods one night and not at all the following one. Nevertheless, this strongly suggests that they still perceived a benefit from their treatment, since one would expect that such a cumbersome therapy would have been completely abandoned if the beneficial effect had been nil. Some data exist suggesting that there is a residual effect of nCPAP, so that, after nCPAP, OSAS returns to its pretreatment level of severity only after several days [29]. According to ENGLEMAN and co-workers [24], 3.3 h of daily nCPAP use significantly decreases daytime somnolence. It is unknown whether lower levels of compliance will also result in symptomatic improvement, and eventually in decrease in mortality. In this respect, the data of HE *et al.* [30] showed that decreased mortality with nCPAP was obtained in patients in whom compliance was not assessed. Probably, they were not more compliant than patients in the studies by KRIBBS *et al.* [13], ENGLEMAN and co-workers [14] and REEVES-HOCHE *et al.* [15]. Therefore, we feel it unjustified to set an arbitrary lower limit of compliance. As long as patients use their devices for any given numbers of hours (less than 1.6 h-day⁻¹ in our experience) (fig. 3) for long periods of time, this probably means that some symptomatic benefit is attained.

In conclusion, we observed in our patients with obstructive sleep apnoea syndrome a high and stable compliance with nasal continuous positive airway pressure over a long period of time, which appears much better than most previous reports. We hypothesize that these good results stem from our approach to initiate nasal continuous positive airway pressure therapy.

Acknowledgements: The authors thank M.P. Bietlot for secretarial assistance.

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