Original article

Evaluation of autoCPAP devices in home treatment of sleep apnea/hypopnea syndrome

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Abstract

Background and purpose: Quality of life (QOL) and sleepiness for patients with sleep apnea/hypopnea syndrome (SAHS) might improve with continuous positive airway pressure devices working in auto-adjust mode (autoCPAP) by allowing pressure modulations following patient needs. Clinical comparisons between devices driven by different algorithms are needed.

Methods: We compared the clinical effectiveness of fixed pressure CPAP and four different autoCPAP devices by assessing compliance and QOL (36-item short-form health survey [SF-36]). SAHS patients were randomly allocated to five groups. Polysomnography (PSG) was performed to titrate the effective pressure in the constant CPAP group and evaluate residual apnea/hypopnea index (AHI) under autoCPAP. Follow-up consisted of clinical visits at three and six months by homecare technicians who assessed compliance, symptom scores and SF-36 scores. A laboratory-based PSG using the same CPAP/autoCPAP device as at home was performed at six months.

Results: Eighty-three patients (mean age 56 ± 10 yrs) with mean body mass index (BMI) $30.8 \pm 5.3 \text{ kg/m}^2$ and severe SAHS (mean AHI: 52.3 ± 17.8/h) were included. There were no differences in clinical symptoms or QOL scores, and similar clinical and PSG improvements were seen in all groups. CPAP use was >5 h per night, without any significant difference between groups.

Conclusions: AutoCPAP is equally as effective as fixed CPAP for long-term home treatment in severe SAHS patients.
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Keywords: Continuous positive airway pressure; AutoCPAP; Compliance; Quality of life; Sleep apnea syndrome

1. Introduction

The usefulness of nasal continuous positive airway pressure (CPAP) in the treatment of the sleep apnea/hypopnea syndrome (SAHS) was first reported by Sullivan et al. in 1981 [1], and CPAP is considered to be the treatment of choice because of the improvement in morbidity that occurs with its use [2,3]. CPAP technology has advanced in recent years with objectives of improving comfort and compliance with this demanding treatment. In France, over 60,000 patients are currently treated with CPAP in the Association Nationale pour le Traitement a Domicile des Insuffisants Respiratoires (ANTADIR) associative homecare network, in which 35% of patients use devices working in auto-adjust mode

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(autoCPAP). These autoCPAP devices permit variations in pressure levels during the night, thereby allowing a decrease in pressure level when apneas (A) and or hypopneas (H) disappear and an increase in pressure level when the sleep respiratory events reappear. The aim of these devices is to adapt the pressure level most effectively to the operating conditions of the upper airways. These conditions may change from one night to another, and throughout the same night, while fixed CPAP always maintains the same level of pressure that was initially determined to be effective, independently of weight changes or any modification in sleep position or nasal permeability. Consequently, autoCPAP was developed in order to improve patient tolerance for the ventilation, while supposedly avoiding the recurrence of sleep-related respiratory disorders.

Since 1992, several autoCPAP appliances have been developed, using signal analysis and algorithms, to control the pressure changes during the night that vary from one device to another. Early autoCPAP algorithms were based on variation in the CPAP level within a pre-determined pressure range ($+2$ cm H_2O and -4 cm H_2O, respectively, around a predetermined effective pressure) according to the flow pattern provided by the CPAP compressor [4] or by snoring detection [5]. Progressively, more sophisticated algorithms were developed in order to allow pressure changes within large limits without any predetermination of an effective pressure level, leading to the possibility of auto-titration of the effective pressure level by the machine itself as well as home treatment in auto-adjust mode [6,7]. More recent devices are able to detect very complex signals mostly reflecting the presence of flow limitation during the inspiratory phase [7,8]. The use of such apparatus has been extensively developed without rigorous clinical evaluation of autoCPAP tolerance and long-term effectiveness. Few studies have been performed regarding the regular therapeutic use of these homecare ventilation devices in auto-adjust mode. Most studies were performed during a single night of PSG or over a short period at home [4,9–12]. Those studies usually found results comparable to conventional CPAP devices, but with a reduction in the mean pressure level required during the night, except with the use of Autoset® (ResMed), with which pressure spent during 95% of the time (P 95) was generally higher than effective pressure on manual titration [12]. In one study, there was an improvement in compliance compared to CPAP during a trial in the home environment for three weeks [4]. Only the Autoset® (Resmed) device has been submitted to a trial at home over an eight-month period in constant pressure mode after an automatic titration of the effective pressure by the Autoset® [13]. No long-term trial has been published with those devices in autoCPAP mode in the home.

Therefore, we have set out to evaluate the effect of different autoCPAP devices in comparison with that of fixed CPAP on clinical symptoms (daytime vigilance, quality of life [QOL]) as well as on polysomnographic (PSG) criteria. We have compared data at an initial titration visit and then during long-term treatment at home in the operating conditions recommended by the manufacturers, which is in an automatic spontaneous pressure adjustment mode. Adherence to CPAP treatment was comparatively evaluated during long-term treatment.

2. Patients and methods

2.1. Patients

Eighty-three SAHS patients prospectively recruited from five sleep laboratories in France, proposed for CPAP treatment, were included in this study. They were naive to nasal CPAP and had not undergone any nasopharyngeal surgery. The study was proposed to patients with an apnea/hypopnea index (AHI) over 30/h of sleep or >10 micro-arousals/h, in accordance with French CPAP reimbursement procedures. Patients with more than 20% of respiratory disturbances characterized as central events, or those taking sedative treatment such as benzodiazepines or other hypnotics were not included. The protocol was authorized by the Institutional Ethics Committee, and written informed consent was obtained.

2.2. Protocol

2.2.1. Study design

We conducted a prospective, randomised, multi-centre trial of five different CPAP devices (four different autoCPAP and one constant CPAP) for patients beginning CPAP therapy after initial diagnosis of SAHS. Initial diagnosis was made using full sleep laboratory polysomnography (PSG). The diagnosis was explained to the patient and informed consent was obtained before discharge following PSG, and the patient was scheduled for overnight titration of CPAP pressure with full PSG at this point. The titration was performed in the laboratory and supervised by experienced technicians. Before polysomnographic titration, the patients were randomly allocated into five different groups according to the type of CPAP machine to be used during the titration night and continued over the study period. In Group 1, patients used a fixed CPAP whose effective positive pressure was manually determined during the laboratory titration by the technician, based on the disappearance of snoring, apnea and hypopnea in all sleep stages and all body positions.

Patients in the four other groups (Groups 2–5) were treated with one of the autoCPAP machines (respectively, Group 2: GK 418 P® [Tyco], Group 3: AutoSet® [ResMed], Group 4: PV 10i® [Breas], Group 5: Somno-

smart 1® [Weinmann]). The versions of apparatus used and their default settings are described in Appendix A. In the four autoCPAP groups, the apparatus were set in auto-adjust mode during the titration night, according to the recommendations of each manufacturer in order to evaluate mean CPAP pressure (P_{mean}) and residual AHI from PSG recordings. We did not try to evaluate the level of effective positive pressure that could be determined by autotitration. The randomization was carried out centrally by randomly coded envelopes opened by a coordinator from envelopes batched for each centre in order to have similar proportions of patients in each group from each centre. Subsequently, patients were treated at home for six months with the same apparatus as used during the titration night, without any modifications in autoCPAP characteristics.

All the patients underwent the same protocol involving a titration night, specific education regarding CPAP use and mask adaptation, and were told to use nasal CPAP each night for a minimum duration of 5 h per night. Each patient completed a symptom questionnaire and the Epworth Sleepiness Scale (ESS) [14], plus a general QOL questionnaire validated in French (36-item short-form health survey [SF-36]) [15].

2.2.2. Follow-up

During the six-month study period, compliance and clinical progress were assessed by homecare technicians of the ANTADIR network during home visits at three and six months. CPAP compliance was measured as well as CPAP tolerance, and level of P_{mean} was recorded by the technicians. At each home visit, patients completed the clinical symptom questionnaire, ESS, and SF-36 as had been done initially.

A laboratory-based PSG recording was performed again at the end of the six-month study period, using CPAP/autoCPAP in the five groups in the same mode as during home treatment, without any modification in the effective positive pressure when CPAP was used in a constant mode and without any change in autoCPAP parameters when used in auto-adjusted mode.

2.3. Data analysis

2.3.1. Polysomnographic recordings

During the initial titration night as well as at six months, PSG recorded electroencephalogram (EEG), electrooculogram (EOG) and submental electromyogram (EMG) using surface electrodes. Airflow was detected using nasal pressure cannula under a nasal mask and an oral thermistor. Snoring was recorded with a microphone attached to the skin just over the throat. Respiratory effort was monitored by inductive plethysmography of the chest and abdominal walls. Body position was analysed using a thoracic sensor, and oxy-

haemoglobin saturation (SpO_2) was recorded by digital oximetry.

Sleep stages were visually scored according to Restchaffen and Kales criteria [16]. Sleep-related breathing disorders were evaluated according to the analysis of the AHI the apnea index (AI), minimal oxygen saturation (min SpO_2), mean SpO_2 and time spent at SpO_2 lower than 90% (SpO_2 90). Apnea was defined as an interruption of oronasal airflow for greater than 10 s; hypopnea was defined as period during which there was a reduction of at least 50% in the respiratory airflow for at least 10 s associated with an oxygen desaturation of at least 4% and/or arousal [17]. Apnea was classified as "central" if no thoracic or abdominal movements were observed, "obstructive" if thoracic and abdominal movements arose during apnea, and "mixed" when respiratory effort, initially absent, began before the resumption of the respiratory airflow.

When using fixed CPAP, initial titration of the effective positive pressure (P_{eff}) was manually determined according to the regression of apnea, hypopnea and snoring in all sleep stages and all body positions. During auto-titration, the mean positive pressure computed for the whole night (P_{mean}) was automatically determined, but the machine settings were not altered. In both modes, we analyzed sleep architecture, AI and AHI, as well as previously defined SpO_2 parameters. At the final (six months) PSG, an identical evaluation was performed in all groups, and P_{mean} was reanalysed in autoCPAP mode.

2.3.2. Evaluation of clinical status and CPAP characteristics

Daytime somnolence was evaluated according to the ESS (normal values <10/24) and a visual analogue scale of 100 mm whose lowest values corresponded to the most pronounced hypovigilance. QOL was evaluated by the SF-36, validated in French and analysed according to eight different domains that were regrouped into physical and mental scores as recommended [18]. Daily CPAP compliance was calculated from readings of built-in hour meters in the machine by technicians from the homecare associations. In the autoCPAP groups, P_{mean} value was recorded by the technicians at the home check-up at three months.

2.3.3. Statistical power and analysis

Our null hypothesis was that there would be no difference between machines regarding clinical improvement as assessed by QOL and symptom scores. Previously published data [9] would indicate that, with a mean reduction in AHI of 40/h of sleep, a difference of less than 10 respiratory events per hour, measured by full PSG, is not noticeable symptomatically by patients. Our power calculation was that a minimum number of 12 subjects were required in each group so as to not miss

a clinically significant difference between autoCPAP and constant CPAP, giving a required total of 60 subjects for the study. We estimated the need for a 25% increase in inclusions in order to compensate for eventual dropouts.

Sample size computations were designed with a view to compare one single autoCPAP device with constant CPAP. The real power of statistical comparisons was slightly increased by the use of analysis of variance that provides a better relative efficiency than two-sample tests. Conversely, the computations were calculated on the basis of assumptions whose validity could affect the sample size needed.

Numeric variables are summarized as arithmetic mean ± standard deviation. Differences between the five groups' characteristics at baseline, and after three or six months were compared by an analysis of variance; Dunnett's post-hoc comparison procedure used the constant CPAP group as controls. Rank-transformation and non-parametric (Kruskal–Wallis) tests were used when the distribution of data deviated markedly from normality. Intragroup differences at three or six months were tested by Wilcoxon rank sum test for paired data. A p value less than 0.05 was considered statistically significant.

3. Results

Eighty-three patients (mean age 56 ± 10 yrs) with a mean BMI of $30.8 \pm 5.3 \, kg/m^2$ and severe SAHS (mean AHI: $52.3 \pm 17.8/h$) were initially included in this study, according to the predetermined inclusion criteria. Initial demographic characteristics and diagnostic data are shown in Table 1 and Table 2. The five groups had severe SAHS with no differences between groups in AHI or level of sleepiness. Initially, the SF-36 QOL index was reduced in all domains and in all groups compared to normal French data, with no difference between groups.

There was no significant difference between the five groups regarding PSG parameters at titration (Table 3). All groups demonstrated a similar improvement in sleep architecture with a significant reduction in the proportion of stage 1–2 sleep and a significant increase in slow wave sleep and rapid eye movement (REM) sleep. We found a significant reduction in the proportion of time spent below 90% SpO_2 as well as a significant increase in mean levels of nadir SpO_2 in all groups. Simultaneously, a significant and comparable reduction in mean AHI was found in all groups, in comparison with baseline values.

Eighteen patients could not complete the study because of technical problems in three of them (1 patient in groups 1, 3 and 4), while the others did not agree to undergo the last PSG study or stopped using CPAP (two patients in group 1, four patients in group 2, one patient in group 3, four patients in group 4 and four patients in group 5 [total 15], not significantly different), so that only 65 patients with PSG data were evaluated at six months. This subgroup of dropout patients was not different from the subgroup pursuing the study in terms of anthropometric and baseline sleep characteristics so analysis was not on an intention-to-treat basis as there were no data for a second PSG.

PSG parameters obtained after a six-month period of treatment (Table 3) confirmed the same improvement in parameters as during a single titration night, in all groups and without any significant difference between groups. However, even if mean AHI value remained below 10/h whatever the group, the maximal value for some individuals reached 28/h and 25/h, respectively, in groups 4 and 5, while it never exceeded 10/h in the three other groups.

The change in mean positive pressure (P_{mean}) was different between groups (Fig. 1). In groups 2, 3, 4 and 5, patients demonstrated important inter-individual variability during the first recorded night under autoCPAP, as well as at the three- and six-month controls, with an

Table 1
Initial demographic and polysomnographic characteristics

	Group1 Constant CPAP $n = 17$	Group 2 GK 418 P $n = 17$	Group 3 AutoSet $n = 17$	Group 4 PV 10 I $n = 17$	Group 5 Somnosmart 4 $n = 15$
Age (yrs)	52.2 ± 9.5	53.5 ± 9.2	$58.1 + 10.2$	54.9 ± 11.2	59.7 ± 11.0
Weight (kg)	95.1 ± 16.4	98.6 ± 17.5	88.8 ± 17.0	87.4 ± 15.7	90.9 ± 17.0
AHI (/h)	56.1 ± 21.4	49.9 ± 16.5	53.4 ± 15.1	48.1 ± 18.7	54.5 ± 17.7
TST (min)	373.8 ± 91.8	400.6 ± 74.4	390.1 ± 65.1	372.5 ± 87.8	371.7 ± 96.1
Stage 1–2 (%)	74.6 ± 10.3	66.5 ± 14.0	74.9 ± 13.8	70.4 ± 10.7	74.5 ± 9.9
Stage 3–4 (%)	8.7 ± 8.3	10.7 ± 11.2	10.8 ± 8.5	10.9 ± 10.1	11.9 ± 7.2
REM (%)	12.5 ± 7.2	16.0 ± 9.8	8.9 ± 6.0	11.1 ± 7.1	11.1 ± 6.6
AwSaO$_2$ (%)	$95 1 \pm 2.5$	95.6 ± 3.1	95.6 ± 2.2	96.4 ± 1.9	95.6 ± 2.5
Mean SaO$_2$ (%)	90.8 ± 6.9	92.5 ± 2.3	91.8 ± 2.0	92.6 ± 3.8	91.9 ± 2.8
Min SaO$_2$ (%)	75.5 ± 16.3	73.0 ± 12.5	74.5 ± 12.1	76.8 ± 11.0	75.8 ± 14.9
SaO$_2$ 90 (%)	19.8 ± 28.7	16.2 ± 16.4	23.3 ± 17.6	11.7 ± 15.1	16.7 ± 18.8

AHI, apnea/hypopnea index; TST, total sleep time; Stage 1–2, light sleep; Stage 3–4, deep sleep; REM, rapid eye movement sleep; SaO$_2$, arterial oxyhaemoglobin saturation; AwSaO$_2$, awake SaO$_2$; Mean SaO$_2$, mean SaO$_2$ during the night; Min SaO$_2$, minimal SaO$_2$ during the night; SaO$_2$ 90, percentage of total recording time spent below 90% SaO$_2$.

Table 2
Quantitative values of daytime sleepiness and quality of life evaluated initially, at three- and six-month controls

	Group1 $n = 14$	Group 2 $n = 13$	Group 3 $n = 15$	Group 4 $n = 12$	Group 5 $n = 11$
Initial values					
Visual Sleepiness Scale (cm)	41.3 ± 16.8	45.0 ± 26.6	41.2 ± 28.9	43.5 ± 29.3	44.6 ± 26.0
ESS	10.6 ± 5.2	11.2 ± 5.6	12.9 ± 4.3	11.3 ± 3.8	10.0 ± 6.2
SF-36 (Emotional items)	43.1 ± 9.4	49.5 ± 8.3	45.7 ± 7.9	43.3 ± 12.3	47.5 ± 7.0
SF-36 (Physical items)	45.6 ± 8.6	42.7 ± 13.8	48.6 ± 5.3	46.2 ± 7.8	46.7 ± 8.7
Three months values					
Visual Sleepiness Scale (cm)	70.5 ± 19.0	72.3 ± 16.6	73.7 ± 13.9	66.5 ± 19.1	67.9 ± 21.0
ESS	4.8 ± 5.5	6.8 ± 5.8	3.8 ± 2.5	5.3 ± 2.8	7.5 ± 5.3
SF-36 (Emotional items)	49.3 ± 7.7	47.8 ± 9.6	49.7 ± 10.0	48.2 ± 8.2	47.8 ± 7.9
SF-36 (Physical items)	48.4 ± 9.2	51.0 ± 7.8	48.6 ± 6.4	50.6 ± 6.7	48.9 ± 7.9
Six months values					
Visual Sleepiness Scale (cm)	75.1 ± 14.4	67.8 ± 22.6	75.6 ± 17.1	64.5 ± 14.3	74.6 ± 20.4
ESS	5.9 ± 5.1	6.5 ± 4.1	5.2 ± 4.1	7.2 ± 4.0	7.5 ± 5.7
SF-36 (Emotional items)	47.3 ± 8.7	46.0 ± 12.9	46.2 ± 13.3	50.8 ± 7.1	42.5 ± 10.5
SF-36 (Physical items)	47.5 ± 9.0	50.5 ± 7.7	47.8 ± 8.7	48.9 ± 6.3	48.8 ± 7.7

ESS, Epworth Sleepiness Scale; SF-36, 36-Item Short-Form Health Survey questionnaire. These results were analysed taking into account patients who were evaluable at six months.

Table 3
Polysomnographic characteristics recorded during initial titration and at six-month control

	Group1 $n = 14$	Group 2 $n = 13$	Group 3 $n = 15$	Group 4 $n = 12$	Group 5 $n = 11$
Titration polysomnography					
AHI (/h)	5.7 ± 6.0	4.4 ± 3.7	5.9 ± 5.5	5.7 ± 4.1	8.5 ± 5.7
TST (min)	362.5 ± 93.4	326.8 ± 85.7	348.1 ± 95.3	351.6 ± 66.6	375.9 ± 64.7
Stage 1–2 (%)	61.9 ± 9.0	54.8 ± 17.3	47.9 ± 20.5	60.3 ± 16.7	61.4 ± 8.9
Stage 3–4 (%)	17.1 ± 7.0	23.5 ± 15.0	25.5 ± 14.7	17.5 ± 10.9	19.2 ± 11.0
REM (%)	19.1 ± 5.9	20.3 ± 8.4	18.9 ± 6.6	19.6 ± 9.8	16.9 ± 6.7
AwSaO$_2$ (%)	96.1 ± 2.3	95.7 ± 2.8	96.1 ± 2.2	96.3 ± 2.6	95.5 ± 2.5
Mean SaO$_2$ (%)	93.6 ± 2.1	93.5 ± 2.1	93.2 ± 1.9	95.0 ± 1.7	93.6 ± 1.9
Min SaO$_2$ (%)	82.3 ± 9.9	82.7 ± 11.1	82.1 ± 12.8	90.3 ± 1.7	84.5 ± 6.2
SaO$_2$ 90 (%)	5.6 ± 10.4	5.8 ± 14.0	2.8 ± 4.9	0	4.9 ± 10.8
Six months polysomnography					
AHI (/h)	2.4 ± 3.4	3.7 ± 3.9	2.3 ± 2.9	8.6 ± 10.0	8.5 ± 9.7
TST (min)	376.6 ± 50.9	382.7 ± 94.7	370.5 ± 65.2	377.4 ± 65.9	356.1 ± 43.9
Stage 1–2 (%)	59.4 ± 10.9	55.6 ± 11.7	59.6 ± 15.3	63.1 ± 12.3	61.1 ± 13.3
Stage 3–4 (%)	17.9 ± 9.3	21.0 ± 9.2	21.1 ± 13.0	14.9 ± 9.5	18.4 ± 12.8
REM (%)	19.6 ± 4.4	19.8 ± 7.6	16.5 ± 7.7	18.0 ± 4.7	16.6 ± 7.5
AwSaO$_2$ (%)	$96 0 \pm 2.3$	96.5 ± 2.1	95.9 ± 2.2	96.3 ± 2.9	95.9 ± 2.6
Mean SaO$_2$ (%)	94.0 ± 1.8	95.0 ± 1.5	94.2 ± 1.5	94.6 ± 2.0	94.3 ± 1.8
Min SaO$_2$ (%)	88.6 ± 3.4	90.1 ± 4.4	88.6 ± 4.9	85.0 ± 9.4	86.2 ± 4.6
SaO$_2$ 90 (%)	2.2 ± 7.7	0.3 ± 0.6	0.3 ± 0.6	3.0 ± 5.3	1.1 ± 2.0

AHI, apnea/hypopnea index; TST, total sleep time; Stage 1–2, light sleep; Stage 3–4, deep sleep; REM, rapid eye movement sleep; SaO$_2$, arterial oxyhaemoglobin saturation; AwSaO$_2$, awake SaO$_2$; Mean SaO$_2$, mean SaO$_2$ during the night; Min SaO$_2$, minimal SaO$_2$ during the night; SaO$_2$ 90, percentage of total recording time spent below 90% SaO$_2$. These results were analysed taking into account patients who were evaluable at six months.

increasing heterogeneity between groups from the beginning to the end of the study. Moreover, we observed increasing P_{mean} values over the study period in some patients, and, in contrast, important decrease in others, independently of the type of autoCPAP used, except for group 5 in which no patient demonstrated any increase in P_{mean} throughout the study.

Initially, patients in all groups had marked daytime sleepiness according to the ESS as well as visual analogue scale values, without any difference between groups (Table 2). We found a significant and identical improvement in these two parameters in all groups at three and six months. However, despite some significant improvement in some SF-36 domains under CPAP, with much heterogeneity between groups, the analysis of emotional and physical scores did not show significant improvement between initial and final evaluation in any of the groups.

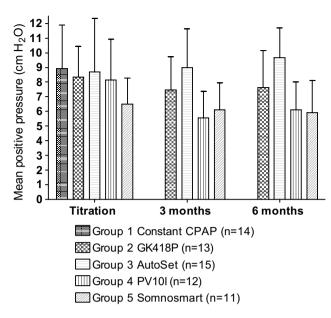Evaluation of CPAP use demonstrated good compliance in all groups (Table 4), at three and six months,

Fig. 1. Mean positive pressure variations in each groups between initial titration, three- and six-month controls.

with mean values greater than 5 h per night and without any significant difference between groups.

4. Discussion

We have shown that auto-adjust CPAP devices can be used at home for the long-term treatment of SAHS and are as effective as fixed-pressure devices regarding improvement in sleepiness when evaluated by ESS, and also regarding levels of compliance with treatment up to six months after CPAP initiation. Furthermore, we demonstrated that PSG outcome was similar in all groups, according to persistent significant improvement in sleep architecture and normalisation of AHI after six months of home CPAP treatment. The lack of significant difference in AHI should be interpreted with regard to statistical power. The statistical power of the study design was calculated to detect a clinically relevant (>10/h) difference in AHI whereas observed differences ranged between 0 and 6/h. We feel that six months is a sufficiently long period to see consistent effects, as compliance patterns seem to be set in the first few weeks of CPAP treatment [19].

The compliance rate in this study is relatively high at 5 h or more per night. This has already been noted in other French studies, particularly from the ANTADIR network, at close to 5 h per night [19]. Furthermore, follow-up was identical in each group so that this could not explain potential inter-group differences in terms of compliance. The study contained predominantly male patients and a few females. The randomisation ensured that there were similar numbers of women in each group. It would be interesting to do subgroup comparisons, but the numbers would be too small; further studies are needed. Patients who dropped out of the study were followed up clinically, but it would be impossible to include patients not using CPAP in the follow-up PSG studies. The number of dropouts is important as this may reflect the comfort and effectiveness of different machines. Patients may not always stop using CPAP for technical reasons alone. Mean pressure may have changed in the fixed pressure group because of dropout patients.

We have shown that all the autoCPAP devices reduced the level of sleep-related breathing disorder to the same degree. We did not evaluate upper airway resistance but found a reduction in mean AHI from around 50/h to less than 10/h, with similar clinical improvement in all groups. The visual sleepiness score improved from 45% to 70% for all groups and the SF-36 improved to a similar degree in all groups. Thus, there were no clinical differences between machine effects. There were some outlying results on some machines which would suggest that perhaps different autoCPAP machines with different algorithms may be suited to different patients according to their circumstances. Further in-depth studies examining machines in relation to their algorithm are needed.

Improvements on the SF-36 with CPAP have been shown after one month and three months of treatment. Furthermore, we have shown similar degrees of improvement in SF-36 scores between time zero and six months in all groups, which confirms that we are unlikely to have missed a difference in improvement in QOL between machines because of type beta statistical error.

We have excluded a clinically significant difference between devices but have not demonstrated a strict equivalence between machines. It was not the aim of

Table 4
CPAP compliance in each group at three- and six-month controls

	Group1 $n = 14$	Group 2 $n = 13$	Group 3 $n = 15$	Group 4 $n = 12$	Group 5 $n = 11$
Three months values					
CPAP time counter (h)	6.1 ± 1.1	5.5 ± 1.1	6.0 ± 1.5	5.5 ± 1.7	7.0 ± 1.8
Six months values					
CPAP time counter (h)	6.5 ± 1.8	5.5 ± 1.4	6.1 ± 1.6	5.1 ± 1.6	7.0 ± 1.9

These results were analysed taking into account patients who were evaluable at six months.

our study to determine which autoCPAP was the most effective in eliminating sleep-related respiratory events. Bench studies have suggested differences in performance of several commercial devices in conditions of simulated upper airway occlusion [20]. We wished to evaluate the clinical efficacy of each autoCPAP device compared to that of a constant device on the basis of clinical improvement as well as changes in PSG parameters. Our results show that the changes in mean pressure were quite variable from one patient to another and from one apparatus to another, probably related to the different algorithms used to drive the positive pressure delivered by the different autoCPAP.

These differences could indicate specific alternative machines for a given patient in case of intolerance towards a specific autoCPAP. The importance of our study is to demonstrate that, even if pressure changes vary from one apparatus to another, these different devices remain effective, even over the long term. While the baseline clinical and PSG data in dropouts were similar to data in the patients continuing treatment, the fact that the fixed CPAP pressure dropped over the duration of the study might indicate that patients requiring higher pressures were more likely to drop out. However, some studies have shown that fixed pressure diminished with time perhaps because of local airway changes. Our study demonstrates the importance of multicentre clinical studies in addition to theoretical analysis of algorithms and bench studies, since subsequent to this study the manufacturers of some devices have made evolutionary changes to their autoCPAP machines.

This study was carried out in 2002, on up-to-date machines as described in the Appendix. Naturally, there have been subsequent evolutions of equipment, but the fundamental algorithms remain. New adjustments to software are perpetual as industry reacts quickly to clinical studies.

AutoCPAP was developed in order to allow variations of the positive pressure according to patients' conditions. It was suggested that such devices could lead to a reduction in mean pressure during the night, resulting in a significant increase in CPAP tolerance and compliance. The theoretical advantages of the auto-adjust devices are the possibility of modulating the pressure with changing circumstances for the patient, such as a head cold or alcohol consumption. Theoretically, lower pressure may yield lower leaks around the mask and greater comfort, although few studies have addressed this question.

Few studies have been performed on the regular therapeutic use of CPAP in auto-adjust mode. Initial studies were performed during a single night of PSG or during a short timeframe at home [4–12]. Some studies evaluated clinical outcome without PSG control of the effectiveness of auto-adjust devices while in use in the home environment [6]. Those studies found results comparable to conventional CPAP devices but showed mostly a reduction in the mean pressure level required.

Although most of studies have demonstrated the absence of improvement in CPAP compliance when using autoCPAP, we previously found a significant improvement in wear time compared to constant CPAP during a trial in the home environment lasting three weeks [4]. Hudgel et al. showed similar results associated with a better tolerance of autoCPAP in a 12-week randomized study involving 33 apnoeic patients [21]. Another recent study compared conventional and auto-adjust CPAP therapy in 50 severe SAHS patients in a single-blinded fashion and demonstrated an identical PSG effect with better compliance in terms of nights per week of mask application [22]. More recent comparative studies on home CPAP use failed to find any improvement in CPAP compliance with auto-adjust devices but found that autoCPAP was associated with better subjective ratings for sleepiness and CPAP comfort [8,23,24]. Furthermore, Massie et al. showed that autoCPAP resulted in better QOL than with conventional CPAP when mean positive pressure was elevated [23]. Only the Autoset has been submitted to a trial at home over an eight-month period [13]. However, in that study, CPAP was used in constant pressure mode, after an automatic titration of the effective pressure by the Autoset.

Nolan et al. [25] compared three different auto-adjustable continuous positive airway pressure (APAP) devices in 27 patients who had already been treated for a median of 53 months in a randomised crossover trial of four weeks' duration with each machine. These patients had severe OSAS with a median AHI of 48/h. Fifty-two percent of patients preferred the APAP device to their fixed CPAP. This is to be expected as the equipment was presented as a ''newer machine''. In this study there was no improvement in compliance as would be expected in severe OSAS patients already treated for over three years. With one machine there was a reduced compliance related to a lower pressure profile, pressure discomfort and poorer sleep quality. It would be interesting to see the raw data for the SF-36 because, as the authors state, the awaited improvement in QOL had already been achieved with fixed CPAP. Our study is different in that we studied treatment-naive patients of a similar degree of severity of OSAS and different machines were tested on different subjects. As the authors state, prior treatment may make interpretation difficult for clinical decisions in newly diagnosed patients since these subjects were familiar with and already compliant to the treatment and local airway changes may have already subsided with CPAP therapy. This is an important difference between the studies, and Nolan et al. rightly conclude that routine switching from CPAP to autoCPAP cannot be recommended.

A recent meta-analysis of published randomized trials comparing autoCPAP with conventional constant CPAP confirmed the same effectiveness of both types of CPAP in reducing the AHI and improving subjective sleepiness [26]. The use of autoCPAP reduced the mean applied pressure by 2.2 cm H_2O in comparison to constant CPAP. However, the authors failed to find any difference in terms of CPAP adherence between the two modes of treatment. Nevertheless, the interpretation of these results must take into account the great variability in length of follow-up as well as the different models of autoCPAP used from one study to another. The only study directly comparing the effectiveness of two different autoCPAP devices (Devilbiss AutoAdjust LT and AutoSet T) demonstrated that both devices were equally effective as fixed-pressure CPAP in improving major outcomes during short-term therapy (1month) for sleep apnea [27].

Our study is the first to prospectively compare multiple auto-adjust and constant CPAP devices in a long-term protocol based on a large population naive to CPAP. As in most of the shorter term studies, our results confirm the efficacy of automatic devices compared to constant CPAP. However, the originality of this study is to illustrate this effectiveness using several comparative criteria such as CPAP compliance, daytime vigilance, QOL and polysomnographic data, despite variations in the modulation of positive pressure level from one autoCPAP to another. This study does not address the question as to whether autoCPAP should be systematically used in first intention when initiating treatment of SAHS, but these results point out the safety of long-term use of such devices. Some recent observations have suggested specific conditions where autoCPAP may be better adapted for SAHS treatment than constant CPAP. Massie et al. demonstrated that patients who required a higher level of pressure when using constant CPAP used auto-titrating CPAP more and reported greater benefit from this therapy [26]. Noseda et al. found that patients with high within-night variability in pressure requirement could benefit more favourably from autoCPAP with increased comfort and improved in daytime sleepiness [27]. It could be suggested that autoCPAP may be indicated in a subset of SAHS patients with nocturnal breathing abnormalities dependent on sleep stage and body position [28]. At least, it could be suggested that autoCPAP might be used in non-compliant patients, though there is no controlled study to confirm such a hypothesis.

In conclusion, fixed CPAP is as effective as autoCPAP for long-term home treatment in severe SAHS without any difference in terms of CPAP compliance.

Appendix A.

In autoCPAP groups, the versions of apparatus and default settings were as follows:

Group 2: GK 418 P, 3.1 version; Tyco healthcare – France.

This model had the same software as the recent 420 E 3.6 silverlining. Default setting: When mean pressure during polysomnographic titration was $\leqslant 10$ cm H_2O, upper limit was 14 cm H_2O, and minimal limit was 4 cm H_2O. When mean pressure during polysomnographic titration was >10 cm H_2O, then upper limit was fixed at 18 cm H_2O, without any change in minimal pressure level.

Group 3: AutoSet Spirit, 302 version; ResMed – France.

The software used in this model did not have any difference from the recent 312 version in terms of the "Advantage" algorithm. Default setting: upper level pressure: 18 cm H_2O; lower pressure limit: 4 cm H_2O.

Group 4: PV 10I, firmware 0.92 version; Breas – France.

Default setting: upper level pressure: 18 cm H_2O; lower pressure limit: 4 cm H_2O.

Group 5: Somnosmart 1, 2.02 version, Weinmann – France.

Default setting: Upper level pressure: 18 cm H_2O; lower pressure limit: 4 cm H_2O.

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