

CPAP titration by an auto-CPAP device based on snoring detection: a clinical trial and economic considerations

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ABSTRACT: This study aimed to assess the ability of an auto-nasal continuous positive airway pressure (nCPAP) device (REM + auto; NPBF, Nancy, France) to predict the optimal constant nCPAP level.

The apnoea/hypopnoea detection facility of the auto-nCPAP device was deliberately disabled and nasal mask pressure vibration detection was the only mode of pressure setting. The auto-nCPAP device was tested on 10 previously untreated patients with obstructive sleep apnoea during a single night, with ambulatory polysomnography performed in a conventional hospital room; the efficacy of the fixed pressure determined by the auto-nCPAP device was assessed by an ambulatory full polysomnography 2 weeks after the initiation of treatment at home.

The fixed nCPAP pressure was effective (apnoea/hypopnoea and arousal indices <10 events·h⁻¹) in all but two of the 10 patients studied. When the fixed nCPAP pressure was increased by 2 cmH₂O in these two patients, sleep and respiration were normalized.

Since only 12 ambulatory polysomnographic recordings were used to determine the effective nasal continuous positive airway pressure level, and as the device restored normal breathing and sleep in all 10 patients, it was concluded that this method of nasal continuous positive airway pressure titration may improve cost-effectiveness and reduce waiting lists in sleep laboratories.

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Nasal continuous positive airway pressure (nCPAP), a concept introduced in 1981 by SULLIVAN *et al.* [1], has considerably improved the treatment of patients with obstructive sleep apnoea syndrome (OSAS). In practice, the optimal nCPAP level is a trade-off between pressure-related side-effects and effective prevention of upper airway obstruction during sleep [2]. This optimal level is generally determined by two conventional in-laboratory polysomnographic recordings: one to determine the effective nCPAP level and one to verify that this nCPAP level restores normal breathing and normal sleep [2]. This is a costly approach, however, and creates long waiting lists. With the aim of improving these two aspects, some investigators have recently proposed a sophisticated new device for nCPAP titration (AutoSet; ResMed Sydney, Australia) which can automatically detect respiratory events (apnoea and hypopnoea), flow limitation and pressure vibration at the mask level, and can therefore continuously maintain pressure at above the level that prevents abnormal breathing causing arousals [3–5]. However, this device may be harmful during leakage and mouth breathing, as both may interfere with the autotitration algorithms and therefore induce an adverse increase in pressure. This may necessitate the intervention of a technician in the sleep laboratory [3–5].

It was recently observed that a simple auto-nCPAP based on snoring detection alone can be effective in the majority of OSAS patients (rapid eye movement (REM) + auto; SEFAM, Nancy, France) [6] and that this device induced no adverse increases in pressure. For these reasons nCPAP titration may be possible with this device, without the need for a sleep laboratory and/or polysomnographic technician. However, as this device may fail to respond consistently to flow limitation in the absence of snoring, the pressure obtained may be suboptimal.

The purpose of this study was to determine the efficacy of nCPAP titration with an auto-nCPAP system based on detection of snoring in a conventional hospital room. The efficacy of a fixed pressure determined by the auto-nCPAP device was assessed by means of ambulatory polysomnography 2 weeks after initiating nCPAP treatment at the same fixed pressure.

Materials and methods

Patients

This study was approved by the ethics committee of the authors' institution. Patients in whom snoring was permanent or quasi-permanent as described previously [6] and

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clinical signs of OSAS were confirmed by full polysomnography with an ambulatory recorder (Mini-Somno; NPBFD, Nancy, France), including electroencephalography (EEG) (C4-A1, C3-A2), electro-oculography, chin electromyography, position, oronasal thermistors, thoracic and abdominal movements and arterial pulse oximetry were enrolled. Patients with heart failure, cerebrovascular disease or lung disease (reference spirometry values determined by the European Community) were excluded. Criteria for inclusion were: 1) an apnoea-hypopnoea index (AHI) >30 events·h⁻¹ of sleep, with obstructive events exceeding 80% of total events; and 2) clinical indication for nCPAP as described by the American Thoracic Society (ATS) [2].

Pressure-setting algorithm of the device

Snoring detection was based on the occurrence of mask pressure vibration. Mask pressure was measured using a high-frequency response pressure transducer placed inside the nCPAP device (REM + auto; NPBFD, Nancy, France). The pressure signal was band-pass filtered (30–280 Hz) and its amplitude analysed using an automatic threshold system to identify amplitude variations as snoring. The mask pressure was increased by 1 cmH₂O if two consecutive snoring breaths were detected. The algorithm of snoring detection was then disabled for 1 min. In contrast, when no vibrations were detected, mask pressure was reduced by 1 cmH₂O every 10 min. Thus, snoring was the only criterion used in this auto-nCPAP device to increase or decrease CPAP pressure.

Clinical trial

All patients underwent overnight nCPAP titration in a conventional hospital room with the auto-nCPAP. To obtain the minimum fixed pressure required to prevent upper airway narrowing, the clinician (M. Berkani) only received data from the software of the auto-nCPAP device. The initial nCPAP was always set at the minimal level, *i.e.* 4 cmH₂O. The algorithm allowed nCPAP pressure to increase up to a maximum of 14 cmH₂O. If the maximum pressure of 14 cmH₂O was attained and snoring was still detected by the auto-nCPAP device under this level of pressure, a second titration was performed with a maximum level of nCPAP set to 16 cmH₂O. The highest pressure obtained during titration was therefore considered as the minimum fixed pressure required to prevent upper airway narrowing. All patients started nCPAP treatment with this fixed pressure for 2 weeks and then underwent, in a conventional hospital room, another ambulatory full polysomnography to determine the efficacy of this fixed-pressure device, *i.e.* constant nCPAP treatment.

Polysomnography during nCPAP treatment was based on an ambulatory recorder (Mini-Somno; SEFAM, Nancy, France), including EEG (C4-A1, C3-A2), electro-oculography, chin electromyography, nasal airflow measured by a pneumotachograph connected to a differential pressure transducer, thoracic and abdominal movements, arterial pulse oximetry, posture detected by a mercury tilt switch and nasal mask pressure measured by a differential pressure transducer.

Data analysis

Sleep was staged according to standard criteria [7]. EEG arousals were detected by an abrupt shift in EEG frequency lasting <15 s and including α -activity and/or frequencies >16 Hz (except spindles) and were scored according to standard criteria [8]. α -Activity lasting for >15 s was considered to indicate awakening. An abnormal breathing event during sleep was defined, according to commonly used clinical criteria, as either complete cessation of airflow lasting for at least 10 s (apnoea) or at least a 50% decrease in airflow compared with the previous breath, lasting for at least 10 s (hypopnoea). Abnormal breathing events were classified as obstructive or central according to whether respiratory effort continued or matched the flow reduction. The average number of apnoeas and hypopnoeas·h⁻¹ of sleep (AHI) was calculated from the sum of sleep-disordered breathing events. nCPAP was considered effective in preventing the sleep apnoea syndrome when: 1) AHI was reduced by $>50\%$, and 2) both AHI and arousal awakening indices were less than the normal values used in our laboratory [9], *i.e.* <10 events·h⁻¹ of sleep.

Statistical analysis

Results of baseline polysomnography and polysomnography during constant nCPAP treatment were compared using paired t-tests. The level of significance was set at 5%. Results are given as means \pm SD.

Results

During 1996 the pulmonary department of Créteil hospital studied 86 patients who underwent ambulatory polysomnography. Twenty-two of these patients fulfilled the ATS clinical indications for nCPAP, all of whom were permanent or quasi-permanent snorers as described previously [6]. Therefore, no patient was excluded by the absence of snoring. Only 10 patients agreed to participate. The remaining 12 patients who did not participate did not differ from the study population in terms of age (53 ± 11 versus 54 ± 6 yrs), body mass index (BMI; 31 ± 5 versus 32 ± 4 kg·m⁻²), Epworth sleepiness scale [10] (14 ± 3 versus 15 ± 5) or AHI (52 ± 10 versus 55 ± 16 events·h⁻¹).

All of the study patients were permanent or near-permanent heavy snorers, who disturbed other family members even though they slept in a separate room [6]. None of the patients had received nCPAP before this study. No sedatives, hypnotics or alcohol were taken by the patients prior to either study. The physical and respiratory characteristics of these 10 patients are listed in table 1. All of the patients used the nCPAP device during the 2 weeks before polysomnography with constant nCPAP treatment, for an average of 5.8 ± 1.8 h daily.

The mean minimum fixed pressure set by the auto-nCPAP device to prevent snoring was 10.5 ± 2.2 (range 7–13) cmH₂O. The main sleep and respiratory parameters obtained at baseline and during constant nCPAP treatment are shown in table 2. Constant nCPAP treatment was effective in eight of the 10 patients, based on decreases in both respiratory event and arousal plus awakening indices (fig. 1). Interestingly, the minimum fixed pressure set by

Table 1. – Characteristics of the 10 patients with obstructive sleep apnoea syndrome

Patients No.	Age yrs	BMI kg·m ⁻²	ESS	AHI events·h ⁻¹	P _a O ₂ mmHg	P _a CO ₂ mmHg	TLC % pred	VC % pred	FEV ₁ % pred	MFP-nCPAP cmH ₂ O
1	55	30	13	38	71	42	68	82	89	8
2	58	26	22	57	84	42	93	99	97	13*
3	52	32	17	71	71	40	87	90	97	12
4	53	36	13	63	82	37	97	92	87	10
5	42	39	15	85	73	38	110	78	78	13
6	61	35	13	48	84	36	87	97	87	9*
7	63	32	12	39	86	43	75	75	64	13
8	55	30	11	47	86	39	113	115	118	11
9	48	31	16	37	95	40	74	83	81	9
10	56	33	15	63	91	38	89	101	81	7
Mean	54	32	15	55	82	32	89	91	88	10
SD	6	4	3	16	8	2	15	12	14	2

BMI: body mass index; ESS: Epworth sleepiness scale; AHI: apnoea/hypopnoea index; P_aO₂: arterial oxygen tension; P_aCO₂: arterial carbon dioxide tension; TLC: total lung capacity; VC: vital capacity; FEV₁: forced expiratory volume in one second; % pred: percentage of predicted value (predicted values were those of the European Community [11]); MFP-nCPAP: minimum fixed pressure set by the auto-nasal continuous positive airway pressure device. *: the two patients for whom MFP-nCPAP was suboptimal. (1 mmHg = 0.133 kPa).

the auto-nCPAP device was insufficient in one patient who had had laryngectomy for laryngeal carcinoma and in one patient who had had uvulo-palato-pharyngoplasty before being referred to our department. Despite a suboptimal nCPAP level in these two patients, sleep fragmentation and AHI were substantially improved by constant nCPAP treatment. Constant nCPAP pressure was then increased by 2 cmH₂O in both cases and another ambulatory polysomnography showed that both AHI and arousal awakening indices were normalized (fig. 1). Finally, a control polysomnographic recording was performed in each patient, which confirmed the efficiency of the nCPAP treatment.

Discussion

Ideally, the nCPAP level required for the treatment of OSAS is determined by two sequential night studies, including one polysomnography performed in the laboratory with the intervention of a technician to determine the effective nCPAP level, and one control polysomnography to check that the chosen nCPAP level restores normal breathing and sleep [2]. However, this approach consumes

considerable financial and laboratory resources. This study suggests that the use of an auto-nCPAP device in a conventional hospital room without the intervention of a technician can determine the effective nCPAP level in 80% of patients, and that the effectiveness of this nCPAP level can be checked by ambulatory polysomnography. Therefore, the initiation of nCPAP treatment may be performed in a conventional pulmonary department without sleep laboratory intervention in the majority of patients. In addition, only 12 ambulatory polysomnography recordings were used to adapt nCPAP in the 10 OSAS patients. Compared to the procedure in the sleep laboratory, this method saved eight polysomnography procedures and replaced two laboratory polysomnography recordings by two ambulatory polysomnography recordings. This method can therefore be considered to be convenient and cost-effective.

Over the past few years several alternative methods have been proposed to improve cost-effectiveness and to reduce waiting lists in sleep laboratories. One such method is a single split-night study for the diagnosis of OSAS and nCPAP titration [12–14]. However, SANDERS *et al.* [12] observed that a substantial proportion of patients (45%) still required a subsequent change in prescribed nCPAP pressure. Therefore, incorrect treatment prescription may

Table 2. – Sleep and respiratory data

	Baseline	Constant nCPAP treatment	p-value
Sleep-onset latency min	24±19	33±45	NS
Stage 4 latency min	372±178	68±38	<0.05
REM sleep latency min	178±144	83±48	<0.05
TST min	386±58	389±65	NS
Wake after sleep onset min	52±31	48±44	NS
Stage 1 min	29±12	18±13	<0.05
Stage 2 min	303±62	228±61	NS
Slow-wave sleep min	18±26	73±21	<0.05
REM min	36±29	69±32	<0.05
Arousal awakening index	47±14	8±3	<0.05
Apnoea index	25±12	2±2	<0.05
Apnoea/hypopnoea index	55±16	7±5	<0.05
Lowest S _a O ₂ %	56±25	81±11	<0.05
S _a O ₂ <90% % of TST	30±26	5±13	<0.05

Values are mean±SD (n=10). nCPAP: nasal continuous positive airway pressure; REM: rapid eye movement; S_aO₂: arterial oxygen saturation; TST: total sleep time.

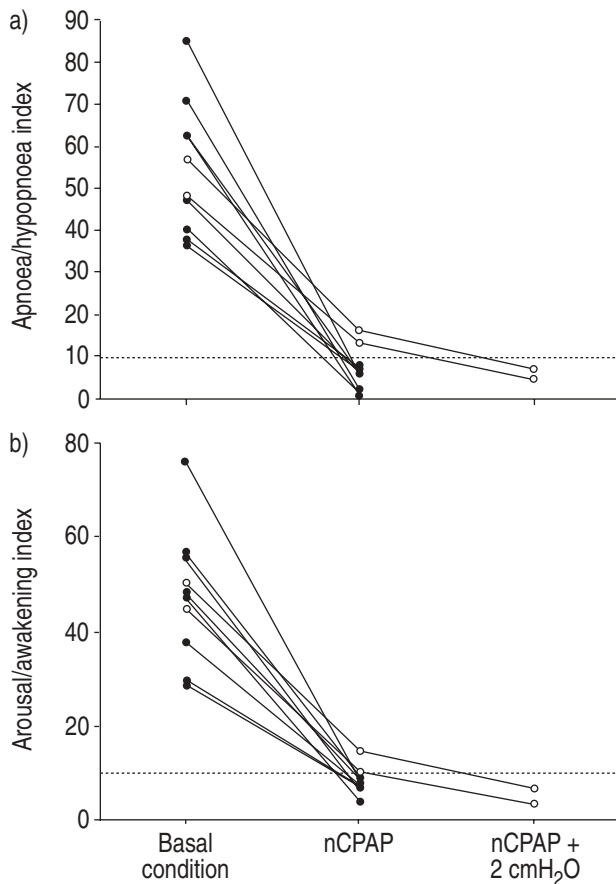


Fig. 1. – Effect of minimum fixed pressure set by the auto-nasal continuous positive airway pressure titration device (nCPAP) and of minimum fixed pressure set by the auto-nCPAP titration increased by 2 cmH₂O (nCPAP + 2 cmH₂O) on a) the apnoea/hypopnoea index and b) the arousal/awakening index. During nCPAP, both values decreased to the normal range (10·h⁻¹,) in all but two patients (●). An increase in nCPAP of 2 cmH₂O normalized sleep in these two patients (○).

result in nCPAP failure, more frequent outpatient visits with nCPAP problems and the need for further sleep studies, which reduce the short-term cost saving. COPPOLA and LAWEE [15] proposed an attractive approach for treating OSAS, in which they adjusted nCPAP pressure over several nights in the home setting on the basis of reports by both the patient and the bed partner. They confirmed the effectiveness of the pressure thus obtained by ambulatory recording of cardiorespiratory variables. However, because patients were selected in this study, this method may not be appropriate in every case. In addition, methodological criticisms of this nCPAP titration protocol [16] included the fact that nCPAP was adjusted in a somewhat arbitrary fashion based on subjective reporting of reduced snoring and daytime sleepiness, and the fact that sleep architecture and arousal frequency were unknown. Nevertheless, this retrospective study was the first formal report of nCPAP treatment outside a sleep laboratory.

Recently, "intelligent" nCPAP devices that self-adjust the required mask pressure level have been developed by several manufacturers. The most sophisticated device is the AutoSet clinical (AutoSet; ResMed, Sydney, Australia), which uses software running on a personal computer to detect apnoea or hypopnoea, snoring and flow limita-

tion [3–5]. The efficacy of this device in predicting the fixed nCPAP level has been demonstrated in two recent studies [4, 5]. Because healthy nonsnorers also have flow limitation [17], the AutoSet device is extremely sensitive and may consider breathing to be abnormal in a normal subject [4]. Consequently, the AutoSet device can increase nCPAP pressure promptly, before respiratory disturbances occur. However, the extreme sensitivity of this device may reduce its specificity. Investigators have observed that AutoSet increases pressure inappropriately when mask and/or mouth leaks reach 0.4 L·s⁻¹ [3–5]. In addition, despite the exclusion of periods of leakage and of highest pressure, TESCHLER *et al.* [4] observed that the fixed pressure determined by the AutoSet device was, on average, 1.3 cmH₂O higher than the optimal pressure determined by a technician [5]. For this reason, if nCPAP titration by the AutoSet is to be performed without polysomnography [5] it needs to be checked by a technician in the sleep laboratory [3–5]. Accordingly, TESCHLER *et al.* [4] reported that AutoSet titration required, on average, two technician interventions per patient.

In the present study, as the pressure-setting algorithm of REM + auto was only based on the detection of snoring (detection of apnoea/hypopnoea was disabled) and therefore, did not induce an adverse increase in nCPAP, no technician intervention was needed during the auto-nCPAP at night. This assertion relies on experience with this device in 37 patients, including 14 patients published recently [6], during polysomnography and during their first nCPAP night. A total of 543 increases in pressure was observed which were never unnecessary, *i.e.* an increase in pressure without detectable preceding snoring since, nCPAP should be raised to a level that eliminates snoring [2]. However, this auto-nCPAP is less sensitive than the AutoSet device, resulting in a suboptimal fixed pressure in two patients, both of whom had had upper airway surgery. This suggests that the REM + auto, which uses a band-pass filter of 30–280 Hz to detect snoring, may fail to detect snoring after upper airway surgery. However, all of the present patients showed a marked improvement in sleep quality and breathing abnormalities during treatment with this suboptimal CPAP level. In addition, because the required nCPAP pressure level gradually decreases with use [18], the suboptimal pressures obtained with this method may eventually become optimal. As proposed previously [2], the prescribed nCPAP pressure was routinely checked by ambulatory polysomnography and AHI and arousal indexes were found to normalize in all patients.

Minimal arterial oxygen saturation (S_{a,O_2}) during nCPAP was quite low (see table 2) and eight patients had a minimal $S_{a,O_2} < 90\%$. However, the time spent under 90% was <1% of the total sleep time in all patients, except for the two individuals in whom nCPAP was suboptimal.

In conclusion, the results of this study strongly suggest that nasal continuous positive airway pressure titration may be performed in a conventional pulmonary department, using an auto-device based on snoring detection, thereby obviating the need for polysomnography and/or sleep laboratory intervention. However, as usually proposed in sleep laboratories, the effectiveness of the fixed nasal continuous pressure determined by titration has to be checked by ambulatory polysomnography to detect possible suboptimal prescription. This method may improve cost-effectiveness and reduce waiting lists in sleep laboratories,

and/or facilitate the diagnosis and treatment of obstructive sleep apnoea syndrome in pulmonary departments without access to a sleep laboratory, provided an ambulatory polysomnograph is available.

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