

Acceptance and long-term compliance of nCPAP in obstructive sleep apnea

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Abstract In a retrospective cohort study, we evaluated whether improvements in nasal continuous positive airway pressure (nCPAP) technology, particularly the introduction of automatic adjustment of the nCPAP pressure (auto-CPAP), have led to better acceptance and (long-term) compliance in patients with obstructive sleep apnea syndrome (OSAS) as compared to earlier reported data. Questionnaires were sent to 256 patients, who were referred to our clinic for an overnight polysomnography from January 1997 to July 2005 and received nCPAP therapy for OSAS. Of the 256 patients, 24 patients were unavailable for follow-up. Of the remaining 232 patients, 58 patients (25%) had discontinued therapy, while 174 patients (75%) were

still using nCPAP after 2 months to 8 years of follow-up. One Hundred and thirty eight (79%) of these 174 patients used nCPAP for at least 4 h/night during ≥ 5 nights/week, 82,1% of the conventional nCPAP (fixed pressure CPAP) group ($n = 78$) and 77,1% of the auto-CPAP group ($n = 96$). Therefore, including the 58 failures, only 59.5% of patients can be seen as compliant. There were no statistical differences between the fixed pressure CPAP and auto-CPAP users, and between the compliant and non-compliant users according to age, BMI, AHI and Epworth sleepiness scale (ESS). Auto-CPAP patients used significantly more cm H₂O. The long-term compliance of nCPAP therapy has have increased only slightly since the introduction of the fixed pressure CPAP 25 years ago, in spite of many efforts to improve it. It seems that a plateau has been reached and that it is unrealistic to aim at a substantially higher compliance rate.

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Introduction

Obstructive sleep apnea syndrome (OSAS) is a clinically defined syndrome associating daytime hypersomnolence and one or more of the following symptoms: severe snoring, nocturnal respiratory arrest, repeated nocturnal awakening, non-recuperative sleep and altered concentration, due to repeated obstruction of the upper airway. An apnea-hypopnea index (AHI) of more than five, obtained by overnight polysomnography, accompanied by daytime symptoms is required for the diagnosis of sleep apnea syndrome. [1] An apnea is a period of complete cessation of oronasal airflow for a minimum of 10 s; periods of more than 30%

reduction in oronasal airflow, accompanied by a decrease of more than 4% in ongoing SaO_2 , are hypopneas.

The prevalence of obstructive sleep apnea in middle-aged people is 2% in women and 4% in men. [2] It has been estimated that at least 80% of all moderate and severe OSAS in the general population is likely to be missed. [3]

OSAS has adverse effects on daytime quality such as daytime sleepiness and diminished intellectual performance. OSAS is of growing significance because of its increasingly recognized high incidence and association with neurocognitive symptoms [4] and cardiovascular disease. [5] In severe OSAS, there is an increased risk to be involved in traffic accidents. [6, 7] Therefore OSAS is not only treated for its symptoms, but also with the aim to reduce associated morbidity and mortality.

In 1981, nasal continuous positive airway pressure (nCPAP), which acts as a pneumatic splint, was introduced as treatment of OSAS and has been considered the gold standard for treatment of severe OSAS since. [8] It is a safe therapeutic option with few contraindications or serious side effects. [9] Unfortunately many patients experience nCPAP therapy as obtrusive and the acceptance and (long-term) compliance of nCPAP are at the most moderate. A vast body of literature was published in the last two decades on the subject of (long-term) compliance of nCPAP. [10–23] Improvements in nCPAP technology, in particular the introduction of automatic adjustments of the nCPAP pressure throughout the night (auto-CPAP), [24–29] and other attempts to enhance acceptance and compliance (positive reinforcement, psychological/educational interventions, heated humidification) have been introduced. [30–34]

We were interested to see if these actions have led to better acceptance, adherence and long-term compliance as compared to earlier reported data. We acquired data on (long-term) compliance and therapy failure. In this paper, we report the results of this follow-up obtained by questionnaires, as well as the analysis of several parameters which can predict compliance.

Methods

All patients with OSAS, as defined previously, who were offered nCPAP between January 1997 and July 2005, were included in the study. Patients with an AHI >30 were offered nCPAP as first treatment. Patients with mild to moderate OSAS (AHI <30) were also offered alternative treatments such as an oral device or surgery.

Polysomnography

From 1997 until 2001, patients were monitored with a digital CNS-sleep I/T-8 recorder (CNS Inc, Chanhassen, MN,

USA) during one night at the hospital. Since 2001, polysomnography was done using a digital Embla recorder (Flaga Medical devices, Reykjavik, Iceland).

In both recorder types, polysomnography consisted of electroencephalogram (derivations: CNS-sleep I/T-8: O1-Cz; Embla: Fp2-C4/Fp1-C3), electrooculogram and submental electromyogram to record the sleep pattern. Thoracoabdominal excursions were registered by either airinflated straps (Nellcor PB; model 5702-x, in the CNS-sleep I/T-8), or by straps containing piezoelectric transducers (Embla). Pulse oximetry was used to monitor oxygen saturation (SaO_2) and heart rate. In addition ECG, movements of the limbs and the intensity of snoring were recorded. Nasal airflow was measured by a pressure sensor with the Embla recorder only.

Electrodes and sensors were placed and equipment was calibrated late in the afternoon. The system was switched on and off at 7.00 p.m. and 7.00 a.m. In case of the Embla recorder all signals were recorded with DDD (digital sampling, digital filtering, digital storage) recording technology. In both recorder types, storage was done on a PCMCIA flash card.

The following day, the data were downloaded to the computer and analyzed by dedicated sleep software (CNS: Sleep I/T software V1.70; Embla: Somnologica 2.0.2). In both cases, the data were manually reviewed by an experienced sleep investigator for final analysis.

nCPAP therapy

Following the initial positive sleep study, patients were again admitted to the hospital to titrate nCPAP therapy. During two nights in the hospital, the optimal fit of the nCPAP mask (silicone-based nose or full face masks and different intranasal systems) was determined and the optimal pressure of nCPAP therapy was established. From January 1997 until January 2002, the CPAP operating mode of the BiPAP S/T-D[®] (Respironics INC, Murrysville, Pennsylvania, USA) was used. The patient's optimal (fixed) level of continuous pressure (cm H_2O) was found by manual titration by an experienced EEG technician during a night session with polysomnography and video registration. Since October 2002, auto-CPAP (AutoSet[®] T, ResMed Limited, North Ride, Australia) was used exclusively. In between there was an overlap period in which both modalities were used.

A first notice of compliance to and problems with acceptance of nCPAP was gathered during the first two nights. Within 1 week after titration, the first evaluation took place on the pulmonary outpatient clinic. Thereafter a test period with nCPAP therapy in the home situation was started. After the test period of about 4–5 weeks, the second evaluation took place on the pulmonary department. The reports

of firms responsible for nCPAP delivery were examined as were the experiences of the patients, after which a definitive form of nCPAP therapy, mask and pressure was chosen. After 4 months a final appointment was made.

Questionnaires

All OSAS patients, who were offered nCPAP, received questionnaires including actual nCPAP usage, a visual analogue scale for satisfaction of the therapy (a scale from zero, not satisfied, to ten, very satisfied) and questions about symptoms such as daytime sleepiness with the help of the Epworth sleepiness scale (ESS). We defined compliance (or adherence) as minimally 4 h/night during five nights per week of nCPAP use. Failure was defined as a refusal beforehand, withdrawal almost directly after the eligibility tests without proper evaluation or failure to reduce the AHI with nCPAP during the tests.

Statistics

All continuous variables were checked for their distributional characteristics. Whenever feasible (i.e., reasonably normally distributed), mean and standard deviation were used as statistics. Differences at baseline and after intervention between fixed pressure and auto-CPAP were tested by means of a two-sample *t* test (based on a pooled standard deviation or a Satterthwaite approximation in case of unequal variances). Categorical variables were tested by means of a Chi-square test.

Results

From January 1997 to July 2005, 256 consecutive patients were diagnosed with OSAS and offered nCPAP therapy at our hospital. Twenty-four (9.4%) patients were lost to follow-up without any information available. Data could be retrieved from 232 (90.6%) patients through returned questionnaires. The follow-up period ranged from 2 months to 8 years. Fifty-eight (25%) of these 232 patients (30 patients had fixed pressure CPAP, 28 patients had auto-CPAP) failed to actually use the therapy. Five patients died before evaluation could be obtained.

Of the evaluable 174 patients who used nCPAP, 78 patients were offered fixed pressure CPAP and 96 patients auto-CPAP. There were 65 men (83.3%) and 13 women (16.7%) in the fixed pressure CPAP group and 75 men (78.1%) and 21 women (21.9%) in the auto-CPAP group. There was no difference in any of the baseline patient characteristics between fixed pressure CPAP and auto-CPAP users (Table 1). Auto-CPAP patients used significantly more cm H₂O ($P < 0.0001$).

Table 1 Baseline patient characteristics

	Type of CPAP		<i>P</i> value
	Fixed CPAP (<i>n</i> = 78)	Auto-CPAP (<i>n</i> = 96)	
Age	58.2 ± 11.5	55.4 ± 11.5	0.1111
BMI	33.0 ± 7.9	33.1 ± 7.0	0.9573
AHI	47.2 ± 22.3	52.0 ± 23.1	0.1814
ESS	5.6 ± 4.5	7.1 ± 5.1	0.0530

The outcome parameters comparing the two groups are shown in Table 2. No difference in the frequency of use of nCPAP in terms of nights/week and hours/night was observed between the two groups. Also in terms of patients' satisfaction, both methods were very similar. For four patients, the number of nights a week and/or the amount of time of nCPAP usage was unknown.

We defined compliance as use of nCPAP at least 4 h/night, ≥5 days/week. According to this definition, overall 138 (79%) of the 174 patients using nCPAP were compliant, 82.1% of the fixed pressure CPAP group and in 77.1% of the auto-CPAP group. Therefore, including the 58 failures, only 59.5% of patients can be seen as compliant. Except for satisfaction of nCPAP usage, no differences were observed between the patients who were compliant and the patients who were not (Table 3).

Discussion

OSAS represents a relatively new disease entity, and is currently the most dynamic area in Otolaryngology/Head and Neck Surgery, both with regard to diagnostic work-up and therapy.

Treatment of OSAS is dependant on the severity of the disease and starts primarily with lifestyle changes (weight

Table 2 Comparison of the use of fixed pressure CPAP and auto-CPAP in terms of nights/week and hours/night, as well according to patients' satisfaction (excluding failures)

Variable	F/A	N	Mean	SD	Min.	Max.	<i>T</i> test <i>p</i> value
Nights/week	F	76	6.4	1.4	2	7	0.5710
	A	96	6.3	1.4	1	7	
	Diff (1–2)		−0.1	1.4			
Hours/night	F	75	6.5	1.5	1.5	9	0.6411
	A	95	6.3	1.8	1	11	
	Diff (1–2)		−0.1	1.7			
Satisfaction	F	76	7.5	1.9	0	10	0.8762
	A	95	7.5	2.3	0	10	
	Diff (1–2)		−0.1	2.1			

F fixed pressure CPAP, *A* auto-CPAP

Table 3 Comparison of parameters between ‘compliant’ and ‘non-compliant’ (excluding failures)

Variable	C/NC	N	Mean	SD	Min	Max	<i>t</i> test <i>p</i> value
Age	C	138	56.9	11.6	27	86	0.4898
	NC	33	55.3	11.7	34	79	
	Diff (1–2)		–1.6	11.6			
BMI	C	138	32.9	7.2	21.9	75.8	0.3777
	NC	32	34.2	8.4	22.3	54.6	
	Diff (1–2)		1.3	7.4			
AHI	C	131	51	21.7	9.7	123	0.3974
	NC	31	47.1	27.3	5	98	
	Diff (1–2)		–3.9	22.9			
H ₂ O	C	137	8.9	2.4	3	15.5	0.6330
	NC	33	8.6	2.6	4	15	
	Diff (1–2)		–0.2	2.5			
ESS	C	136	6.1	4.9	0	23	0.1083
	NC	33	7.6	4.6	0	16	
	Diff (1–2)		1.5	4.9			
Satisfaction	C	137	8	1.7	1	10	<0.0001
	NC	33	5.7	2.6	0	10	
	Diff (1–2)		–2.2	1.9			

C compliant patients, NC non compliant patients, H₂O cm H₂O pressure

reduction, cessation of alcohol abuse, sleep hygiene), if indicated. When complaints persist after these, additional therapies are needed. These can be subdivided into conservative treatment (oral device or nCPAP), surgery (minimal invasive to invasive) or combination of both.

NCPAP has become the “gold standard” treatment of OSAS in the last decades. [35] In the pioneering phase of management of OSAS this view was understandable since uvulopalatopharyngoplasty (UPPP) was the almost exclusive surgical alternative for the treatment of OSAS and meta-analysis by Sher et al. in 1996 showed a success rate of UPPP (in unselected patients) of only 41% [36].

To be successful, nCPAP therapy in OSAS has to be accepted by the patient. Unfortunately, some patients simply refuse to use it upfront or later on, others try it but experience such serious problems such as nasal congestion and dryness, rhinorrhoea, dryness in the mouth, mask discomfort, claustrophobia, aerophagia, air leakage and irritation from device noise, that they have to give up. Other patients use nCPAP only several days a week, and/or only a limited number of hours per night sleep.

Various studies have analyzed compliance. However, the results are not always consistent, mainly because of the lack of common criteria. Furthermore, there are no precise recommendations available concerning the necessary duration of daily and weekly use. In our study 58 (25 %) of 232 patients with sufficient information available, never started

nCPAP at all or stopped treatment (early). The compliance, defined as nCPAP use for minimally 4 h during five nights per week, in the remaining 174 patients in our series, was 79% (82.1% for fixed pressure CPAP vs. 77.1% for auto-CPAP) as compared to earlier reported data, ranging from 46 to 89%. [10–23] Overall, only 59.5% of cases were successful, taking the non-compliant cases and the 58 (25%) failures together. Although it was to be expected that patients with a higher AHI and ESS and lower required pressure would be more compliant, no difference was found. Also age and BMI played no role of significance.

Patients with auto-CPAP used higher pressure levels than patients with fixed pressure CPAP. A reason for this statistical difference is that while titrating for fixed pressure CPAP with the auto-CPAP, the choice for the lowest pressure needed is often taken, because to minimize side effects too much pressure while not needed has to be avoided.

A limitation of our study is that the use of nCPAP in our series was estimated by the patient and not recorded by a clock-time counter, and it can therefore not be excluded that the actual use is even lower; discrepancies between subjective and objective duration and frequency of nCPAP use have been reported. [15] When looking back at 2 decades (1986–now) [10–23] of all reported series on nCPAP use, the conclusion is that in spite of many improvements in the machinery, adjustment, intensive support, and all attempts (positive reinforcement, psychological/educational interventions, heated humidification) to increase compliance otherwise, the overall compliance has only improved marginally, if at all.

Currently, we are witnessing an increasing awareness that an exciting new era in OSAS treatment is dawning. Besides the disappointing compliance rates, the use of nCPAP therapy does not change the anatomy of the upper airway and therefore patients remain dependant, lifelong. In particular for young patients, the prospect to use nCPAP lifelong is unattractive and with increasing frequency patients ask for surgical alternatives with acceptable success rates.

Also in the light of failure rates for nCPAP therapy, it is hard to maintain that nCPAP should always be preferred above other treatments. Success rates of UPPP in well-selected patients (obstruction on retro palatal level only) currently reach 70–80%, as compared to the low 40% in earlier meta-analyses in non-selected patients. [37,38] In patients with obstruction at the retrolingual level, comparable surgical success rates of hyoid suspension have been reported in well-selected patients. [39, 40] Many other surgical and non-surgical approaches are being explored as stand-alone therapy, or in combination. [41, 42] Therefore, a gradual shift can be expected to take place to alternatives to nCPAP, being a combination of surgery, lifestyle alterations and if possible positional therapy, [43, 44] in well-

selected, well-informed patients, while nCPAP therapy in those patients will still be in reserve in case of failure.

In conclusion, the long-term compliance of nCPAP therapy has increased only slightly since the introduction of nCPAP 25 years ago, in spite of many efforts to improve it. It seems that a plateau has been reached and that it is unrealistic to expect substantially higher compliance rates. The great challenge for the ENT-community is to accept the responsibility to endeavour to develop viable alternatives to nCPAP therapy, both for the high percentage of patients who are nCPAP failures as well as for primary treatment.

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