Use of Conventional and Self-Adjusting Nasal Continuous Positive Airway Pressure for Treatment of Severe Obstructive Sleep Apnea Syndrome*

A Comparative Study

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Study objectives: To compare conventional and self-adjusting nasal continuous positive airway pressure (nCPAP) therapy in patients with severe obstructive sleep apnea syndrome with respect to suppression of respiratory disturbances, quality of sleep, mean mask pressure, and patient compliance.

Design: Cohort study of consecutive patients with obstructive sleep apnea syndrome, single-blinded.

Setting: Clinical sleep laboratory in Germany.

Patients: Fifty patients (44 men, 6 women who ranged in age from 35 to 71 years) with polysomnographically confirmed severe obstructive sleep apnea syndrome (respiratory disturbance index [RDI], >20/h).

Measurements and interventions: After baseline polysomnography, patients were randomly treated with nCPAP either in conventional (group 1) or in automatically adjusting (group 2) mode. Three to 6 months after adjustment, all patients underwent polysomnography again. They also were examined with a portable monitoring device and received a questionnaire on subjective well-being and device evaluation.

Results: Anthropometric and respiratory data were comparable in both groups; body mass index had not changed significantly in the follow-up. RDI dropped by 91.5% (from 38.3±13.9/h to 3.6±4.4/h) in conventional and by 93.6% (from 35.5±9.6/h to 2.4±1.6/h) in self-adjusting mode (statistically not significant [NS]). Sleep efficiency decreased by 4.0% in conventional and increased by 2.0% in self-adjusting mode (NS). In both groups, normal sleep structure was largely restored. Mean mask pressure was 8.1±2.5 cm H_2O in group 1 and 6.5±1.7 cm H_2O in group 2 ($p<0.01$). Patient compliance in terms of nights per week of mask appliance was better in the self-adjusting mode (5.7±0.7 to 6.5±0.4; $p<0.01$).

Conclusion: Self-adjusting nCPAP demonstrates the same reliability in suppression of respiratory disturbances as fixed-mask pressure therapy. Sleep quality is slightly superior, patient compliance is highly significantly better. ***(CHEST 1998; 113:714-18)***

Key words: nCPAP pressure; nCPAP therapy, obstructive sleep apnea syndrome; self-adjusting nCPAP

Abbreviations: BMI=body mass index; nCPAP=nasal continuous positive airway pressure; RDI=respiratory disturbance index

Nasal continuous positive airway pressure (nCPAP) is the most effective treatment of severe obstructive sleep apnea syndrome.[1,2] It aims at completely suppressing the apneic and hypopneic episodes, the associated oxygen desaturations, and the arousals. Varying with sleep stages and body position, however, the required mask pressure does not remain constant throughout the night.[3,4]

Conventional nCPAP treatment, therefore, necessitates the selection of a sufficiently high pressure setting to ensure that respiratory disturbances are reliably inhibited in the least favorable situations. A needlessly high mask pressure, thus, has to be ac-

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Table 1—*Characteristics of Sample*

Factors	nCPAP Conventional	nCPAP Self-Adjusting
No. of patients	23	25
Age, yr	53.5±11.0	55.4±7.8
BMI, kg/m^2	32.5±4.3	31.7±10.4
RDI/h	38.3±13.9	35.5±9.6
Mean apnea duration, s	23.4±4.7	22.5±5.3
Maximal apnea duration, s	75.8±56.7	78.8±22.3
Minimal SaO_2, %	74.5±10.7	76.5±12.4
Mean SaO_2, %	91.9±2.6	90.5±2.6

cepted for other sleep phases. Because of hemodynamic factors as well as because of a lower incidence of side effects and patient discomfort, the lowest possible nCPAP pressure is to be preferred.[5-7]

Some recently available devices (Horizon; DeVilbiss; Langen, Germany) offer the option to automatically adjust mask pressure to the lowest effective mask pressure according to the varying requirements during the night.[5,8,9] The aim of this study was to compare conventional and self-adjusting nCPAP therapy with respect to suppression of respiratory disturbances, quality of sleep, patient compliance, and subjective patient comfort.

Methods

Fifty consecutive patients (44 men and 6 women who ranged in age from 35 to 71 years) were prospectively studied. Inclusion criteria were severe obstructive sleep apnea syndrome (respiratory disturbance index [RDI], >20/h in combination with typical clinical features), acceptance of nCPAP therapy, and agreement to the study protocol. Patients were randomly assigned to receive either automatically adjusting or conventional nCPAP. In order to avoid product-specific differences, such as design, noise level, or flow, both groups were treated with the automatically adjusting Horizon nCPAP device, which permits ventilation in both modes. As a consequence, the design of the study was single-blinded.

In both groups the devices were adjusted in the sleep laboratory in one or two nights. In both groups, the Respironic (Murrysville, Pa) mask was used. The optimum size was determined individually before treatment. Polysomnography was performed according to previously published recommendations.[10] In the conventional mode, nCPAP titration was started at 4 cm H_2O and increased until abolition of all apneas and arousals. If this necessitated a pressure greater than 14 cm H_2O, patients were excluded from the study and bilevel positive airway pressure therapy was initiated. The self-adjusting nCPAP permits both continuous monitoring of airway pressure, oscillations and flow and incremental adjustments of airway pressure to prevent obstructive breathing. The default setting for this automated adjustable device defined a flow reduction of 85% for at least 10 s as apnea and a flow reduction of 50% for at least 10 s as hypopnea. Minimal and maximal pressures as well as pressure increase and decrease can be programmed. The minimal pressure in this study was kept at 5 cm H_2O, and the pressure range was 4 to 14 cm H_2O in order to avoid hemodynamic side effects possibly associated with a pressure greater than 14 cm H_2O.[11] If the patients were not well treated within these pressure limits, they were excluded from the study.

Polysomnographic follow-up took place 3 to 6 months after initial adjustment. The patients also were examined with a portable screening device adjusted to the nCPAP device (Surveyor; DeVilbiss), recording respiratory data (oxygen saturation, flow, breathing efforts, snoring, pulse) as well as nasal mask pressures.

With each examination, polysomnography was scored manually for the following parameters: RDI, mean apnea duration, maximum apnea duration, minimum and mean arterial oxygen saturation (SaO_2) values, time during sleep with an SaO_2 value greater than 90%, sleep efficiency (relationship between total sleep time and total time in bed), arousal index, and percentage of sleep stages 1 and 2, 3 and 4, and rapid eye movement sleep. Follow-up examinations further included evaluation of mean mask pressure and compliance (mean number of hours per night with nCPAP in use; and nights per week during follow-up with nCPAP application for more than 4 h). These data were downloaded from the portable screening device.

Results are given as means with 1 SD. The results were analyzed using two-way analysis of variance with Scheffe's test as a post-hoc test. A probability value less than 0.05 was defined as significant.

Results

Forty-eight of the 50 patients concluded the study; the two dropouts could not tolerate the treatment.

Table 2—*Changes in BMI and Respiratory Factors*

	nCPAP Conventional E1	nCPAP Conventional E2	nCPAP Self-Adjusting E1	nCPAP Self-Adjusting E2	Difference Between Groups
BMI, kg/m^2*	32.5±4.3	30.5±5.1	31.7±10.4	32.1±6.3	NS
Mean apnea duration, s	23.4±4.7	14.0±5.0	22.5±5.3	10.5±4.5	$p<0.05$
Maximal apnea duration, s	75.8±56.7	25.0±22.4	78.8±22.3	13.0±3.6	NS
Minimal SaO_2, %	74.5±10.7	87.2±9.2	76.5±12.4	90.3±3.6	NS
Mean SaO_2, %	91.9±2.6	94.3±2.4	90.5±2.6	94.7±1.4	NS
SaO_2>90, %*	80.2±18.5	97.2±6.7	88.8±12.6	99.0±9.4	NS
nCPAP pressure, millibar		8.1±2.5		6.5±1.7	$p<0.01$

*Time of SaO_2 >90%.

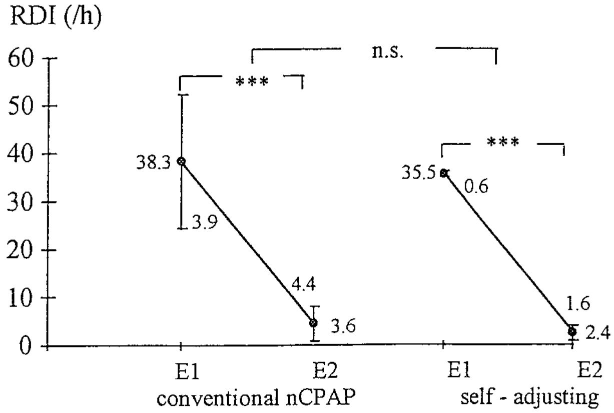

FIGURE 1. Changes of the RDI. ***=p<0.001; n.s.=not significant; E=examination.

They both belonged to the group of patients treated with conventional nCPAP.

Age, sex, body mass index (BMI), and respiratory data at the initial adjustment were comparable between both groups (Table 1). In either group, no significant change of BMI took place in the course of the study (Table 2).

Both forms of treatment ameliorated sleep-disordered breathing. RDI, maximum and mean apnea duration, minimum and mean SaO_2, and time during sleep spent with an SaO_2 level more than 90% improved significantly (Fig 1 and Table 2). Improvement of mean apnea duration was significantly more pronounced with the self-adjusting device. Parameters of sleep architecture and sleep quality are given in Table 3. In both groups, sleep structure was largely restored. There was an increase in slow-wave sleep and rapid eye movement sleep and a decrease in stages 1 and 2 sleep and of the arousal index (Fig 2) in both groups as compared with the baseline study. Improvement of the latter parameter and increase of slow-wave sleep were significantly higher in the auto-adjust group. There was a significant difference between conventional and self-adjusting mode with respect to patient compliance (amount of nights per week with nCPAP use for more than 4 h [Fig 3]) and mean mask pressure (Table 2).

Discussion

Recently, self-adjusting nCPAP devices for the treatment of obstructive sleep apnea syndrome have been developed. Since the required mask pressure may vary depending on body position and sleep stage,[4,5,12] self-adjusting nCPAP is supposed to change the pressure during the night and keep it as low as possible, whereas in conventional nCPAP treatment a mask pressure is required that constantly meets the maximum pressure needs of the patients and that is unchanged across the night.

Self-adjusting devices aim at reducing the mean mask pressure in order to lessen hemodynamic and local side effects and to improve patient compliance.[11,13-16]

As yet, it has not been clarified whether the self-adjusting nCPAP devices are as reliable as fixed mask pressure therapy in the supression of respiratory disturbances during the night and whether the repeated pressure variations might even result in more arousals with significant worsening of sleep structure.

Earlier studies on self-adjusting systems used an intra-individual design, examining patients in a crossover fashion with consecutive application of conventional and self-adjusting devices.[5,8,9] In these studies, an influence of one treatment modality on the other was not excluded. Furthermore, device-specific differences were not always ruled out. Therefore, this study was conducted with an inter-individual design with a device that permits both the conventional and the self-adjusting mode.

The autotitrating machine applied in this study uses a pneumotachograph to sense decreases in air flow in order to detect apneas and hypopneas and oscillations of the flow-time curve for the detection of snoring and central apneas. Breathing through the mouth is detected by an abrupt fall in mask pressure.

Table 3—*Changes in Sleep Factors*

	nCPAP				
	Conventional		Self-Adjusting		
	E1	E2	E1	E2	Difference Between Groups
Sleep efficiency, %	89.2±13.7	85.2±18.7	94.5±5.4	96.5±2.8	NS
Awake, %	5.7±13.3	12.2±13.5	6.5±7.8	7.0±6.8	NS
Sleep stage 1 & 2, %	73.5±20.3	55.9±24.8	61.2±15.4	41.4±18.7	NS
Sleep stage 3 & 4, %	11.4±10.4	17.6±18.4	13.2±12.2	27.2±16.5	p<0.01
Sleep stage REM, %*	5.4±6.0	10.2±7.7	8.2±8.1	20.1±10.0	NS

*REM=rapid eye movement; E=examination.

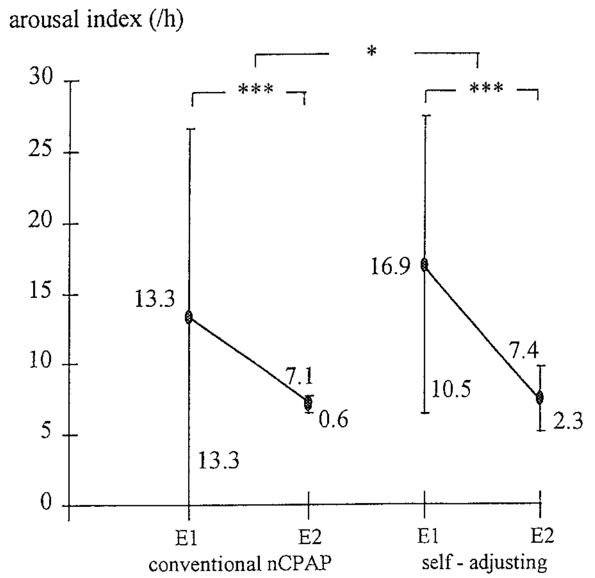

FIGURE 2. Changes of the arousal index. The statistical significance reflects the difference between the changes of arousal indexes, not between the end points. ***=p<0.001; *=p<0.05; E=examination.

Obstructive events induce an increase of mask pressure; minimum and maximum pressure as well as speed of pressure rise or fall can be programmed. Detection of central apneas or breathing through the mouth induces reduction of the nCPAP pressure with a time constant that can be programmed.

The results of this study demonstrate that self-adjusting nCPAP proved to be as effective as conventional nCPAP in suppressing respiratory disturbances. The improvement of sleep structure was comparable in both treatment modalities, although a more pronounced increase of slow-wave sleep and suppression of arousals were achieved with the self-adjusting device. Therefore, the pressure changes during the night even seem to have a positive influence on sleep structure and frequency of arousals.

Clearly, the present results do not allow ultimate conclusions as to the potential benefit of self-adjusting devices. Nevertheless, the results indicate that with these devices patients can be treated with similar success as with the conventional nCPAP devices. Although the patient compliance appeared to be slightly higher with the self-adjusting device, the small difference needs further confirmation.

Although the patients were not supposed to differentiate their assigned treatment modality, those supplied with the self-adjusting device could recognize changes in mask pressure. It must, therefore, be concluded that the study design cannot really be termed single-blinded. This circumstance has to be kept in mind with respect to the study analysis.

Whether the reduction of mean mask pressure by self-adjusting devices can lessen cardiac strain and thus be beneficial is not certain yet and could only be asserted in longitudinal long-term follow-ups of hemodynamic data. It might, however, influence patients' compliance, which in this study proved better in the self-adjusting group. The overall acceptance of therapy was very good in the entire study group. This is probably due to an intensive tutoring as well as high motivation on the part of the study participants.

Further studies are necessary to determine which subgroups of patients experience a benefit from the self-adjusting devices, especially since these devices are more expensive than conventional ones. Automatically adjusting treatment may be beneficial for elderly patients because their characteristically light sleep might be disturbed more easily by constantly high pressures,[17] for those patients who require

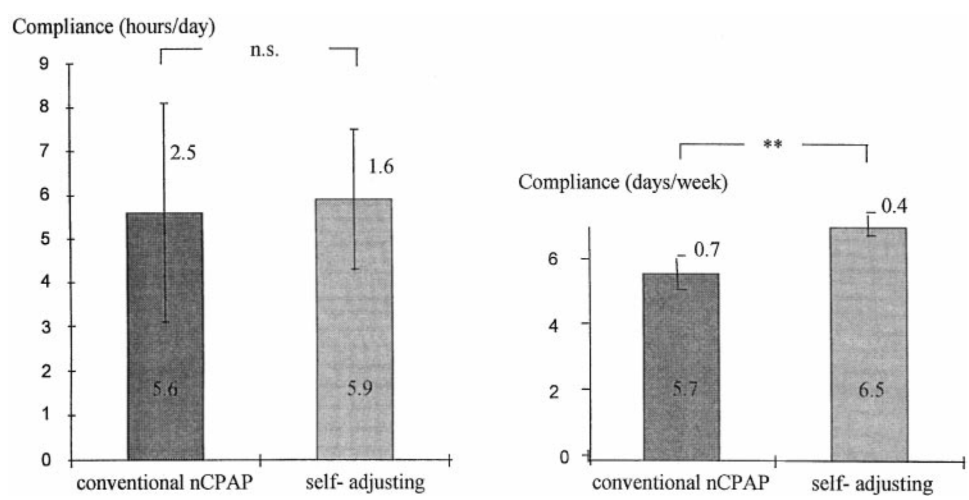

FIGURE 3. Differences in patient compliance. **=p<0.01; n.s.=not significant.

extremely different mask pressures depending on sleep stage or body position, or for those who need high pressures only for short periods.

In conclusion, nCPAP treatment in the self-adjusting mode with the Horizon device demonstrates the same reliability in supression of respiratory disturbances as fixed mask pressure therapy. Sleep quality and patient compliance were slightly better, and mean pressure level was lower. Further studies will have to determine whether this reduced pressure presents a hemodynamic advantage.

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