

Evaluation of a New Automatic CPAP Algorithm in the Treatment of Obstructive Sleep Apnea Syndrome

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Abstract

Background: Automatic Continuous Positive Airway Pressure (automatic CPAP, APAP) is an effective treatment option for Obstructive Sleep Apnea Syndrome (OSAS). The differentiation of obstructive and central respiratory events is crucial in adjusting the optimal pressure in this treatment mode. In this pilot study we evaluated a new automatic CPAP algorithm in OSAS patients.

Methods: Fourteen (14) patients with newly diagnosed Obstructive Sleep Apnea Syndrome were enrolled. After a diagnostic polysomnography, patients were treated for one night with a new APAP device equipped with an algorithm based on flow, snoring, relative minute volume and the obstructive pressure peak signal.

Results: The total apnea/hypopnea index (AHI) was 30.0 ± 21.4 /hr at baseline and 3.7 ± 5.3 /hr with APAP ($p < 0.005$). Both obstructive AHI (22.7 ± 20.5 /hr at baseline, 1.5 ± 3.5 /hr with APAP, $p < 0.005$) and central AHI (7.3 ± 4.9 /hr and 2.2 ± 2.5 /hr, respectively, $p < 0.01$) and the arousal index (25.4 ± 18.1 /hr and 5.1 ± 3.8 /hr, respectively, $p < 0.005$) were reduced significantly with the new algorithm.

Conclusions: The new algorithm of an automatic CPAP device is effective in the treatment of Obstructive Sleep Apnea Syndrome.

Introduction

Self-adjusting CPAP devices (auto-CPAP devices, APAP) have been available for the treatment of Obstructive Sleep Apnea Syndrome (OSAS) since the middle of the 1990s [1±5]. The principle of APAP therapy is to record the current degree of obstruction in the patient's airways and to adjust the CPAP pressure as prescribed by the device's software algorithm [6]. In contrast to conventional CPAP therapy with a fixed pressure, APAP can reduce the mean pressure and still achieve the same efficacy as measured by a reduction in the Apnea Hypopnea Index and subjective daytime sleepiness [7 – 9].

This makes automatic CPAP therapy interesting for patients with intolerance of a fixed CPAP pressure and for patients with Sleep Apnea Syndrome (SAS) which is particularly dependent on sleep stage or body position [10]. It should be noted, however, that thus far most studies have been unable to ascertain any improvement in nighttime device usage attributable to APAP devices [11] even though patients in comparative studies prefer APAP therapy to conventional CPAP therapy [8].

The principle of self-adjusting CPAP therapy has been technically implemented by different ways and means. Some devices react to snoring, variations in respiratory flow, flattening of the inspiratory flow curve, the generator speed or a combination of those signals [2, 3,12,13]. Another device based on Forced Oscillation Technique (FOT) manages the CPAP pressure by determining resistance in the upper airways [14, 15]. Bench tests have verified that the varied algorithms in APAP devices react differently to simulated respiratory disorders [16, 17]. Consequently the devices are not simply interchangeable; for a single patient they can result in completely different courses of pressure throughout the night [18].

An automatic CPAP device has recently been introduced whose newly developed algorithm should effectively suppress obstructive respiratory disorders. In a pilot study this algorithm was clinically tested for the first time on patients with OSAS and evaluated.

Method

Patients

Fourteen patients (7 females, 7 males; aged 60.4 ± 11.9 years; Body Mass Index 31.2 ± 6.0 kg/m²) with newly diagnosed Obstructive Sleep Apnea Syndrome were recruited for the test. Based on nighttime polysomnography data, OSAS requiring treatment was defined as an Apnea/Hypopnea Index (AHI) ≥ 5 /hr accompanied by typical clinical symptoms. Exclusion criteria were: less than 18 years of age, lack of consent, additional sleep disorders requiring treatment (parasomnia, narcolepsy, Restless Legs Syndrome, insomnia), pregnancy, exacerbated Chronic Obstructive Pulmonary Diseases (COPD), heart failure in NYHA Classes III and IV, inadequately treated arterial hypertension or malignant diseases. All patients were required to submit written informed consent prior to the study. Approval of the study was received from the ethics committee.

Study Design

After a diagnostic polysomnography (PSG), patients were treated in the first night with PSG-monitored therapy provided by the newly developed automatic CPAP device (SOMNObalance, Weinmann, Hamburg). In the second PSG-monitored night of therapy, an automatic CPAP device was used (SOMNOsmart, Weinmann, Hamburg), which discharged patients then took home with them.

During polysomnography the following parameters were recorded:

EEG (C4A1, C3A2), EOG, submental EMG, thoracic and abdominal efforts (inductance plethysmography), respiratory flow (measured via nasal cannula), snoring signals (microphone), oxygen saturation (finger pulse oximeter), body position (position sensor). All data were automatically recorded (Alice 4, Heinen&Löwenstein, Bad Ems; SOMNOlab, Weinmann, Hamburg) and manually scored. The analysis of sleep stages was made according to the guidelines of Rechtschaffen und Kales [19]. Arousals were classified in accordance with ASDA criteria [20].

An apnea was defined as a complete interruption in respiratory flow for at least 10 seconds. A hypopnea was defined as a 50 % reduction in nasal flow in comparison to baseline for at least 10 seconds, associated with a 3% drop in oxygen saturation or a 30% reduction in nasal flow of at least 10 seconds, accompanied by a 4% drop in oxygen saturation or an arousal [21].

Automatic CPAP Therapy Algorithm

The newly developed automatic CPAP device SOMNObalance (Weinmann, Hamburg) was used in this pilot study. Regulation of the applied therapy pressure was based on this device's four signals, namely, respiratory flow, snoring, relative respiratory minute volume and OPP (Obstructive Pressure Peak). The OPP is based on the following ideas:

During an obstructive event a pressure difference arises between mask and the lower airways as a result of respiratory effort and the consequential negative intrathoracic pressure. At the end of an obstruction, the pressure equalization between the mask and the lower airways leads to a brief dip in mask pressure, which is detected in a corresponding pressure channel. In addition to obstructive apnea, events of obstructive hypopnea, obstructive snoring and flow limitations are

identified on the basis of corresponding vibrations in the OPP channel. As no pressure equalization takes place between the mask and the lower airways after a central event, there is no amplitude in the OPP channel. Depending on the severity of the event detected by the OPP signal, the automatic CPAP device increases the pressure. When an obstructive apnea is detected, the increase is immediate; otherwise the pressure is increased after a waiting period of two minutes ("epoch principle").

No pressure increase is made after central events. If no obstructive event is detected within an epoch of two minutes, pressure is decreased at the end of the epoch, with the extent of the reduction dependent on the previous events and the current pressure level. The lower pressure limit of the device is set to 4 mbar and the upper limit to 18 mbar. The device's typical reactions to obstructive and central events are shown in Figures 1 and 2, respectively.

Statistics

Numerical variables such as anthropometric parameters and polysomnography data are given as mean values \pm standard deviation. Calculations for significant differences between diagnostic PSG and therapy night PSG were made by means of the Wilcoxon test. A $p < 0.05$ was considered statistically significant.

Data analysis was made with the statistical program packages SAS (1999) and SPSS 11.5 (2003).

Figure. 1 Obstructive apnea with clearly recognizable signal in the Obstructive Pressure Peak (OPP) channel at the end of an event followed by an increase in therapy pressure.

Figure 2: Central apnea without any recognizable signal in the Obstructive Pressure Peak (OPP) channel. Therefore, the therapy pressure is not increased.

Results

The total AHI in the diagnostic PSG was $30.0 \pm 21.4/\text{hr}$, which was significantly reduced by automatic CPAP therapy in the first night to $3.7 \pm 5.3/\text{hr}$ ($p < 0,005$). The improvement in AHI involved both the obstructive portion ($22.7 \pm 20.5/\text{hr}$ vs. $1.5 \pm 3.5/\text{hr}$) and the central portion (7.3 ± 4.9 vs. $2.2 \pm 2.5/\text{hr}$). The Arousal Index and oxygen desaturation also improved significantly under APAP therapy (**Table 1**).

No significant differences were observed between the diagnosis night and therapy night as far as Total Sleep Time and the percentage distribution of the individual sleep stages were concerned, although a positive trend was seen in prolonged deep and REM sleep during the APAP night. Conversely, a negative trend was seen in sleep efficiency (TST%SPT) (67.1%) during the APAP night compared to the baseline measurement (76.5%), without its falling to a significant level ($p= 0.30$) (**Table 1**).

The mean therapy pressure during the night with the new APAP device was 8.6 ± 2.1 cm H₂O, while the mean pressure applied in the following night with the previously established automatic CPAP process was 6.2 ± 2.2 cm H₂O.

Discussion

The new algorithm in an automatic CPAP device was shown to be effective therapy of OSAS in this clinical pilot study involving 14 patients. Obstructive respiratory events were sufficiently suppressed and central events were not induced by the automatic therapy.

Automatic CPAP devices were developed with the idea that a self-adjusting CPAP device could more efficiently counter changes in obstruction in the upper airways, which is evident in night-to-night variability, body position and sleep stage dependency. The device continuously adjusts the applied CPAP pressure to the changing pressure needs of the patient and thus reduces the mean pressure applied throughout the entire night [22]. A meta-analysis confirmed that it was possible to reduce the mean therapeutic pressure by 2.2 cm H₂O under APAP and achieve the same therapeutic effectiveness as therapy with a fixed CPAP pressure [11]. In unselected OSAS patients, however, no higher compliance could be achieved with automatic CPAP therapy, leading to the conclusion that decisions regarding this type of therapy have to be made on a case-by-case basis [23].

Table 1: Polysomnography parameters in the baseline recording and during automatic CPAP therapy.

	Baseline	APAP
SPT (min)		
TST (min)		
Sleep efficiency (TST%SPT)		
S1/S2 (%TST)		
S3/S4 (%TST)		
REM (%TST)		
AHI total (/h)		
AHI obstructive (/h)		
AHI central (/h)		
Arousal Index (/h)		
SaO ₂ min (%)		
Time < 90 % SaO ₂ (min)		

*p < 0.05 vs. Baseline; **p < 0.005 vs. Baseline; ***p < 0.01 vs. Baseline
APAP: Automatic CPAP therapy; SPT: Sleep Period Time; TST: Total Sleep Time; S1 - S4: Sleep stages 1 - 4; AHI: Apnea/Hypopnea Index.

The crucial technological challenge of automatic CPAP therapy lies in the reliable recognition of respiratory disorders and in the exact differentiation between obstructive and central events on the one hand and of artefacts on the other. In recent years a device algorithm that combines different signals to detect respiratory events has proven to be more effective than relying on one signal alone. In a study by Berkani et al., for example, 20% of patients were insufficiently treated by an APAP device that reacted to snoring signals only [13]. The newly developed algorithm of the device used in this pilot study is based on different parameters, namely, flow, snoring signal, relative respiratory minute volume and the OPP (Obstructive Pressure Peak) signal. A detailed description of the algorithm can be found in the Methods section of this article. Central apnea or hypopnea with open airways can be differentiated from obstructive events in the absence of the OPP signal. Rühle et al. examined the reaction of the OPP signal on a total of 284 obstructive and central events in four patients. Amplitude in the OPP channel occurred primarily with obstructive apnea and hypopnea and the device quickly responded with a corresponding increase in CPAP pressure. In about one-third of central apneas, however, a pressure peak occurred which could have been induced by so-called "closed" central apnea [24].

In our study of 14 patients with OSAS we were able to achieve sufficient suppression of sleep-disordered breathing with the previously described algorithm during the first night of therapy. The reduction in obstructive events and arousals occurred to the same extent as reported with other automatic CPAP devices [11]. APAP devices can theoretically induce central apnea if therapy pressure is not adequately increased. However, that did not occur in this study. In fact, a significant reduction of the central Apnea-Hypopnea Index was effected by the therapy algorithm. Suppression of central apnea and hypopnea was observed in earlier studies of

therapy with fixed CPAP pressure (e.g., CANPAP Study) [25]. A slight but insignificantly lower sleep efficiency was noted in the therapy night with the new device. This leads to the conclusion that sleep may be disrupted by the algorithm. However, the obvious and significant reduction in arousals under APAP therapy contradicts that conclusion. The slightly lower sleep efficiency is more likely attributable to the unfamiliar situation during the initial night of treatment, which, experience shows, may involve adjustment difficulties, mask problems or leakage. Several studies have proven that automatic CPAP therapy per se does not lead to deterioration in sleep quality. The work of Fuchs et al., for example, showed no relevant number of pressure-associated micro arousals under APAP therapy [26]. Furthermore, random studies confirmed an improvement in sleep quality (reduction in arousals, increase in REM and deep sleep) under APAP equal to conventional CPAP therapy [27]. However, in an earlier study with another APAP device – similar to that in this work – a reduction in sleep efficiency was observed [28].

Although it was not the objective of this study, the comparison of the mean applied pressure of both APAP devices (SOMNObalance vs. SOMNOsmart) sheds light on an interesting aspect. Apparently the mean pressure in the new APAP algorithm was considerably higher than in the conventional impedance-managed system. It must be noted, however, that no randomization took place and that the new device was always used in the first night by each patient and that night-to-night variability certainly played a role. Nevertheless, this observation underscores the known phenomenon that APAP devices react differently and therefore are not simply interchangeable.

Obviously this pilot study was limited by the small number of patient cases, the lack of a control group and only one night of therapy. As a result, it is not possible to rule out the influence of night-to-night variability in Sleep-Disordered Breathing on the reduction of respiratory events in the therapy night. Other random and controlled studies are required to confirm the reported results in a larger group and over a longer period of time. A bench test could examine the reaction of the algorithm to a variety of simulated respiratory events in comparison to other APAP devices.

In summary, according to the results of this pilot study, the previous therapy spectrum of Obstructive Sleep Apnea Syndrome has been expanded by a new, effective algorithm in an automatic CPAP device.

Conflict of Interest

W. Galetke and W. Randerath have received financial support from Weinmann, Geräte für Medizin GmbH + Co. KG, Hamburg, for travel expenses and congress fees and remuneration for presentations and consultation.