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Effective comparison of two auto-CPAP devices for treatment of obstructive sleep apnea based on polysomnographic evaluation

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Abstract

Background: Automatic continuous positive airway pressure (auto-CPAP) machines differ mainly in algorithms used for respiratory event detection and pressure control. The auto-CPAP machines operated by novel algorithms are expected to have better performance than the earlier ones in the treatment of obstructive sleep apnea syndrome (OSAS).
Objectives: The purpose of this study was to determine the therapeutic characteristics between two different auto-CPAP devices, i.e., the third-generation flow-based (f-APAP) and the second-generation vibration-based (v-APAP) machines, during the first night treatment of OSAS.
Methods: We retrospectively reviewed the polysomnography (PSG) recordings of 43 OSAS patients who were initially performed an overnight diagnostic PSG to confirm the disease and afterwards received the first night auto-CPAP treatment with using either the f-APAP ($n = 22$) or v-APAP ($n = 21$) device under another PSG evaluation.
Results: There were 13.6% and 61.9% patients who remained a residual apnea/hypopnea index more than 5 during the f-APAP and v-APAP application, respectively ($P < 0.005$). The f-APAP was more effective than the v-APAP in reducing apnea/hypopnea index ($P = 0.003$), hypopnea index ($P = 0.023$) and apnea index ($P = 0.007$), improving the lowest oxygen saturation index ($P = 0.007$) and shortening stage 1 sleep ($P = 0.016$). However, the f-APAP was less sufficient than the v-APAP in reducing arousal/awakening index ($P = 0.02$).
Conclusion: These findings suggest that the f-APAP works better than the v-APAP in abolishing breathing abnormities in the treatment of OSAS; however, the f-APAP device might still have some potential limitations in the clinical application.

Keywords: Obstructive sleep apnea; Continuous positive airway pressure; Auto-CPAP devices; Polysomnography

1. Introduction

Automatic continuous positive airway pressure (auto-CPAP) machines have increased in popularity in the treatment of obstructive sleep apnea syndrome (OSAS) during the last decade. Ideally, these devices can automatically sense respiratory signals and instantly match the patients with an appropriate pressure at which apneas, hypopneas, snoring, desaturations, and respiratory-related arousals/awakenings decrease to within a normal range [1]. Some previous studies have demonstrated the efficiency of auto-CPAP machines in treating OSAS [1–3].

Auto-CPAP devices differ principally in the algorithms adopted to detect respiratory events. The algorithms used by auto-CPAP machines to adjust pressure have continued to improve. The second-generation auto-CPAP device changes pressure mainly based on sensing vibrations of the upper airway, while the novel third-generation auto-CPAP measures subtle flow restrictions measured at the nasal mask [4]. Although the third-generation auto-CPAP device was expected to have better performance than the earlier one, there has been no study so far on the therapeutic effects between auto-CPAP machines of different generations based

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on polysomnography (PSG) evaluation. The present study was the first to compare the PSG parameters between these two auto-CPAP applications, and the aim was to determine their potential advantages or limitations without compromising the treatment pressures.

2. Patients and methods

The data of all patients that presented to the Sendai Snoring Research Centre (SSRC) for their OSAS were reviewed. Only the patients who received both the whole night diagnostic PSG and an unattended autotitration PSG within an interval less than 2 months were considered for enrollment. The criteria for further exclusion were the existence of chronic obstructive pulmonary disease or cardiac disease, clinically manifest nasal obstruction, and predominantly central sleep apnea. No patients had previous OSAS treatment history.

The Virtuoso LX Smart and REMstar Auto machines (Respironics Inc., Murrysville, PA, USA) were employed in the present study. The two devices differ in algorithms for pressure control. The Virtuoso LX Smart, a vibration-based auto-CPAP (v-APAP), uses a pressure transducer to monitor the airway by vibration pattern. The REMstar Auto, a novel flow-based auto-CPAP (f-APAP), works primarily by measuring the instant flow limitation at the mask with the aid of a pneumotachograph.

The patients were divided into two treatment groups, depending on the auto-CPAP device that they used. From January 2002 to August 2002 all patients were treated with the v-APAP, while from November 2002 to April 2003 all patients were routinely treated with the f-APAP, both based on a well informed consent. During September to October 2002, one of these two devices was utilized for treatment based on the selection of the patients themselves, and the data of these patients were excluded from the present analysis on purpose of diminishing the selection bias. The treatments made during the autotitration course were preformed at the default settings.

The diagnostic and autotitration PSG examinations were both performed by a computerized Alpha Sleep System (Somnostar, Sensormedics, Yorba Linda, CA, USA). The recorded PSG signals included electroencephalography (EEG) of C3/A2, C4/A1, O1/A2, O2/A1 and Cz, separate electrooculogram (EOG), submental electromyogram (EMG), oral and nasal airflow measured by thermistors, thoracic and abdominal movements measured by strain gauges, snoring detected by microphone, and body position.

Apnea was defined as a cessation of oronasal airflow lasting for at least 10 s and classified as central, mixed, or obstructive [5]. Hypopnea was considered as a decrease in the airflow signal by at least 50% for at least 10 s. Apnea/hypopnea index (AHI) was calculated as the number of apneas plus hypopneas per hour of sleep time. Arousal was defined as an increase in the frequency of the EEG lasting for more than 3 s subject to certain conditions based on the guidelines [6]. Events lasting >15 s were classified as awakening. Arousal/awakening (ArAw) index was calculated as the number of arousals plus awakenings per hour of sleep time. Arterial oxygen saturation (SaO_2) was monitored by pulse oximetry (finger probe). During the PSG tests a technician was in attendance, but she did not intervene during the night unless the mask was pulled off and had to be repositioned.

All numeric variables, such as anthropometric and sleep study data, are given as arithmetic means $\pm$ standard deviation (S.D.). Difference of the two groups' characteristics at baseline values was compared by an unpaired Student's *t*-test. To compare the differences after two auto-CPAP applications, analysis of covariance (ANCOVA) with the baseline value as a covariate was performed. The comparison of the frequency with a residual AHI more than 5 between two groups was performed using a two-tailed χ^2-test. A P-value < 0.05 was considered statistically significant.

3. Results

A total of 43 patients (male/female; 40/3) who met the above criteria were finally included. The mean age of the entire group was 47.4 years (range, 29–75) and the mean body-mass index was 27.7 (range, 19.5–37.5). 21 patients (male/female; 19/2) were treated with the v-APAP and 22 (male/female; 21/1) with the f-APAP. There were no significant differences between the two groups in regards to age, gender and body-mass index ($P > 0.05$, Table 1).

PSG parameters before and after auto-CPAP application are shown in Table 2. Among the baseline values, the two groups were comparable in most parameters, except the

Table 1
Descriptive data of patients enrolled in two treatment groups

	f-APAP (n=22)	v-APAP (n=21)	*P* value
Sex, % male	95.5	89.5	NS*
Age, years	45.0 ± 12.4	49.4 ± 11.4	NS**
BMI, kg/m^2	28.0 ± 4.3	27.3 ± 3.8	NS**

Data of age and BMI are presented as mean ± S.D. f-APAP, flow-based auto continuous positive airway pressure; v-APAP, vibration-based auto continuous positive airway pressure; BMI, body mass index; NS, not significant. *Compared by χ^2-test. **Compared by *t*-test.

Table 2
Effective comparison of two auto-CPAP devices based on PSG evaluation

	Diagnostic PSG			Autotitration PSG		
PSG parameters	f-APAP	v-APAP	*P* value*	f-APAP	v-APAP	*P* value**
TTB, minutes	434.8 ± 49.0	450.4 ± 37.0	NS	416.3 ± 45.9	441.7 ± 52.5	NS
TST, minutes	400.4 ± 46.0	402.5 ± 51.9	NS	391.4 ± 52.0	392.7 ± 54.9	NS
Sleep efficiency, %	91.6 ± 6.2	88.5 ± 7.7	NS	92.1 ± 7.7	87.7 ± 10.7	NS
ArAw index, /hour	24.4 ± 23.6	47.3 ± 38.6	0.02	18.1 ± 16.8	11.1 ± 6.9	0.028
AHI, /hour	55.8 ± 18.5	55.8 ± 19.7	NS	2.3 ± 2.7	8.4 ± 8.4	0.003
AI, /hour	53.2 ± 19.5	52.7 ± 19.1	NS	1.9 ± 2.3	6.9 ± 7.8	0.007
HI, /hour	1.7 ± 1.6	0.9 ± 1.3	NS	0.4 ± 0.5	1.7 ± 2.6	0.023
Central apneas	0.7 ± 1.1	3.2 ± 10.6	NS	0.7 ± 1.5	0.2 ± 0.5	NS
Mixed apneas	28.7 ± 37.4	34.3 ± 58.1	NS	1.6 ± 3.5	0.5 ± 8.4	NS
Stage 1 sleep, %TST	30.3 ± 20.9	33.6 ± 15.6	NS	11.5 ± 7.7	17.1 ± 6.4	0.016
Stage 2 sleep, %TST	43.1 ± 20.0	42.0 ± 15.0	NS	42.5 ± 11.9	41.1 ± 11.9	NS
Stage 3+4 sleep, %TST	7.9 ± 10.0	12.1 ± 11.4	NS	20.2 ± 12.0	25.7 ± 15.7	NS
REM sleep, % TST	19.1 ± 7.2	13.2 ± 7.0	NS	26.8 ± 6.2	22.4 ± 5.9	NS
Mean SaO_2, %	86.4 ± 6.4	88.6 ± 5.5	NS	95.6 ± 1.1	95.0 ± 2.1	NS
Lowest SaO_2, %	65.7 ± 10.6	66.9 ± 7.3	NS	87.6 ± 4.5	83.0 ± 8.0	0.007

Data are presented as mean ± S.D.
CPAP, continuous positive airway pressure; PSG, ploysomnography; f-APAP, flow-based auto-CPAP; v-APAP, vibration-based auto-CPAP; TIB, total time in bed; TST, total sleep time; ArAw, arousal and awakening; AHI, apnea/hypopnea index; AI, apnea index; HI, hypopnea index; REM, rapid eye movement; SaO_2, oxygen saturation; NS, not significant.
*Compared by *t*-test. **Compared by ANCOVA.

ArAw index which was greater in v-APAP group than f-APAP group (47.3 ± 38.6 versus 24.4 ± 23.6, $P = 0.02$). Both machines were able to lower AHI in all subjects; however, there still were 13 patients (61.9%) in the v-APAP treatment group and 3 patients (13.6%) in the f-APAP treatment group respectively in whom a residual AHI more than 5 was remained. A significant difference was between the two groups ($P < 0.005$).

Using ANCOVA with the diagnostic parameter as the covariance, we then compared the PSG parameters between two groups after auto-CPAP treatment. As shown in Table 2, the f-APAP was more effective than the v-APAP in reducing AHI (2.3 ± 2.7 versus 8.4 ± 8.4, $P = 0.003$), apnea index (AI; 1.9 ± 2.3 versus 6.9 ± 7.8, $P = 0.007$), and hypopnea index (HI; 0.4 ± 0.5 versus 1.7 ± 2.6, $P = 0.023$). The f-APAP was also better than the v-APAP in improving the lowest SaO_2 (87.6 ± 4.5 versus 83.0 ± 8.0, $P = 0.007$), but not mean SaO_2 ($P > 0.05$). No significant difference was found between the two devices in abolishing central or mixed apneas ($P > 0.05$).

No statistical difference in stage 2, stage 3 + 4, and rapid eye movement (REM) sleep was found between the two treated groups ($P > 0.05$); but stage 1 sleep during the f-APAP application was significantly decreased in comparison with that during the v-APAP application (11.5 ± 7.7 versus 17.1 ± 6.4, $P = 0.016$). Although ArAw index before treatment was statistically higher in v-APAP group, ArAw index during treatment was conversely significantly greater in the f-APAP group than that in the v-APAP group (18.1 ± 16.8 versus 11.1 ± 6.9, $P = 0.028$).

4. Discussion

Different types of auto-CPAPs based on different signals to sense airway instability. Some of these differences might be irrelevant, but others might have impacts on the clinical outcomes. Farre et al. [7] previously carried out a bench study to compare the responses of different automatic CPAP devices, in which both the f-APAP and the v-APAP were employed. The responses of various devices to apnea, hypopnea, flow limitation and snoring were considerably different. The v-APAP did not respond effectively to some types of hypopneas unless the hypopneas were simultaneously presented with high-frequency oscillation characterizing snoring, while the investigated f-APAP showed better response than the v-APAP when subjected to persistent flow limitation. Our clinical study also showed that the f-APAP did work better than the v-APAP abolishing breathing abnormities in the treatment of patients with OSAS. Furthermore, our data extend the previous bench findings by showing that the f-APAP was more effective in

improving the lowest SaO_2. This might be attributed to the more sufficient reduction in respiratory events, especially the hypopnea events during the f-APAP application. Further analysis of the present data revealed that residual AHI and AI during the v-APAP treatment were significantly reduced ($P < 0.001$), but residual HI was conversely deteriorated in comparison with that before treatment ($P = 0.05$). These results might imply the potential limitation of this v-APAP, which had not been reported previously.

In another study, Senn et al. [8] first compared the efficiency of two auto-CPAP devices operated by different algorithms. They reported no significant differences between two auto-CPAP devices in improving major outcomes. However, detailed PSG information, such as comparison about sleep structure was not available from their study. According to the results of the present study, stage 1 sleep was significantly shortened in the f-APAP treatment group than that in the v-APAP treated group. The alteration of sleep structure may play role in effecting sleep quality. Recent studies have suggested that higher pressure was usually needed during stage 1 sleep, while only the patients showing significant reduction of stage 1 sleep reported subjective improvement after the first night CPAP treatment [9,10]. Unsatisfactorily, the relationship between reducing stage 1 sleep and subjective improvement in our study is unknown because data was not recorded with respect to the subjective evaluation during and after auto-CPAP therapy in the present study, although the f-APAP was shown to be more effective than the v-APAP in diminishing light sleep.

Sleep fragmentation caused by sleep respiratory events result in increased daytime somnolence, confusion, poor memory and attention deficits [11,12]. Arousals can increase the severity of the disorder by promoting greater ventilatory instability [13]. In this study, the f-APAP was found better than the v-APAP in abolishing respiratory event indices, which might be attributed to its acute ability to sense the ventilatory alterations and output the pressure needs promptly. However, ArAw index during the f-APAP application was significantly higher than that during the v-APAP application. These results might raise the question that even in this generally working well auto-CPAP there still have some potential limits. The algorithm allowing prompt changes in airway pressure, although it was helpful for abolishing respiratory events, could generate more sleep fragmentation by increasing arousals [14]. Some spontaneous normal respiratory activities were usually followed by undeserved pressure alterations and arousals during flow-based auto-CPAP application, too [15]. Meanwhile, a recent study had noted that it was not the pressure augmentations but the excessive pressure decrease that disturbed sleep continuity and caused subsequent arousals [16]. Farre et al. [7] reported in their bench study that after normalizing the breathing abnormalities at maximum pressure the vibration-based auto-CPAP maintained pressure for a short time and then decreased pressure in a gentle step; while the flow-based auto-CPAP usually started a linear pressure reduction immediately. The different patterns of these auto-CPAP machines in decreasing pressure might possibly result in their different abilities in diminishing Ar/Aws.

In the present study, an unattended autotitration was performed for each subject following a whole night PSG recording, which represented patients' initial exposure to auto-CPAP treatment. Although some theoretical pictures of auto-CPAP machines might become manifest only after long-term application, the first treatment experience was a crucial factor in determining their subsequent use of the treatment modality [17]. According to the results of this study, under the same unattended autotitration environment, AHI was successfully lowered by less than 5 in 86.4% patients during the application of the f-APAP; while over half patients still remained a residual AHI more than 5 during the v-APAP application. Furthermore, there were significant differences between the two machines in abolishing AHI, AI and HI as well. These results can support the opinion that the f-APAP generally works better than the v-APAP in abolishing nocturnal respiratory events.

Recent technologic advances and issues of availability, convenience and cost have led to a rapid increase in the use of auto-CPAP [4]. Some authors declared that once the diagnosis of OSAS had been made patients could start their treatments much earlier by an immediate prescribe of auto-CPAP machine instead of the need for PSGs used for CPAP titration [18,19]. However, even in the device that generally works well, there still remains a part of patients in whom automatic titration does not accomplish treatment goals. Since the reactions of a given auto-CPAP system cannot be predicted and the indiscriminate use of auto-CPAP may lead to patients' being inadequately treated and experiencing extra complications, an overnight PSG recording is still needed to confirm the efficiency of treatment [4]. Meanwhile, PSG recordings can provide information about the alterations of sleep stage and structure after treatment, which are also necessary for the evaluation of sleep quality. Therefore, the possible method to use auto-CPAP is to apply it during an unattended PSG, so-called level II recording [20]. By means of this procedure, the efficiency can be assessed and the cost of a technician constantly supervising the patients during PSG examination may be saved as well. Only for a minority of patients who undergo failure automatic titration, manual pressure setting will be performed.

In conclusion, flow-based auto-CPAP works better than vibration-based one in abolishing nocturnal respiratory events and improving the lowest SaO_2. However, the latter is more effective than the former in reducing sleep fragmentation. Therefore, even in devices that generally work well there still have some principal limitations. Since the auto-CPAP available now still has its potential limitations, a possible appropriate method to use auto-CPAP is to apply it firstly during an unattended PSG evaluation. Also, further studies are needed, importantly, to evaluate the efficacy of long-term use of auto-CPAP therapy for OSAS.

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