

A Novel Expiratory Pressure Device to Treat OSA

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Introduction

The purpose of this study was to evaluate the efficacy of a disposable expiratory pressure device (Provent; Ventus Medical, Inc.) in OSA patients.

Methods

The device consists of a small valve attached to adhesive tape placed over each nostril. The valves create expiratory positive airway pressure (EPAP) while providing negligible resistance to inspiration.



The study design involved overnight polysomnographies administered in a Latin-square design (PSGs; 1-control and 3 different expiratory resistances [50, 80, and 110 cmH2Osec/liter] to identify the therapeutic device resistance to be used at home for one month. After the one month trial, a follow-up device night PSG was conducted. Participants completed subjective measures including the Pittsburgh Sleep Quality Index (PSQI) and Epworth Sleepiness Scale (ESS) before and after the one month period; they also completed a daily log indicating whether or not the device was still in place in the morning.

There was no order effect of the initial four PSGs and there were no significant differences between the three treatment nights in terms of sleep parameters.

Figure 1

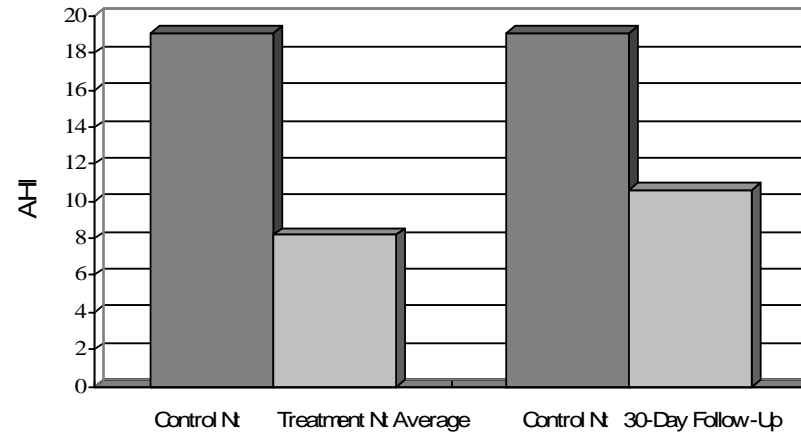


Table 1

	Control	Tx Nights	Follow-up
Sleep Efficiency	78.8 ± 15	78.5 ± 11.5	75.9 ± 16.8
Stage 1%	19.4 ± 15.7	20.7 ± 13.4	21.7 ± 11.4
Stage 2%	50.4 ± 14.4	51.3 ± 10.2	52.4 ± 9.7
Stage 3 / 4 %	6.0 ± 8.0	5.4 ± 5.8	4.3 ± 4.8
Stage REM%	24.2 ± 6.6	22.6 ± 5.1	21.6 ± 7.9
% of Nights Snoring	31.4 ± 23.6	11.2 ± 13.7	14.8 ± 21.8
Desaturation Index	6.3 ± 5.7	5.1 ± 4.1	5.5 ± 5.3
Mean O ₂ Saturation	95.0 ± 3.1	95.6 ± 1.3	95.8 ± 1.2
Min O ₂ Saturation	83.8 ± 16.6	86.1 ± 6.9	87.2 ± 5.1
Apnea Duration (sec)	18.7 ± 4.1	18.7 ± 3.3	18.7 ± 4.2

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Methods (con't)

Thus, matched pairs t-tests were used to compare the control to the average of the three treatment nights and to the follow-up night on PSG variables. Matched pairs t-tests were used to compare the PSQI and ESS from control to follow-up.

Results

There were 23 males and 5 females (age 49.3 ± 10.4, BMI 29.4 ± 4.6). The average apnea/hypopnea index (AHI) on the control night was 19.1 ± 13.0, on the average of the three treatment nights 8.2 ± 4.9, and at the 30-day follow-up 10.6 ± 7.6

Participants used the device for an average of 30 out of 32 nights, or 94.3% of the time.

The treatment nights' average AHI was significantly lower than the control night AHI ($p < .001$). The 30-day follow-up AHI was also significantly lower than the control night AHI ($p < .01$). See Figure 1.

See Table 1 for additional PSG variables. The percent of time spent snoring decreased significantly from control night to the treatment nights' average ($p < .001$), and also from control to 30 day follow-up ($p < .01$).

Analyses for changes in sleep efficiency, sleep stages, desaturation index, mean and minimum oxygen saturation, and duration of apneas were not significant.

The global score on the PSQI significantly decreased ($p = .04$) from 6.3 ± 3.4 to 5.3 ± 3.4 at 30 day follow-up. ESS scores decreased significantly ($p < .001$) from 8.2 ± 4.1 on control night to 5.9 ± 4.1 at follow-up.

Conclusions

The results confirm the efficacy of the device in the treatment of OSA. It significantly reduced AHI and sleepiness over a one month therapeutic trial. In addition, adherence rates were remarkably high. From the patient perspective, it significantly decreased snoring, which likely contributes to increased acceptance of this novel device.