THE USE OF A NASAL RESISTANCE VALVE TO TREAT SLEEP DISORDERED BREATHING

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INTRODUCTION

- We have recently [1] evaluated a nasal resistance valve (Ventus Medical Inc.) as a treatment for OSA.
- The study reported data from 30 subjects with a range of sleep disordered breathing severity.
- Device use was associated with significant improvements in Apnea Hypopnea Index (AHI), Oxygen desaturation index (O2DI) and percentage of the night spent with an O2 saturation < 90%.
- The initial study had several limitations including: a single night of device use; the absence of a sham control comparison, the use of a only one resistance level and no intranasal pressure recordings.
- The present study had two aims:
  1. To replicate the earlier result showing the device caused a significant decrease in obstructive breathing events during sleep as indexed by the AHI and measures of oxygen saturation during sleep.
  2. To address the limitations of the first study in a more comprehensive design.

METHODS

- 9 subjects (7 men) attended the SRI sleep laboratory on four or five non-consecutive nights.
- All subjects were > 18 years (30 – 64 yrs), reported snoring, had BMI ranging between 23 and 38 kg/m^2, were healthy and not using CPAP at the time of the study and had no history of nasal trauma, or a diagnosed sleep disorder other than OSAS.
- Subjects slept for one night without and three or four nights with a nasal EPAP device (Ventus Medical Inc.) worn in each nostril.
- Devices were calibrated to provide either zero (sham condition), 40, 80 or 150 cmH2O*sec/liter resistance. expiratory resistance. (only seven subjects were tested with the 40 cmH2O*sec/liter device).
- The order of nights was randomized across subjects using a modified Latin square.
- The EPAP device consists of two nasal inserts composed of soft foam surrounding a valve body constructed of a urethane copolymer (Pebax®). The valve body houses a Silicone valve mechanism that serves to increase the expiratory pressure by creating expiratory resistance resulting in airway positive back-pressure during expiration while not affecting inspiratory airway pressure. (See figures 1 and 2 for a description of the device and its placement).
- Standard clinical polysomnography was used, with sleep and respiratory event scoring being conducted off-site by an experienced RPGST, blind to the nature of the study, and the condition used on each night
- Output variables included apnea-hypopnea index and oxygen desaturation index (3% desaturations).
- Intranasal pressure was recorded using a separate pressure transducer from an additional cannula glued to the device (not shown in figures1 or 2).

Figure 1. Description of the Ventus device

Figure 2. The Ventus device in situ.

- All variables were analyzed using a repeated measures ANOVA with planned contrasts between the control condition and each of the sham, 40, 80 and 150 cmH2O*sec/liter conditions (based on the seven subjects with data from all three active resistance devices). Expiratory pressure contrasts were based on data from the sham device.
- Follow-up analyses were conducted to assess REM sleep separately from NREM sleep and to compare supine and non-supine body positions using two-way repeated measures ANOVA (resistance and body position).

RESULTS

AHI displayed a significant main effect of condition ($F_{3,24} = 6.9$, $p = .001$) the control condition was not different to sham ($p = .646$), but significantly greater than the 40 ($p = .024$), 80 ($p=.007$) and 150 cmH2O ($p=.027$) conditions.

O2DI displayed a significant main effect of condition ($F_{3,24} = 4.3$, $p = .009$) the control condition was not different to sham ($p = .529$), but significantly greater than the 40 ($p = .044$), 80 ($p=.021$) and 150 cmH2O ($p=.043$) conditions.

Expiratory Pressure displayed a significant main effect of condition ($F_{3,24} = 27.1$, $p < .001$) the sham condition was significantly greater than the 40 ($p < .001$), 80 ($p < .001$) and150 cmH2O ($p=.001$) conditions.

The device impact on AHI and O2DI was not significantly impacted by **Body Position.**

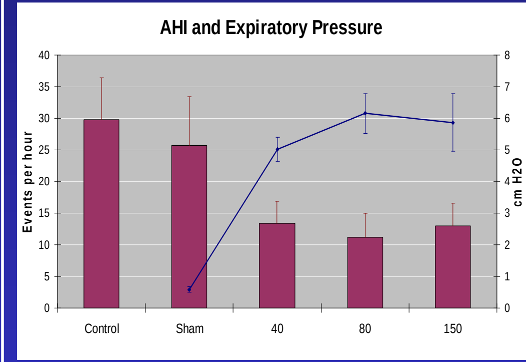

Figure 3. Histogram of the AHI (left hand Y axis) and a line graph of mean expiratory pressure (right hand axis) for each condition. Data are presented as group means with error bars representing the standard error scores.

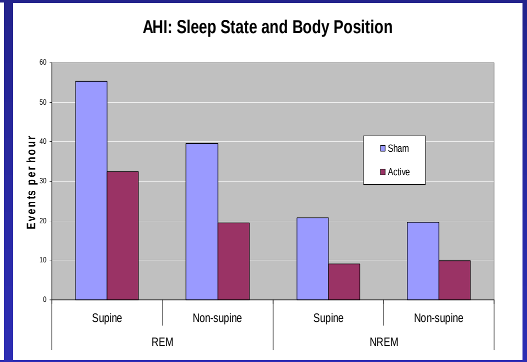

Figure 4. Histogram of the apnea hypopnea index for the sham condition (blue) and the average of the three active resistance conditions (red). Data are presented separately for REM and NREM sleep and for supine and not body positions.

CONCLUSIONS

- The data confirm the efficacy of the nasal resistance device on sleep disordered breathing across multiple nights of use.
- There was no impact of the sham device on AHI or O2DI, indicating that the effect is not produced by nasal dilation.
- The three conditions with active resistance all showed significant improvements in breathing relative to the untreated control and sham treatment conditions.
- Device efficacy was not impacted by body position and was evident in both REM and NREM sleep.
- There was no difference in effectiveness of the three active devices, despite substantial differences in their bench calibrated resistances.
- The uniformity in efficacy is explained by the lack of difference in measured inspiratory pressure, indicating that subjects possibly "titrate" the resistance by varying how they breathe with the resistor in place.

REFERENCES

1. Colrain IM, Brooks S, Black J. (2008) A pilot evaluation of a nasal expiratory resistance device for the treatment of obstructive sleep apnea. *Journal of Clinical Sleep Medicine,* In Press.

Funding Ventus Medical Inc.