Comparison of Exhalation Pressure Relief to Standard Pressure Delivery Among OSA Subjects on Auto-Adjust Therapy

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Background

Continuous Positive Airway Pressure (CPAP) represents the treatment of choice for patients with moderate to severe Obstructive Sleep Apnea (OSA). Efforts at improving therapeutic adherence have included mechanical interventions involving the way positive pressure is delivered; among these, expiratory pressure relief and auto-titrating (APAP) devices have been embraced by clinicians and are available from most manufacturers. However, no conclusive clinical advantages have been documented from the use of these technologies; furthermore, clinical experience has suggested that they might at times deliver sub-therapeutic PAP settings. DeVilbiss Healthcare has recently introduced exhalation relief technology (SmartFlex™) and Flow Rounding™, which allows for independent adjustment of transitions in and out of IPAP/EPAP.

Objectives

Primary Aim: To determine if the SmartFlex™ technology (DeVilbiss Healthcare Inc; Somerset, PA) yields equivalent therapeutic benefit to standard delivery of PAP among treatment naïve subjects receiving Auto-Adjust Therapy.

Secondary Aims:

A. To compare adherence to therapy and oxygen desaturation index (ODI) between the two modes of therapy.

B. To compare comfort, ease of use and reported outcome measures (Epworth Sleepiness Scale [ESS] and Sleep-Wake Activity Inventory [SWAI] between the two modes of therapy.

Methods

- Two center, randomized, prospective, double-blinded, crossover study compared outcomes between SmartFlex (at a setting of 3 and inspiratory /expiratory rounding at 3) and standard Auto-Adjust therapy (6-15 cm H2O).
-Subjects age ≥ 18, AHI ≥ 15, CPAP naïve with ESS ≥ 10 and no other sleep co-morbidity or acute medical condition, and adequate response to in-laboratory CPAP titration were eligible to participate. Subjects signed an IRB approved consent form prior to participation. Each site had a separate, but complementary randomization scheme.
-Subjects used each treatment (SmartFlex / Standard APAP) for 2-weeks. Three days prior to the end of each 2-week treatment arm, subjects were asked to complete 3-nights of in-home overnight oximetry while continuing treatment.
-Prior to initiation of therapy and at the end of each treatment period subjects completed the ESS and the SWAI.

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Methods (b)

- At the completion of each two-week treatment period, objective data (AHI, hours of use, Oximetry data) were downloaded from the APAP devices. Subjective assessment about the experience of PAP therapy using 1 to 5 Likert-type scales were completed at the end of each period (ratings about noise level [1=very loud; 5=very quiet], time taking to adjust to therapy [1=never adjusted; 5=immediately] and bed-partner's rating of improved sleep [1=totally disagree; 5=totally agree).

- The SWAI consists of 59 items that provide six-subscale scores: Excessive Daytime Sleepiness (alertness), Nocturnal Sleep (sleep), Ability to Relax (relax), Energy Level (energy), Social Desirability (social des), and Psychic Distress (psych comf). Each item is rated on a 1 to 9 semi-continuous Likert-type scale from "always" to "never", based on the previous seven days (1).

- The protocol a priori defined evaluable subjects as those who achieved treatment adherence for ≥4 hours/night on 70% of the nights.

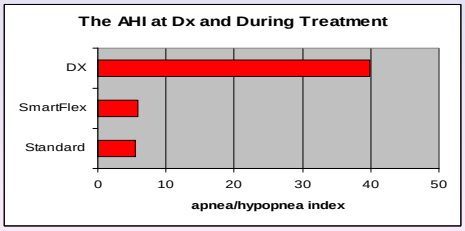
- The primary aim of the study was evaluated using Blackwelder's test to demonstrate that SmartFlex is 'at least as good as' standard therapy (AHI ±5).

- The secondary aims were evaluated using paired t-tests. An estimate of percent improvement (worsening) for each scale of the SWAI was derived at the end of each therapeutic period.

Results

A total of 30 subjects were enrolled (M=16; 57%); 2 subjects were withdrawn (one subject was incorrectly randomized; the other lost to follow-up). A total of 28 subjects (14 per site) completed the study. Evaluable subjects (M=10; F=7) were representative of adult patient's diagnosed with OSA (age: 48.4 ±9.9; BMI: 34.8±7.6; AHI: 39.8±21.5; ESS: 15.1±2.9).

Average hours of use were 6.2±0.9 when on SmartFlex and 5.8±0.9 when on standard APAP (difference 0.39+0.85, p 0.08). The AHI during the period of treatment with SmartFlex was 5.9±3.7 while on Standard therapy it was 5.6±3.3 (Blackwelder test at mu=5, p<.0001). ODI (≥4%) was comparable (5.5±7.9 vs. 5.5±7.3 respectively). Average leak rate was lower on SmartFlex (31.1±6.2) when compared to Standard APAP (34.1±6.8; difference -3.0±5.9, p 0.055).

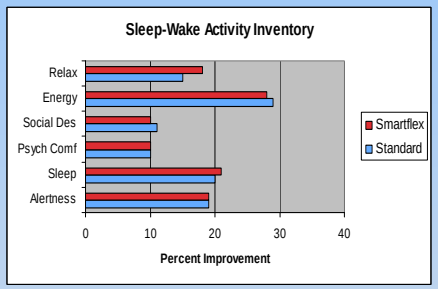


Results (b)

Both therapy delivery modes resulted in comparable perceptions about the blower; subjects reported taking 1 to 4 days adjusting to APAP. The blower was rated as quiet in both modes of PAP delivery. Partners rated their sleep as equally improved with both air-delivery modes.

The cohort reported moderate subjective sleepiness at baseline (ESS: 15.1±2.9). Decreased ESS scores were comparable for both SmartFlex and Standard APAP (-6.3±4.6; -7.2±4.1).

The SWAI was administered before initiation of therapy and at the end of each treatment period. Scores for each scales of the SWAI were derived and compared. Significant changes in scores ($p < 0.05$) were documented for each scale when compared to baseline; no significant differential improvement was documented between the two modes of therapy. All changes in scores reflected expected clinical improvement. The scores were converted to percent change in scores to visually demonstrate clinical improvement (see below):



Conclusions

The results of the study demonstrate comparable effectiveness of the new SmartFlex technology when compared to standard APAP therapy. Consistent with previous research (2,3), a higher (but not statistically significant) average use was demonstrated with pressure modification. Of interest, a lower leak rate was demonstrated on SmartFlex which could explain greater comfort using expiratory pressure modification (3). Furthermore, comparable improvement in the level of alertness was documented on the ESS. The use of the SWAI provided further insight of the daytime benefits of PAP-therapy, which demonstrated increased energy levels and improved ability to relax. Of interest, the SWAI nocturnal sleep scale also demonstrated improved sleep with PAP-therapy.

References

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