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, AH1≥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, independent, IRB committee to review the protocol. DeVilbiss received approval from the U.S. FDA (510k).
- 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.

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A total of 30 subjects were enrolled (M=16; 57%); 2 subjects were withdrawn (one subject was incorrectly randomized; the other lost to follow-up).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. Evaluative subjects (M=10; F=7) were representative of adult patient’s diagnosed with OSA (age: 48.4 ±9.9; BMI: 34.8±7.6; AH1: 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±2.7 while on Standard therapy it was 5.6±3.3 (Blackwelder test at mu-5, p<0.0001). ODI (≤4%) was comparable (5.5±7.9 vs. 5.1±7.3, respectively). Average leak rate was lower on SmartFlex (3.1±1.62) when compared to Standard APAP (34.1±6.8; difference -30±2.9, p = 0.055).

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 (-3.2±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 considerable 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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