Evaluation of auto bi-level algorithm to treat pressure intolerance in obstructive sleep apnea

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Abstract

Purpose The objective of this study was to evaluate whether a new auto-adjusting bi-level algorithm was comparable to a standard method for prescribing bi-level therapy.

Methods This study was a prospective randomized, double-blinded crossover evaluation of the equivalency of the auto-adjusting bi-level mode (VAuto™) compared to standard bi-level mode, using a pre-determined difference in Apnea–Hypopnea Index (AHI) of five events per hour. Data were obtained during sleep studies performed on two separate nights. Twenty-two subjects met the entry criteria and were enrolled in the study at four investigational sites in the USA.

Results Mean AHI for the auto-adjusting bi-level mode was 6.2±5.4 events per hour and for the standard bi-level mode 8.3±5.8 events per hour. The AHI for the two modes were clinically equivalent. The difference in median pressure between these two modes was −3.8 cm H₂O±3.6 (p=0.0008) in favor of the auto-adjusting bi-level mode. In addition, the maximum pressure was significantly higher in the auto-adjusting bi-level mode (16.0 cm H₂O vs. 14.1 cm H₂O, p=0.02).

Conclusions Our results demonstrated that the auto-adjusting bi-level mode normalized AHI comparable to the standard bi-level mode. The results of this study have several significant implications for the clinical management of sleep apnea. Obstructive sleep apnea (OSA) is a common condition and is associated with untoward complications. Non-compliance with positive airway pressure (PAP) limits the efficacy of the PAP therapy. The auto-adjusting bi-level mode provides a potentially reliable alternative for sleep clinicians faced with prescribing bi-level PAP for non-compliant patients. This study documents that this type of auto-adjusting device provides effective treatment of OSA.