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A RANDOMIZED CONTROLLED TRIAL OF NASAL EXPIRATORY RESISTANCE AS A TREATMENT FOR OBSTRUCTIVE SLEEP APNEA

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Introduction: Positive airway pressure (PAP) is an effective treatment for patients with obstructive sleep apnea (OSA) but adherence to treatment is only around 50%. Upper airway surgery and oral appliances may be effective in some patients. However, other treatment alternatives for OSA are urgently needed. Two pilot studies of 24 and 34 patients with OSA found that a nasal expiratory resistance appliance (NERA) significantly reduced the apnea-hypopnea index (AHI). The NERA (Provent®, Ventus Medical, Inc.) consists of two expiratory resistance valves each covering a nostril and held in place by an adhesive tape. The valves have negligible inspiratory resistance but have sufficient expiratory resistance to create a back pressure. A large multi-center double blind randomized sham controlled 3 month trial of the NERA was undertaken to better document efficacy.

Methods: Patients with a diagnosis of obstructive sleep apnea (AHI > 10/hour) without significant co-morbidities were randomized to treatment with the NERA or a sham device for 3 months. A device trainer instructed the patients on use of the NERA and sham devices and was the only non-blind participant in the study. On the first week of use the patients underwent polysomnography (PSG) on two non-consecutive nights. In random order the study device was worn (Device-ON) or not worn (Device-OFF). The PSGs were scored by a central scoring laboratory using AASM recommended criteria. The two PSGs were repeated after 3 months of device use. Results for the first week PSGs are reported here. The three month results are not yet available.

Results: Nineteen sites enrolled a total of 250 patients. Patients were randomized to sham device (125 patients) and to the NERA (125 patients). Data for 119 NERA patients and 110 sham patients were available. The median Device-OFF/Device-ON AHI values for the NERA were (13.8 and 4.9 events/hour) and for the sham device were (11.1 and 11.6 events/hour). The reduction in the AHI with the NERA device was highly significant ($P < 0.0001$). The median decrease in the AHI in the NERA group was 53%. Analysis of subgroups of mild, moderate, and severe OSA patients was performed and the median improvement was > 50% in all groups. For example, in the severe OSA group (N = 17) the median AHI fell from 48.2 to 18.9 events/hour.

Conclusion: The nasal expiratory resistance appliance resulted in a statistically and clinically significant reduction in the AHI in a group of patients with mild to severe OSA.

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