

Acceptance and Adherence of a Novel Device in the Treatment of Sleep Apnea

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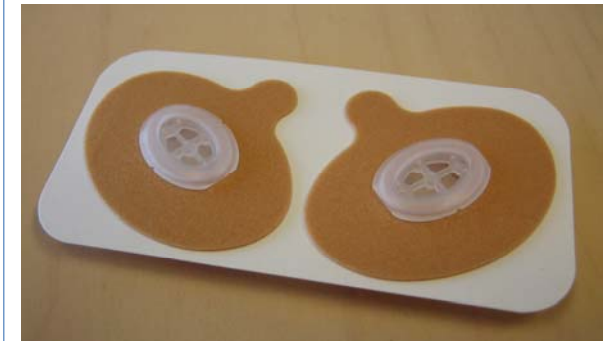
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METHODS: The Provent™ device (Ventus Medical, Inc.) is a small nasal insert which provides expiratory positive airway pressure (EPAP). The device consists of a valve which is placed into the nares, anchored externally by an adhesive tape. In this prospective study, OSA subjects were studied with three types of EPAP resistances (50, 80 and 110 cmH₂Osec/liter). Subjects were given the most effective resistance to use at home for 30 days, and were instructed to maintain daily logs of device use. Acceptance was defined as the subject's agreement to begin home use of the device. Adherence was defined as a subject's report of a device placed at bedtime that was still attached to the nares at final out-of-bed time. The number of adherent nights was divided by the total number of nights of potential use. Nightly sleep hours were calculated by diary report.

INTRODUCTION: Acceptance and adherence are paramount to treatment success. Prescribed therapies for OSA may be accepted by patients and tried initially, but many patients who initially accept therapy may fail to adhere to it. Novel mask designs and pressure delivery systems have enhanced some patients' acceptance of and adherence with CPAP therapy. For other patients, particularly those with mild to moderate disease, simpler therapeutic options may be a better alternative.

RESULTS: Twenty-nine subjects received a device to use in the at home portion of the study. One subject was withdrawn during the home use period by the Investigator due to an adverse event not related to the device. Across all 29 subjects, the device was worn for 854 of 905 potential nights for an adherence rate of 94%. Mean reported sleep time for nights used was 7.4 hours.



CONCLUSIONS: High levels of acceptance (100%) and adherence (94%) were observed with this new therapeutic option for the treatment of OSA.