Continuous Negative External Pressure (cNEP) for the Treatment of Obstructive Sleep Apnea (OSA): A Pilot Study

Jerrold A. Kram, MD¹, Robyn Woidtke, MSN, RN, RPSGT, CCSH¹,², Kenneth B. Klein, MD¹, Richard M. Rose, MD².
¹California Center for Sleep Disorders, Alameda, CA, USA, ²Sommetrics, Inc., San Diego, CA, USA, ³Endpoint, LLC, Bainbridge Island, WA, USA.

Abstract:

Introduction

Although CPAP is highly effective in treating OSA, compliance is poor. We studied a novel treatment approach that avoids some important limitations of CPAP. Continuous negative external pressure (cNEP) is applied to the anterior neck by means of a soft silicone collar, which leaves the mouth and nose free. This pilot study evaluated subjects with documented OSA to determine the efficacy and possible predictors of response to cNEP.

Methods

Adult male and female subjects were eligible if a PSG within the prior 6 months showed the apnea-hypopnea index (AHI) to be >15/hr, with <20% of the apneas central. The cNEP collar was applied at the start of a full night sleep study, and the negative pressure within the collar was titrated from -20 to -45 cmw, according to a protocol similar to that used for CPAP, to identify the optimal pressure for minimizing AHI. Response was categorized using criteria similar to those of the AASM for CPAP titration. An “excellent response” required a treatment AHI of <5/hr, and a “partial response” required a reduction in AHI of >50% from baseline, and an AHI of <15/hr.

Results

Fifteen subjects were studied. The mean age was 56 (range 39-65), 53% were males, and mean baseline AHI was 44 (20-80). Thirteen subjects (87%) were responders; nine (60%) showed an excellent response and four (27%) a partial response. In this small sample, neither age, gender, baseline AHI, BMI, Mallampati score, nor previously established effective CPAP pressure predicted a response. Three patients (20%) reported mild erythema or blistering around the collar site, which quickly resolved without treatment.

Conclusion

A high proportion of patients with documented OSA showed a response to cNEP, including those with high baseline AHIs. cNEP was well-tolerated. No predictors of response were identified. Further studies are indicated.

Support

This study was supported by Sommetrics, Inc. San Diego, CA.