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

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INTRODUCTION

- Obstructive sleep apnea (OSA) is a common and serious condition which results in significant cardiovascular, endocrine and neurocognitive comorbidity. It is estimated that 10-17% of males and 3-10% of females have OSA. (Peppard, 2013)
- Continuous positive airway pressure (CPAP) remains the first line therapy. Other therapies include oral appliances (OA), surgery, and genioglossal implants.
- With CPAP and OA, initial acceptance and adherence to therapy is poor. Other therapeutic options are needed to maximize compliance, and thus lead to better outcomes.
- We studied a novel treatment approach that avoids some important limitations of CPAP. Continuous negative external pressure (cNEP) is applied to the anterior upper airway by means of a soft silicone collar which, when applied to the neck, pulls the structures of the anterior airway forward, helping to prevent airway collapse. (Kato, 2015)
- cNEP has been shown to be effective in reducing respiratory impairment during conscious sedation. (Kais, 2016)
- This pilot study evaluated subjects with OSA to determine the efficacy, safety, and possible predictors of response to cNEP.

METHODS AND MATERIALS

Study Design

- Open label
- Two collar sizes were used to establish the one that fit best at a pressure of -25 cm water in the supine position
- Subjects who met all eligibility criteria were scheduled for overnight in-lab attended polysomnography (PSG) for titration of cNEP pressure
- Negative pressure range tested was between -20 and -45 cm water
- The study was approved by Western IRB

For investigational use only. Presented at SLEEP 2016.

Key Inclusion Criteria

- Male or female subjects
- Documented OSA
- PSG or Home Sleep Testing (HST) within the prior 6 months indicated AHI >15 and <20% central apneas
- Age 22-70 years old
- Subjects sign informed consent

Key Exclusion Criteria

- Severe cardiopulmonary or neurologic disease
- Excessive facial hair in the region where the cNEP collar is positioned
- Carotid vascular disease
- Previous major neck surgery or radiation therapy to the cervical region
- Anatomical abnormalities in the neck or pharyngeal region

Standard AASM protocols (2012) for the conduct of PSG and scoring of sleep and related respiratory data were used. Hypopnea was scored using the 4% criteria. The subject's response was categorized according to criteria similar to those of the AASM for response to CPAP titration.

An "excellent" response required the achievement of an AHI of <5, and a "partial" response required a reduction in AHI of >50%, with an AHI of <15/hr.

Fig 1: The cNEP collar fitted along the mandible over the upper airway.

RESULTS

Fifteen subjects were studied. The mean age was 56 (range 39–65), 53% were males, and mean baseline AHI was 43.9 (15.5–79.6). Thirteen subjects (87%) were responders; nine (60%) showed an excellent response and four (27%) a partial response.

Table 1. Demographics and Clinical Characteristics

n=15	MEAN	RANGE
Gender (8 M, 7 F)		
Age	56	39 - 65
BMI	34.8	25 - 48.6
Baseline AHI	43.9	15.5 - 79.6
Neck Circumference (cm)	40.5	33 - 48

Table 2. Key Findings (means)

	AGE	% MALE	BMI	MALLAMPATI	NECK CIRC	BL AHI*	BL CPAP**
Excellent responders n=9/60%	56	22%	35	3.8	37.6	37	9
Partial responders n=4/27%	56	100%	32	2.8	44.3	58	10
Non-responders n=2/13%	52	100%	40	4	46	44	16

* Baseline AHI; **Baseline CPAP Pressure

In this small sample, there were no clear predictors of a response.

ADVERSE EVENTS

Adverse events were limited to mild cutaneous erythema, at the site of contact of the cNEP collar with the neck (3/15 subjects). One subject developed mild blistering. In all cases, adverse events resolved spontaneously without clinical intervention.

LIMITATIONS

- Small sample size
- Single night in-laboratory PSG

DISCUSSION

New treatment options, which are efficacious and simple to use for patients with OSA, are greatly needed. This study has demonstrated that cNEP has the potential to improve OSA in patients with moderate to severe OSA. The wide range of baseline AHI, BMI and neck circumference suggests that a partial or excellent response can be expected in most patients with OSA. This technology shows promise for adding to available options for treatment of OSA with a favorable safety profile. In general, subjects found the collar to be comfortable and would be willing to try using the technology. No predictors of response were demonstrated in this sample.

CONCLUSIONS

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.

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