

# Continuous Negative External Pressure (cNEP) Reduces Respiratory Impairment During Conscious Sedation

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## INTRODUCTION

Sedatives and opiate analgesics administered during conscious sedation are associated with increased collapsibility of the upper airway. This may lead to respiratory impairment, with potentially serious clinical consequences.

Continuous negative external pressure (cNEP) is a novel approach to airway management. A soft silicone collar is affixed to the anterior neck (Fig 1). When a negative pressure is applied, the structures of the anterior airway are pulled forward, helping to retard airway collapse. We hypothesized that cNEP would lessen the occurrence of apneas and impaired oxygenation during a commonly performed gastrointestinal endoscopic procedure where conscious sedation is administered.

## METHODS

Adults undergoing screening colonoscopy were enrolled after providing informed consent. All received standard care, which included IV midazolam, an IV opioid, and nasal oxygen at 2L/min. Comprehensive monitoring was done with the Nox T3 respiratory monitor (CareFusion), which measures O<sub>2</sub> saturation, nasal airflow, and respiratory effort. If SpO<sub>2</sub> fell below 92%, the attending nurse was to increase the oxygen flow rate.

The primary outcome measure was Respiratory Impairment ("RI"), defined as either 1) an episode of apnea of ≥20 sec, or 2) a decline in SpO<sub>2</sub> of >4% from baseline.

The initial group of ~25 patients was to receive standard care ("no-cNEP" group). If >30% of this control group experienced at least one episode of RI, the next 25 - 30 patients would receive standard care plus cNEP. The cNEP collar was connected to a vacuum pump which maintained an internal negative pressure of -45 cm water.

Statistical analyses included the Student's t-test to compare means, and Fishers' exact test for dichotomous data. All p-values were two-sided, and no correction was made for multiple comparisons.

## RESULTS

The initial 24 patients received standard care ("no-cNEP" group) and the next 30 standard care plus cNEP. Two patients were excluded from analyses because of incomplete data.

### Demographics and Clinical Characteristics (Table 1)

- the two groups were well-matched on demographic and clinical characteristics, except that the cNEP group contained a greater proportion of women
- procedure time and drug doses were similar
- the cecum was intubated in every patient

**Table 1**

		OVERALL (N=54)	NO-CNEP (N=24)	CNEP (N=30)
Gender	F	27	9	18
	M	27	15	12
Age		59.5 ± 12.5	60 ± 12.2	60 ± 13
BMI		26 ± 5.1	25.9 ± 4.6	26.8 ± 5.6
STOP-BANG score		2.6 ± 1.6	2.8 ± 1.5	2.4 ± 1.8
Study duration (min)		27.1 ± 9.7	27.9 ± 8.2	26.4 ± 10.9
Midazolam total dose (mg)		5.4 ± 1.6	4.8 ± 1	5.1 ± 1.3
Meperidine total (mg)		84.8 ± 20.1	88.6 ± 24.1	81.5 ± 16.4

(means ± SD)

### Key Findings (Table 2)

- mean episodes of RI, the primary outcome measure, were reduced by 45% with cNEP (p=0.022)
- increased supplemental oxygen was required in 76% fewer patients receiving cNEP (p=0.01).
- the occurrence of apneas of ≥20 sec, ≥30 sec, and ≥1 min were all significantly reduced with cNEP

**Table 2**

	NO-CNEP (N=23)	CNEP (N=29)	P-VALUE
Respiratory impairment (mean episodes)	3.50 (2.3 - 4.6)	1.92 (1.1 - 2.8)	0.022
O <sub>2</sub> flow increased by nurse	42% (24% - 61%)	10% (3% - 26%)	0.01
Apneas of ≥20 sec (% of pts w/ any)	74% (53% - 88%)	28% (15% - 46%)	0.002
Apneas of ≥30 sec (% of pts w/ any)	65% (45% - 81%)	17% (7% - 35%)	< 0.001
Apneas of ≥1 min (% of pts w/ any)	26% (8% - 44%)	3% (0% - 9%)	0.035

(means, 95% Confidence Interval)

### Apneas of ≥20 Seconds (Table 3)

- mean episodes of apneas of all types were very significantly reduced with cNEP (p<0.001)
- mean number of obstructive apneas was reduced by 92% with cNEP (p=0.006)
- 82% fewer patients had an obstructive event with cNEP (p=0.007)
- mean episodes of mixed apnea were reduced (p=0.046)
- central apneas did not significantly differ between groups

**Table 3**

	NO-CNEP (N=23)	CNEP (N=29)	P-VALUE
<b>Apnea, all types</b>			
Mean	1.78 (0.97 - 2.60)	0.38 (0.10 - 0.66)	<0.001
Percent of patients with one or more	74% (53% - 88%)	28% (15% - 46%)	0.002
<b>Obstructive apneas</b>			
Mean	0.91 (0.31 - 1.61)	0.07 (0.0 - 0.22)	0.006
Percent of patients with one or more	39% (22% - 59%)	7% (1% - 23%)	0.007
<b>Central apneas</b>			
Mean	0.74 (0.11 - 1.22)	0.31 (0.06 - 0.56)	NS
Percent of patients with one or more	39% (22% - 59%)	24% (12% - 42%)	NS
<b>Mixed apneas</b>			
Mean	0.13 (0.03 - 0.38)	0.0 (0 - 0)	0.046
Percent of patients with one or more	13% (3% - 38%)	0% (0% - 0%)	NS

(means, 95% Confidence Interval)

### Findings Were Robust

Since this was a sequential assignment rather than a randomized study, propensity score matching and multiple imputation analysis were employed to progressively bias the results against showing cNEP success (data not shown). Both techniques showed that the cNEP effect remained robust despite the gender imbalance as well as other possible confounders.

### Adverse Events

Adverse events were limited to mild cutaneous erythema at the site of contact of the cNEP collar with the neck (40% of the cNEP group). In all cases this resolved spontaneously within 20 minutes of removal of the collar.

## SUMMARY

- apneas, sometimes prolonged, are common in patients undergoing conscious sedation for colonoscopy
- cNEP was highly effective in reducing respiratory impairment in this population
- the need for supplemental oxygen was reduced
- as would be expected by its mechanism of action, cNEP was especially successful in lessening the frequency of obstructive apneas
- cNEP was safe and well-tolerated

## CONCLUSIONS

- cNEP appears to be useful in maintaining a patent airway during conscious sedation
- it may also have applications in other situations where upper airway obstruction occurs, such as OSA and snoring



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