

# Treatment of Laryngopharyngeal Reflux Using a Sleep Positioning Device: A Prospective Cohort Study.

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**Introduction:** Laryngopharyngeal reflux (LPR) is defined as the reflux of gastroduodenal contents to the laryngopharynx, causing symptoms such as cough, globus, throat clearing, and hoarseness. Proton pump inhibitors (PPIs) are often used for treatment; however, these are often not effective. Among patients with LPR, nocturnal symptoms are common. Recent studies have demonstrated that use of a positional therapy device (PTD) significantly decreased typical gastroesophageal reflux symptoms; however, use of a PTD for LPR symptoms has not been previously studied.

**Methods:** This is a single center prospective trial of a PTD consisting of a two-component wedge-shaped base and a lateral positioning body pillow (MedCline, Amenity Health, Inc., San Diego, CA) in patients with a clinical diagnosis of LPR and nocturnal symptomology. Patients were supplied the PTD and asked to sleep using the device for at least 6 hours per night for 28 consecutive nights. Patients completed the Nocturnal Gastroesophageal Reflux Symptom Severity and Impact Questionnaire (NGSSIQ) and Reflux Symptoms Index (RSI) at baseline and after 2 and 4 weeks of PTD use. The primary endpoint of this study was reduction from baseline RSI at 4 weeks.

**Results:** A total of 23 patients (70% female; mean (SD): age  $60 \pm 12.9$ ; BMI  $28.1 \pm 8.0$ ) were recruited. 70% patients were on PPI prior to enrollment. At baseline, mean N-GSSIQ was  $50.0 \pm 7.9$  and mean RSI of  $22.5 \pm 9.6$ . All patients completed the study protocol. Matched-pair analysis showed that subjects' total NGSSIQ scores decreased by an average of 24.0 ( $p=0.0024$ ) points by two weeks and 30.5 points by 4 weeks ( $p=0.0002$ ). RSI decreased an average of 9.5 points by 2 weeks ( $p=0.015$ ) and an average of 16.8 points by 4 weeks ( $p=0.0023$ ). Mean RSI improvement at 2 weeks and 4 weeks was 42% and 75%, respectively. N-GSSIQ subsets all reached statistical significance at 4 weeks of use: nocturnal reflux ( $p=0.0019$ ), morning impact of nocturnal reflux ( $p=0.0002$ ) and concern about nocturnal reflux ( $p=0.0006$ ). No adverse events were reported, no patients withdrew from the study.

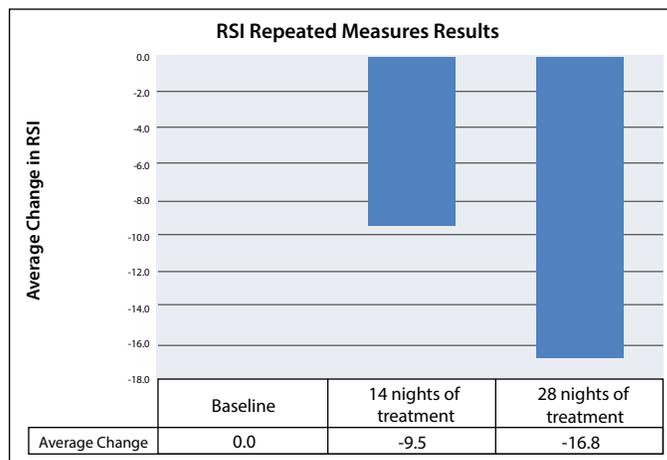


Figure 1 : RSI before and after use of SPD

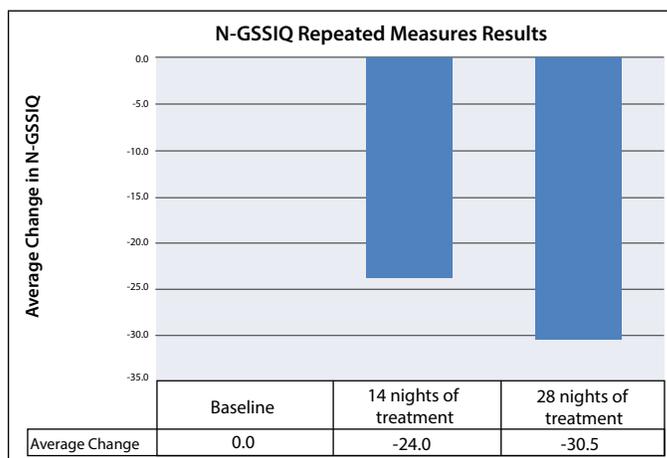


Figure 2 : N-GSSIQ before and after use of SPD

**Conclusion:** In patients with LPR, use of a PTD significantly improves self-reported symptoms of typical nocturnal reflux symptoms as well as symptoms specific to LPR. Use of a PTD may be considered as a potential treatment option for patients with nocturnal LPR symptoms.