

Use of a Positional Therapy Device Significantly Improves Nocturnal Gastroesophageal Reflux Disease Symptoms in Pregnant Women

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Introduction: Previous studies have demonstrated the benefit of using an incline wedge pillow inpatients with nocturnal gastroesophageal reflux disease (GERD). A positional therapy device (PTD) consisting of a 2-component incline base (9 inches in height) with a lateral positioned body pillow (MedCline, Amenity Health, Inc. San Diego, CA) has recently been shown to decrease nocturnal acid reflux in healthy volunteers. The goal of this study is to determine if the use of an PTD decreases nocturnal symptoms of GERD and improves sleep quality in pregnant women.

Methods: This is a single center prospective trial involving pregnant women in their second or third trimester with frequent moderate to severe nocturnal heartburn and regurgitation. Patients completed the Nocturnal GERD Symptom Severity and Impact Questionnaire (N-GSSIQ) and the Pittsburgh Sleep Quality Index (PSQI) at enrollment. The N-GSSIQ is a validated questionnaire comprised of three parts (Nocturnal GERD Symptoms, Morning Impact of GERD, Concern About Nocturnal GERD). The PSQI is a self-rated questionnaire which assesses sleep quality and disturbances, generated from seven component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Patients used the PTD every night for 2 weeks and then repeated the N-GSSIQ and the PSQI.

Results: A total of 17 pregnant women (age 30.7±4.5 years, pre-pregnancy BMI 27.8±5.9) were recruited from an outpatient obstetrics clinic. Significant improvements in N-GSSIQ total score (52.7 [pre] vs. 18.5[post], $p < 0.001$), Nocturnal GERD (32.8 vs. 9.7, $p < 0.001$), Morning Impact of Nocturnal GERD (6.6 vs. 2.8, $p < 0.001$) and Concern about Nocturnal GERD (13.5 vs. 6.2, $p < 0.001$) were noted. A significant improvement in PSQI global score (10.5 vs. 5.4, $p < 0.001$) was also noted. No adverse events were reported.

Table 1: Patient Characteristics

Factor	Total: N=17
Age at Baseline Survey (yrs)	30.7±4.5
Pre-Pregnancy BMI	27.8±5.9

Table 2 - N-GSSIQ Questionnaire

NGSSIQ	Baseline Survey	Post Survey	Paired t-test p-value
Nocturnal GERD	32.8±12.3	9.7±9.0	7.86 E-7
Morning Impact of Nocturnal GERD	6.6±2.6	2.8±2.9	0.000268
Concern about Nocturnal GERD	13.5±5.3	6.2±4.9	0.000262
Total N-GSSIQ Score	52.7±18.6	18.6± 5.3	2.05 E-6

Table 3 - PSQI

	Baseline Survey	Post Survey	Paired t-test p-value
Global PSQI score	10.5±3.0	5.4±2.7	8.46 E-6

Conclusion: In pregnant women with nocturnal heartburn and regurgitation, the PTD significantly reduced nocturnal GERD symptoms, morning impact of nocturnal GERD, concern about nocturnal GERD, and significantly improved overall sleep quality after two weeks of use.