EFFICACY OF COMBINING WEDGE PILLOW USE WITH SINGLE-DOSE PROTON PUMP INHIBITOR (PPI) VS. TWICE-DAILY PPI IN TREATING NOCTURNAL GASTROESOPHAGEAL REFLUX DISEASE (GERD) SYMPTOMS: A RANDOMIZED CONTROLLED TRIAL.

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Abstract

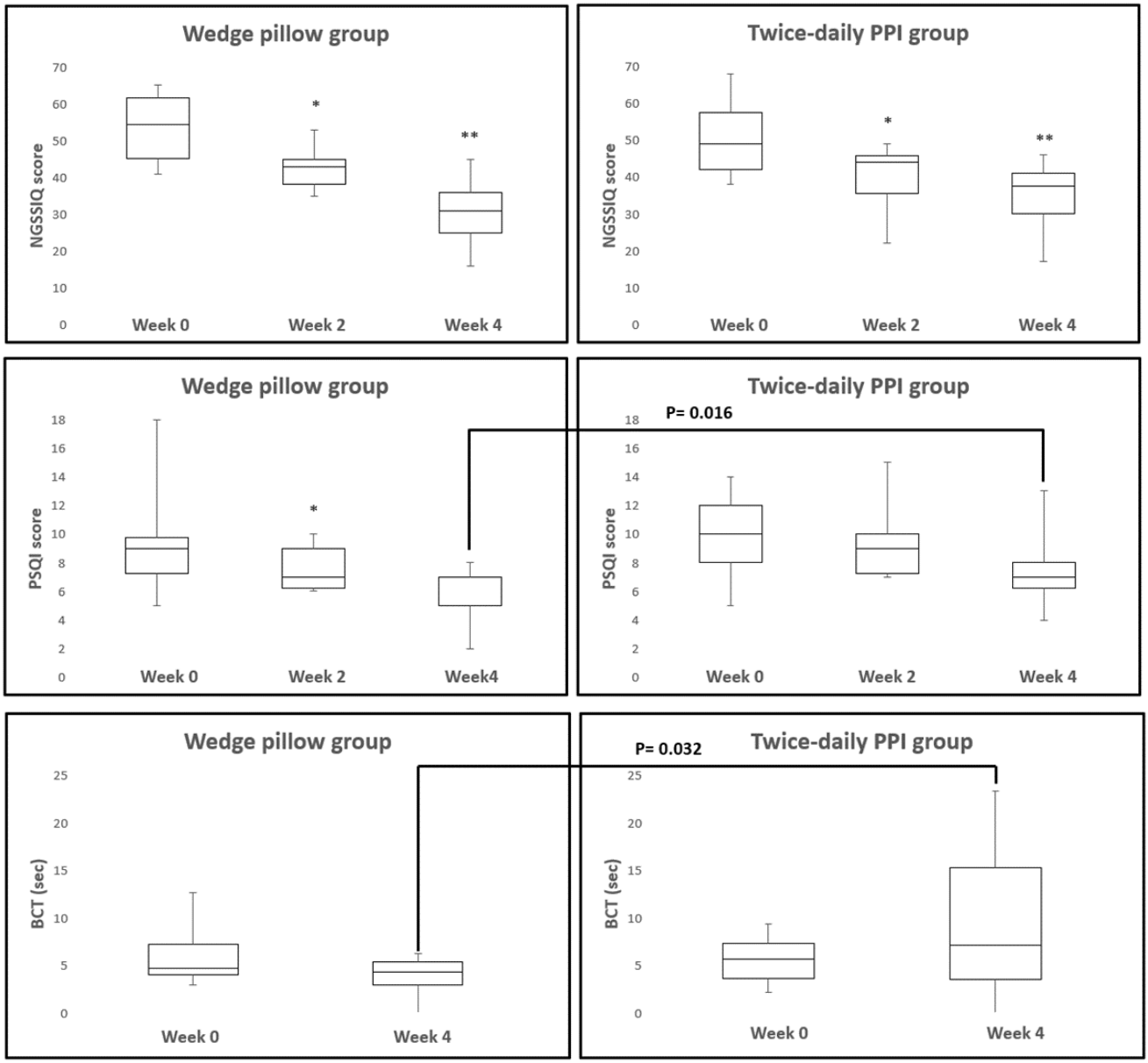
Certain GERD patients continue experience nocturnal symptoms with standard daily dose PPI. This study explores the efficacy of combining a wedge pillow with a morning single-dose PPI vs. twice-daily PPI for treating nocturnal reflux symptoms.

Methods: In this single-blinded study, we enrolled patients with ≥ 2 times/week of nocturnal heartburn and/or regurgitation despite a morning standard dose PPI for ≥ 4 weeks. Exclusions included severe OSA, morbid obesity, esophageal motility disorders, esophageal cancer, past esophageal surgery, and recently use of other acid suppressors. Participants were randomized into a 20-cm-head-elevation wedge pillow with a morning PPI or twice-daily PPI for 4 weeks. Nocturnal GERD symptoms evaluated by the nocturnal gastroesophageal reflux disease symptom severity and impact questionnaire (NGSSIQ) score at week 0, 2, 4. Quality of life, daytime sleepiness, and sleep quality were also assessed. 24-H pH-impedance monitoring was conducted at baseline and at the end of the 4th week. The pillow compliance was evaluated by electronic pressure-sensing timekeeper.

Results: Twenty-four patients (M:F 7:17, age 57±13 years) were enrolled. Baseline characteristics and NGSSIQ scores were similar between groups [NGSSIQ: wedge pillow 54.5 (45.2-61.8) vs. twice-daily PPI 49.0 (42.0-57.5),p>0.05]. After treatment, the NGSSIQ score in both group significantly decreased at week 2 and week 4 compared to the baseline (all p<0.05). Although, the NGSSIQ score at week 4 were not significantly different between groups, the changes from baseline to week 4 in wedge pillow group significantly higher than twice-daily PPI group [23.5 (16-26) vs. 11.5(9.3-21), p=0.02] Moreover, the sleep quality was significantly better in the pillow group than twice-daily PPI group [Pittsburgh sleep quality index: 5(5-7) vs. 7(6-8) points, p=0.01]. Bolus contact time during supine position at night the pillow group was significantly shorter than twice-daily PPI group (4.3(2.9-5.4) vs. 7.4(3.5-15.5) s, p = 0.032). However, quality of life, daytime sleepiness, number of refluxes, and acid exposure time were similar. The pillow with pressure sensor demonstrated an average of 8.7(8.4-9.9) hours of sleep per night. 66.6% (8/12) of participants in wedge pillow group reported minor adverse events such as neck and back pain. None of these participants discontinued their use, and all of them desired to continue using it.

Conclusion: The combination of wedge pillow and morning PPI had more efficacy in improving sleep quality and reducing bolus contact time than twice-daily PPI. Both interventions effectively alleviated nocturnal reflux symptoms with comparable effect. Participants exhibited good compliance with wedge pillow, reporting high preference for its use. This intervention might be an alternative approach for patients with nocturnal reflux symptoms.

<u>Figure 1</u> The box plot illustrates the median NGSSIQ score, PSQI score and bolus contact time with interquartile range for the wedge pillow group and the twice-daily PPI group at baseline and post-intervention.



*p<0.05 comparing week 0 vs. week 2 , **p<0.05 comparing week 0 vs. week 4

Table 1 **Study outcomes related to nocturnal GERD symptoms, quality of life, sleep quality, daytime sleepiness, and 24-hr esophageal pH parameters.**

	Wedge pillow group (N=12)			Twice-daily PPI group (N=12)			p value*
	Baseline	Week 2	Week 4	Baseline	Week 2	Week 4	
Primary endpoint (median, IQR)							
NGSSIQ	54.5 (45.3-61.8)	43 (38.3-45)	31 (25-36)	49 (42-57.5)	44 (35.5-45.8)	37.5 (30-41)	0.151
Secondary endpoints (median, IQR)							
36-Item short form survey (SF-36)							
- Physical component summary (PCS)	64.7 (41.3-76.1)	65.3 (53.1-71.6)	73.8 (67.5-86.1)	53.1 (43.6-68.1)	60 (52.3-72.5)	73.1 (55-80.6)	0.309
- Mental component summary (MCS)	63.1 (46.9-75.3)	65.5 (60.8-74)	77.7 (68.2-82.7)	53.5 (28.7-69)	56.7 (51.2-69.2)	73.9 (62.2-78.8)	0.396
Epworth sleepiness scale (ESS)	6 (4-9)	5 (4-6)	4 (3-6)	6 (4-10)	7 (4-8)	5 (3-7)	0.268
Pittsburg sleep quality index (PSQI)	9 (7-9)	7 (6-9)	5 (5-7)	10 (8-12)	9 (7-10)	7 (6-8)	**0.016**
pH-impedance parameters							
Number of reflux (times/night)	8 (5-10)		3 (2-5)	6 (4-11)		5 (2-7)	0.224
Proximal extension (cm) from LES	7 (5-9)		5 (5-7)	5 (5-7)		5 (5-9)	0.116
Bolus contact time at night (sec)	4.7 (4-7.2)		4.3 (2.9-5.4)	5.8 (3.8-7.7)		7.4 (3.5-15.5)	**0.032**
% Time pH<4 at distal esophagus	0.9% (0.2%-3.7%)		1.3% (0.1%-3.1%)	1.4% (0.9%-4.6%)		0.1% (0%-0.9%)	0.115
% Intragastric pH > 4	62.4% (46.9%-72.6%)		68.9% (54.6%-88.9%)	53.8% (40.8%-62.7%)		79.5% (60.6%-88.4%)	0.907

* The p-value signifies statistical significance when comparing differences between the baseline and week 4.