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# Investigation of the Effect of Laparoscopic Nissen Fundoplication on Sleep Quality: A Pilot Exploratory Study

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## Abstract

**Aim:** Gastroesophageal reflux disease (GERD) is a significant burden on the healthcare systems of countries. GERD can lead to poor sleep quality, which affects quality of life and worker productivity. The aim of this study was to investigate the effects of laparoscopic Nissen fundoplication (LNF), the surgical treatment for GERD, on sleep quality.

**Material and Methods:** The study was designed prospectively. The study included 40 patients with extraoesophageal reflux symptoms who underwent LNF. Patients' reflux symptoms and sleep quality were evaluated using the Reflux Symptom index (RSI) and the Pittsburgh Sleep Quality index (PSQI) preoperatively and at 1 month postoperatively.

**Results:** There was a statistically significant decrease in RSI and PSQI in the postoperative 1st month compared with preoperative values. Preoperative and 1st-month postoperative values for RSI were 23.775 and 4.775, respectively, and for PSQI were 11.250 and 5.580, respectively ($p<0.05$). There was no correlation between decreases in RSI and PSQI.

**Conclusion:** At 1 month postoperatively, LNF improved extraoesophageal reflux symptoms and sleep quality. No correlation was found between improvements in sleep quality and reflux symptoms.

**Keywords:** Poor sleep quality, laparoscopic Nissen fundoplication, extraoesophageal reflux symptoms

## Introduction

Gastroesophageal reflux disease (GERD) is the most common disease of the gastrointestinal (GI) tract (1). It has an important share in the health expenditures of countries (2). Gastroesophageal reflux (GER) is a clinical condition associated with reflux of gastric contents back into the oesophagus (1), causing uncomfortable symptoms and complications (3) and decreased quality of life (4). Low lower oesophageal sphincter (LES) pressure (usually less than 10 mmHg) and increased intragastric pressure are accepted mechanisms for the development of GER (5).

Laryngopharyngeal reflux (LPR) is the name given to the clinical condition in which GERD has atypical symptoms (hoarseness, sore throat, persistent cough, asthma, laryngospasm and less common symptoms) in the upper aerodigestive system (6). Reflux Symptom index (RSI) was developed by Belafsky et al. (7) to diagnose LPR, and its Turkish reliability and validity were evaluated by Akbulut et al. (8). Laparoscopic Nissen fundoplication (LNF) was introduced in 1991 (9) and attracted interest in the treatment of GERD (10). LNF aims to reduce reflux episodes by anatomically restoring the anti-reflux barrier (11). It provides a significant improvement in LES pressure (12). Studies have found the efficacy of LNF superior to proton pump inhibitors (PPI) for up to 2 years (13,14).

GERD has been associated with sleep disorders and impairments in daily functioning (1,5,15). Sleep disturbance due to GER is an important cause of decreased worker productivity (16). It is thought that there is a bidirectional relationship between GERD and sleep disorders (17). GER has previously been associated with increased sleep disturbance in various studies (15,18,19). Studies showing an

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increased incidence of GER in patients with sleep disorders are also available in the literature (20,21). Hung et al. (22) found that sleep quality decreased with increased nocturnal acid reflux. Patients with nocturnal reflux symptoms are more likely to experience sleep disturbance (23). Increased nocturnal acid reflux may be considered a preventable cause of poor sleep quality. Previous studies have shown that treatment of nocturnal GER (lifestyle changes, PPIs and antireflux surgery) improves both subjective and objective sleep measures (17). Indications for surgical treatment are failure of medical treatment, side effects of drugs or complications arising from GERD (24). Findings of an increase in quality of life with effective reduction of symptoms in GERD-related LPR were presented in the literature in previous studies (25,26).

The Pittsburgh Sleep Quality index (PSQI) was developed in 1989 for the evaluation of sleep disorders (27). In a previous study, it was reported that 52% of patients diagnosed with GERD experienced sleep disturbance defined as a PSQI score >5.5 (28). Information on the efficacy of LNF for sleep disturbance, one of the extraoesophageal symptoms associated with GERD, is limited in the literature.

In our study, we investigated the efficacy of LNF in improving sleep quality in patients whose extraoesophageal symptoms were evaluated using RSI. We assessed sleep quality using PSQI. The primary aim of our study was to evaluate the change in sleep quality 1 month after LNF. The secondary aim of our study was to examine the relationship between the effects of LNF on RSI and those on PSQI. According to our hypothesis, the change in RSI will parallel the change in PSQI after LNF.

## Materials and Methods

This study was designed prospectively. The study was conducted in accordance with the Declaration of Helsinki and the study was approved by Karamanoğlu Mehmetbey University Non-Interventional Clinical Research Ethical Committee (decision no: 08-2022/06, date: 31.08.2022). Permission to conduct the study at Karamanoğlu Mehmetbey University was obtained from the authorised committee of the hospital. The study was registered with the Australian New Zealand Clinical Trials Registry on 02.11.2022 (registration number ACTRN12622001406796). Participants were informed, and informed consent was obtained before participation in the study.

### Primary Outcome

Evaluation of the effects of LNF on sleep quality.

### Secondary Outcome

The effect of LNF operation on both RSI and PSQI, and the relationship between them, were determined.

### Study Population

Between September 2022 and November 2023, the study population consisted of individuals aged 18-65 years with extraoesophageal symptoms who were scheduled for LNF operation for a diagnosis of GER and who had signed written consent documents.

### Inclusion

Patients with documented GERD symptoms were included in the study. The diagnosis of GERD was confirmed by the clinical presence of oesophageal and extraoesophageal symptoms, by upper GI endoscopy (to provide evidence of oesophagitis), and by inadequate response to PPI therapy.

### Exclusion

Those who had previously undergone anti-reflux surgery and bariatric surgery, those with achalasia and other oesophageal motility disorders, those with chronic diseases that were not in remission (such as uncontrolled diabetes), those who could not read and write Turkish, those with psychiatric disorders, those who did not give consent and those who could not complete the questionnaires were excluded from the study (29).

### Evaluation of GER Symptoms

Patients admitted for LNF procedure were evaluated using the RSI in face-to-face interviews on the morning of the operation and at 1 month after discharge, when they presented to our hospital for outpatient follow-up. The purpose of using the RSI was to accurately document the improvement in postoperative extraoesophageal symptoms. The RSI is a 9-item questionnaire that can be completed in less than 5 minutes, with a maximum score of 45 points. The scale for each question ranges from 0 (no problem) to 5 (serious problem). An RSI score higher than 13 indicates the presence of LPR (7,29). The RSI was developed in 2002 (7). Turkish validation was performed in 2020 (8).

### Assessment of Sleep Quality

Patients who underwent LNF were evaluated using the PSQI on the morning of the operation and at 1 month after discharge. PSQI was developed in 1989 for the evaluation of sleep disorders (27). In 1996, Turkish validation was performed by Ağargün et al. (30). The PSQI is a 19-item questionnaire that assesses self-reported sleep quality. It evaluates subjective sleep quality, sleep latency (sleep transition time), sleep duration, habitual sleep

efficiency, sleep disorders, sleep medication use and daytime dysfunction in a 1-month period (27).

### Surgical Technique

Laparoscopic surgery was performed using a standard technique under general anaesthesia. Induction of anaesthesia was performed using propofol, rocuronium, and fentanyl, dosed according to ideal body weight. Maintenance anaesthesia was provided with 2% sevoflurane in a 50% air-50% $O_2$ mixture. The intraoperative process was monitored by the anaesthesiologist involved in the study.

The patient was placed on the operating table in the supine position with the legs suspended. Five trocars were placed: at the umbilicus (10 mm) for the optical port; at the right midclavicular line (10 mm) for the liver retractor; at the subxiphoid (10 mm) and the left midclavicular line (5 mm) for the working ports; and at the left anterior axillary line (5 mm) for the assistant port. After excluding the liver, the stomach was pulled from the fundus, and the distal oesophagus was exposed with an ultrasonic dissector. The right and left diaphragmatic crura were exposed while preserving the vagus nerve. The oesophagus was suspended. The right and left crura were approximated with 3 number-0 silk sutures. Then the fundus of the stomach was mobilised by separating it from the spleen through division of the short gastric vessels. The fundus of the stomach was then pulled behind the abdominal oesophagus to create a 360-degree fundoplication. Three 2/0 silk sutures were used for fundoplication. Looseness of the fundoplication was checked, bleeding was controlled, and the operation was completed. All trocars were withdrawn under endocamera guidance (31).

Patients were hospitalised for at least 1 day. Swallowing functions were evaluated before discharge. They were discharged when no problems were observed. A liquid diet was given for the first 10 postoperative days. Solid foods were introduced slowly to prevent dysphagia caused by mucosal oedema (31).

The need for re-hospitalisation, emergency surgery, or elective surgery was assessed at the 1st postoperative month.

### Statistical Analysis

The data obtained in the study were analysed using SPSS (Statistical Package for Social Sciences) for Windows, version 22.0. Number, percentage, mean, and standard deviation were used as descriptive statistical methods in the evaluation of the data. A dependent-groups t-test was used to compare repeated measurements. Pearson's correlation analysis was performed between continuous variables.

## Results

Forty-four patients who underwent LNF were enrolled. 1 patient was excluded because he was over 65 years of age, and 3 patients did not attend the planned outpatient clinic visit at the end of the 1st postoperative month. Data from 40 patients were analysed. The findings on the patients' descriptive characteristics are presented below.

When the descriptive characteristics of the patients were analysed according to Table 1, the mean age of the sample was calculated as 41.57±10.22 years. When body mass index (BMI) categories were analysed, 72.5% of the patients were overweight, 20% were normal weight and 7.5% were Obesity class 1 (32).

**Table 1. Distribution of patients according to identifier characteristics**

| Groups | Variable (N) | Percentage (%) |
|---|---|---|
| **Sex** | | |
| Male | 10 | 25.0 |
| Female | 30 | 75.0 |
| **BMI** (kg/m$^2$) | | |
| 18.5<BMI<24.9 (normal weight) | 8 | 20.0 |
| 25<BMI<29.9 (overweight) | 29 | 72.5 |
| 30<BMI <34.9 (obesity class 1) | 3 | 7.5 |
| **Smoking status** | | |
| Yes | 12 | 30.0 |
| None | 28 | 70.0 |
| **Alcohol use status** | | |
| Yes | 3 | 7.5 |
| None | 37 | 92.5 |

| Table 1. Continued | | |
|---|---|---|
| **Groups** | **Variable (N)** | **Percentage (%)** |
| **PPI drug use status** | | |
| Yes | 30 | 75.0 |
| None | 10 | 25.0 |
| | **Mean** | **SD** |
| **Age** | 41,570 | 10,223 |
| **Height (cm)** | 164,880 | 6,568 |
| **Weight (kg)** | 72,780 | 8,707 |
| **BMI (kg/m²),** | 26,737 | 2,431 |
| BMI: Body mass index (kg/m²), PPI: Proton pump inhibitor, SD: Standard deviation, [1]n (%); Mean ± SD; median (25%-75%) | | |

This distribution shows that females and overweight individuals predominated in the sample.

The distribution by smoking status showed that 30% of the patients were smokers and 70% were non-smokers. The prevalence of alcohol use was: only 7.5% of patients used alcohol. Analysis of PPI use showed that 75% of the patients used these drugs.

According to the sleep quality components in Table 2, significant improvements were observed postoperatively compared with preoperatively. The overall sleep quality score decreased from a preoperative mean of 11.25 to a postoperative mean of 5.58, and the difference was statistically significant (t=10.725, p=0.000).

Analysis of the subcomponents showed that the subjective sleep quality score decreased from 1.75 preoperatively to 0.50 postoperatively (t=10.648, p=0.000). Postoperative sleep latency, the time to fall asleep, decreased significantly from 2.30 to 1.30 (t=6.774, p=0.000).

Sleep duration also increased postoperatively, and the scores decreased from 1.23 preoperatively to 0.7 postoperatively. This difference was statistically significant (t=3.365, p=0.002). Although a small change was observed in the sleep efficiency component (from 0.88 to 0.60), this difference was not statistically significant (t=1.638, p=0.109). This result may indicate that patients' habits of going to bed and getting up were preserved postoperatively.

The s leep disturbance score decreased from 2.90 preoperatively to 1.73 postoperatively, and this difference was statistically significant (t=5.262, p=0.000).

A postoperative decrease in the use of sleeping pills (0.65 before, 0.33 after) was observed, and this decrease was statistically significant (t=2.481, p=0.018).

A postoperative decrease was observed in the use of sleeping pills (from 0.65 to 0.33), and this decrease was statistically significant (t=2.481, p=0.018).

Finally, a significant improvement in daytime dysfunction was observed (t=6.260, p=0.000). These data may support the conclusion that the operation improved patients' overall sleep quality.

Results of the reflux assessment (Table 3) show that the operation resulted in a significant improvement in reflux symptoms. T he mean reflux assessment score was 23.775 before the operation and decreased to 4.775 after the operation. This difference was statistically significant (t=15,149, p=0,000).

According to the correlation analysis in Table 4 and Figure 1, a strong and positive relationship was found between the before and after measures of sleep quality (r=0.713, p=0.000). This correlation suggests that individuals show continuity in sleep quality. Similarly, the before-and-after measures of reflux assessment show a significant correlation (r=0.434, p=0.005). There is a moderate positive correlation between previous measurements of sleep quality and reflux assessment (r=0.511, p=0.001). A significant correlation was also found between the subsequent sleep quality and reflux assessment measurements (r=0.579, p=0.000), suggesting that changes in sleep quality may be related to reflux symptoms. Although there was no significant correlation between change in sleep quality and change in reflux assessment (r=0.161, p=0.320), the change in reflux assessment was strongly and negatively correlated with the previous reflux assessment score (r=0.807, p=0.000), suggesting that changes in reflux symptoms may differ depending on the initial reflux level.

Complications were evaluated in individuals who underwent LNF for a diagnosis of GERD. There was no need for re-hospitalisation, emergency surgery, or elective surgery in the 1st postoperative month.

**Table 2. Sleep quality components**

| | Preoperative | | Postoperative 1st month | | N | t | p |
|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | |
| PSQI score | 11,250 | 3,835 | 5,580 | 4,722 | 40 | 10,725 | 0,000* |
| Subjective sleep quality | 1,750 | 0,776 | 0,500 | 0,784 | 40 | 10,648 | 0,000* |
| Sleep latency | 2,300 | 1,018 | 1,300 | 1,181 | 40 | 6,774 | 0,000* |
| Sleep duration | 1,230 | 1,074 | 0,700 | 0,966 | 40 | 3,365 | 0,002* |
| Habitual sleep activity | 0,880 | 1,202 | 0,600 | 1,033 | 40 | 1,638 | 0,109 |
| Sleep disorders | 2,900 | 0,496 | 1,730 | 1,450 | 40 | 5,262 | 0,000* |
| Sleep medication use | 0,650 | 1,145 | 0,330 | 0,764 | 40 | 2,481 | 0,018* |
| Daytime dysfunction | 1,550 | 1,300 | 0,420 | 0,813 | 40 | 6,260 | 0,000* |

PSQI: Pittsburgh Sleep Quality index, SD: Standard deviation, [1]n (%); Mean ± SD; median (25%-75%), *The p-value is <0.05

**Table 3. Reflux evaluation measurements**

| | Preoperative | | Postoperative 1st month | | N | t | p |
|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | |
| RSI score | 23,775 | 8,657 | 4,775 | 5,196 | 40 | 15,149 | 0,000* |

RSI: Reflux Symptom index, SD: Standard deviation, [1]n (%); Mean ± SD; median (25%-75%), *p-value is below the threshold of <0.05

**Table 4. Correlation analysis for preoperative and postoperative 1st month RSI and PSQI values**

| | | Preoperative PSQI score | Preoperative 1st mouth PSQI score | Preoperative RSI score | Postoperative 1st mouth RSI score | Sleep quality change | Reflux evaluation change |
|---|---|---|---|---|---|---|---|
| **Preoperative PSQI score** | r | 1,000 | | | | | |
| | p | 0,000 | | | | | |
| **Preoperative 1 st mouth PSQI score** | r | 0,713* | 1,000 | | | | |
| | p | 0,000 | 0,000 | | | | |
| **Preoperative RSI score** | r | 0,511* | 0,494* | 1,000 | | | |
| | p | 0,001 | 0,001 | 0,000 | | | |
| **Postoperative 1st mouth RSI score** | r | 0,336* | 0,579* | 0,434* | 1,000 | | |
| | p | 0,034 | 0,000 | 0,005 | 0,000 | | |
| **PSQI change** | r | -0,140 | 0,595* | 0,111 | 0,432* | 1,000 | |
| | p | 0,388 | 0,000 | 0,494 | 0,005 | 0,000 | |
| **RSI change** | r | -0,338* | -0,160 | -0,807* | 0,182 | 0,161 | 1,000 |
| | p | 0,033 | 0,324 | 0,000 | 0,262 | 0,320 | 0,000 |

RSI: Reflux Symptom index, PSQI: Pittsburgh Sleep Quality index, *p-value is below the threshold of <0.05

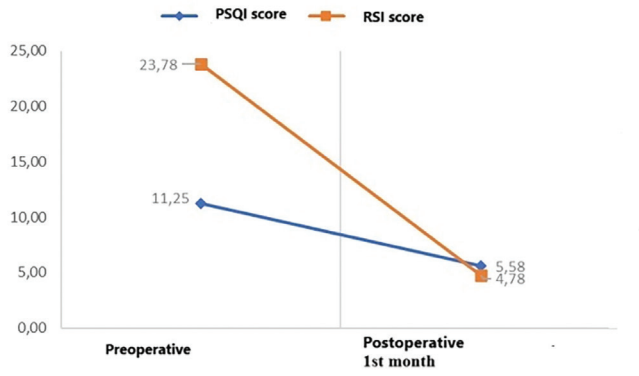


**Figure 1.** The effect of LNF on RSI and PSQI values preoperatively and at 1 month postoperatively

RSI: Reflux Symptom index, PSQI: Pittsburgh Sleep Quality index, LNF: Laparoscopic Nissen fundoplication

## Discussion

In our study, individuals diagnosed with GERD who underwent LNF showed improvement in RSI and PSQI values at the end of the 1st postoperative month compared with preoperative values. No statistically significant correlation was observed between preoperative and postoperative 1st-month changes in RSI and PSQI. This may indicate that LNF has positive but limited effects on improving poor sleep quality. According to the results of our study, habitual sleep efficiency did not show a statistically significant improvement. This result may support the idea that individuals' sleep quality is significantly affected by habits acquired over time.

Obesity, alcohol and smoking are known risk factors for GERD (33). In previous studies, it was found that increased oesophageal acid load caused an increase in symptoms in individuals with obesity (34). The same study concluded that obesity was not effective on oesophageal motor functions (34). When the demographic data of the participants with GERD in our study were analysed, 72.5% of the patients who underwent LNF operation were found to be 25<BMI<29.9 (overweight) (35). The rates of smoking and alcohol use were 30% and 7.5%, respectively. The high prevalence of elevated BMI is consistent with previous studies (36,37). In our study, the rate of alcohol and cigarette use, which we thought was related to the high number of female participants, was low.

In our study, the efficacy of LNF for GERD was evaluated using RSI. RSI is an easily applicable and reproducible tool that can determine the severity of symptoms for LPR in patients diagnosed with GERD (7). The mean RSI values at the end of the preoperative period and the postoperative 1st month were 23.775 and 4.775, respectively (Table 3). This finding suggests that LNF is effective in the treatment of LPR caused by GERD.

In our study, the effects of LNF on sleep quality were evaluated using the PSQI. PSQI scores at the preoperative and postoperative 1st-month time points were compared. The mean total sleep quality scores at the two time points were 11.250 and 5.580 for the preoperative and postoperative 1st month, respectively. This difference was statistically significant (p=0.000). The PSQI is the most commonly used assessment tool among clinical and non-clinical populations (38). It can assess both quantitative aspects of sleep (i.e. sleep duration, sleep latency, number of awakenings) and subjective aspects (depth or restfulness) (38). The total score on the PSQI is between 0 and 21. Scores of 0-5 are associated with good sleep quality and scores of 5 and above are associated with poor sleep quality (27). Our results show that poor preoperative sleep quality improved after LNF. However, the postoperative 1st-month PSQI mean values were above 5. This result may be related with many conditions affecting sleep quality such as obesity, hormonal changes, personal obligations, and differences in emotional state (39). In our study, 80% of our participants had high BMI. The fact that the PSQI values of our participants did not fall below 5 may support the presence of obesity-related sleep disorders.

In our study, 75% of the participants were using PPIs. Patients who underwent upper GI endoscopy and surgery continued their current PPI use. There is no consensus regarding whether PPI use should be discontinued before anti-reflux surgery. In our study, PPI use was not stopped preoperatively considering the risk of development of acid hyper secretion with abrupt discontinuation of PPI (40). We emphasise the importance of evaluating the effects of LNF on sleep quality in patients not using PPI in future studies. Our sample size was insufficient to assess this parameter.

Dysphagia after LNF is an undesirable but possible complication (12). Dysphagia, which is a parameter evaluated by the RSI, may have affected our results, given our short follow-up period. Although this effect could not be ruled out, we observed a statistically significant decrease in RSI after LNF. We emphasise that future studies should include a longer follow-up period to reduce this effect.

### Study Limitations

Our study has limitations. Our study was conducted at a single centre, and the operations were performed by a single surgeon. This is advantageous for data standardisation. However, it is disadvantageous for generalising the results. The short follow-up period can be considered another limitation. We preferred to keep our follow-up period short to ensure participants' continued participation in the study and to observe the effect of the acquired sleep habits. We did not calculate the sample size because the number of participants was relatively small. We

hope that professional organisations will develop collaborative approaches to facilitate data collection for specialised surgeries such as LNF.

We hope that future studies will employ methodologies to eliminate the effect of PPI use. We also emphasise that the efficacy of LNF should be evaluated with longer follow-up periods.

## Conclusion

This study was conducted to evaluate the effect of LNF on sleep quality. The study found that sleep quality improved in individuals with extraoesophageal symptoms of GERD who underwent LNF. However, this improvement was not as significant as that observed in the extraoesophageal symptoms of GER. Our findings support the notion that sleep quality may be affected by multiple conditions. In particular, we reported that habitual sleep patterns did not change 1 month after LNF. The study supports the idea that sleep quality, which plays an important role in increasing employee productivity, may improve with LNF. We suggest that future studies with longer follow-up periods will contribute to the literature.

This study showed that LNF is an effective treatment protocol for reducing the extraoesophageal symptoms of GERD and contributes to improving sleep quality, although the improvement in sleep quality is smaller than the improvement in extraoesophageal reflux symptoms.

### Ethics

**Ethics Committee Approval:** The study was conducted in accordance with the Declaration of Helsinki and the study was approved by Karamanoğlu Mehmetbey University Non-Interventional Clinical Research Ethical Committee (decision no: 08-2022/06, date: 31.08.2022).

**Informed Consent:** Participants were informed, and informed consent was obtained before participation in the study.

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### Footnotes

### Authorship Contributions

Surgical and Medical Practices: Ş.S.T., C.P., H.P., Concept: Ş.S.T., H.P., Design: Ş.S.T., C.P., H.P., Data Collection or Processing: H.P., Analysis or Interpretation: Ş.S.T., H.P., Literature Search: H.P., Writing: Ş.S.T., H.P.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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