doi: 10.53446/actamednicomedia.1635665

Acta Medica Nicomedia

Cilt: 8 Sayı: 3 Ekim 2025 / Vol: 8 Issue: 3 October 2025
https://dergipark.org.tr/tr/pub/actamednicomedia

Research Article | Araştırma Makalesi

EVALUATION OF QUALITY OF LIFE IN PATIENTS UNDERGOING LAPAROSCOPIC NISSEN FUNDOPLICATION FOR GASTROESOPHAGEAL REFLUX DISEASE USING THE GERD-HRQL SCALE

GASTROÖZOFAGEAL REFLÜ HASTALIĞI NEDENİYLE LAPAROSKOPİK NİSSEN FUNDOPLİKASYON UYGULANAN HASTALARDA GERD-HRQL ÖLÇEĞİ İLE YAŞAM KALİTESİNİN DEĞERLENDİRİLMESİ

Mehmet Fatih Ozsaray[1*], Turgay Simsek[1], Nuh Zafer Canturk[1]

[1]Kocaeli University, Faculty of Medicine, Department of General Surgery, Kocaeli, Türkiye.

ABSTRACT

Objective: The aim of this study was to evaluate changes in the quality of life among patients who underwent laparoscopic Nissen fundoplication (LNF) for gastroesophageal reflux disease (GERD) using the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) scale.

Methods: Between June 2019 and June 2024, 300 patients who underwent LNF at our clinic were retrospectively reviewed, and those meeting the inclusion criteria were selected. The GERD-HRQL scale was administered preoperatively and postoperatively to assess quality of life. The scale was administered face-to-face with explanatory guidance to ensure accurate responses. The collected data were statistically analyzed.

Results: Preoperative GERD-HRQL scores indicated significantly impaired quality of life and severe symptoms, including heartburn, regurgitation, and chest pain. Postoperatively, 82% of patients exhibited significant improvements in symptom scores, with mean GERD-HRQL scores decreasing from 24.8 to 6.3 ($p<0.001$). Notable symptom improvements were observed in heartburn (85% reduction) and regurgitation (68% reduction).
Patient satisfaction was high postoperatively, with 90% reporting improved quality of life and overall satisfaction with the procedure. Mild complications, such as dysphagia (5%) and transient gas-related complaints (8%), were reported but resolved without long-term consequences.

Conclusion: LNF was an effective surgical intervention for alleviating symptoms of GERD and improving HRQL. This study highlights the clinical benefits of LNF in managing GERD symptoms and enhancing quality of life. Further multicenter and prospective studies are needed to assess the long-term outcomes of the procedure. The GERD-HRQL scale serves as a valuable tool for objectively evaluating surgical outcomes and standardizing assessments of surgical success.

Keywords: Laparoscopic Nissen fundoplication, gastroesophageal reflux, quality of life, GERD-HRQL

ÖZ

Amaç: Bu çalışmanın amacı, gastroözofageal reflü hastalığı (GERD) nedeniyle laparoskopik Nissen fundoplikasyon (LNF) uygulanan hastalarda yaşam kalitesindeki değişimi, Gastroözofageal Reflü Hastalığına Özgü Yaşam Kalitesi (GERD-HRQL) ölçeği kullanarak değerlendirmektir.

Yöntem: Haziran 2019 ile Haziran 2024 tarihleri arasında kliniğimizde LNF uygulanan 300 hasta retrospektif olarak incelendi ve dahil edilme kriterlerini karşılayan hastalar çalışmaya dahil edildi. GERD-HRQL ölçeği, yaşam kalitesini değerlendirmek amacıyla preoperatif ve postoperatif dönemlerde uygulandı. Ölçek, doğru yanıtların alınabilmesi amacıyla yüz yüze ve açıklayıcı rehberlik eşliğinde gerçekleştirildi. Elde edilen veriler istatistiksel olarak analiz edildi.

Bulgular: Preoperatif GERD-HRQL skorları, yaşam kalitesinde belirgin bozulma ve şiddetli semptomları (özellikle mide yanması, regürjitasyon ve göğüs ağrısı) ortaya koydu. Postoperatif dönemde hastaların %82'sinde semptom skorlarında anlamlı düzelmeler gözlendi ve ortalama GERD-HRQL skoru 24,8'den 6,3'e düştü ($p<0,001$). Özellikle mide yanmasında %85, regürjitasyonda ise %68 oranında belirgin iyileşmeler kaydedildi.

Postoperatif dönemde hasta memnuniyeti yüksekti; hastaların %90'ı yaşam kalitesinde artış ve genel memnuniyet bildirdi. Hafif komplikasyonlar arasında disfaji (%5) ve geçici gazla ilişkili yakınmalar (%8) yer aldı; bu durumlar uzun vadeli sonuçlara yol açmadan kendiliğinden düzeldi.

Sonuç: LNF, GERD semptomlarının hafifletilmesi ve yaşam kalitesinin artırılması açısından etkili bir cerrahi yöntemdir. Bu çalışma, LNF'nin klinik yararlarını ve yaşam kalitesi üzerindeki olumlu etkilerini ortaya koymaktadır. Uzun dönem sonuçların değerlendirilmesi amacıyla çok merkezli ve prospektif çalışmalara ihtiyaç vardır. GERD-HRQL ölçeği, cerrahi sonuçların nesnel olarak değerlendirilmesi ve başarı kriterlerinin standartlaştırılması açısından değerli bir araçtır.

Anahtar Kelimeler: Laparoskopik Nissen fundoplikasyon, gastroözofageal reflü, yaşam kalitesi, GERD-HRQL

***Corresponding author/İletişim kurulacak yazar:** Mehmet Fatih Ozsaray; Kocaeli University, Faculty of Medicine, Department of General Surgery, Kocaeli, Türkiye.
Phone/Telefon: +90 (505) 775 01 10, **e-mail/e-posta:** f_ozsaray@hotmail.com
Submitted/Başvuru: 07.02.2025 • **Accepted/Kabul:** 14.07.2025 • **Published Online/Online Yayın:** 22.10.2025

Introduction

Gastroesophageal reflux disease (GERD) is a common gastrointestinal disorder characterized by the backflow of stomach contents into the esophagus. This condition not only leads to bothersome symptoms but can also result in esophageal mucosal damage and reduced quality of life. While proton pump inhibitors are frequently used to manage GERD, surgical intervention may be necessary for some patients.

Laparoscopic Nissen fundoplication (LNF) is a well-established surgical procedure for treating GERD, aimed at restoring the functionality of the lower esophageal sphincter (LES) by wrapping the stomach's fundus around the esophagus. The effectiveness of the procedure is typically assessed based on symptom relief and improvements in quality of life.

The Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) scale, a disease-specific tool, is widely used to evaluate changes in symptoms and quality of life before and after surgery. This study used the Turkish version of the GERD-HRQL scale to assess quality-of-life improvements in patients undergoing LNF at a single tertiary center.

Methods

Study Design and Patient Selection

This study was designed as a retrospective analysis of prospectively collected data. Patients who underwent laparoscopic Nissen fundoplication (LNF) at a single tertiary referral center between June 2019 and June 2024 were reviewed.

Inclusion criteria were:

1. Age between 18 and 65 years,
2. A confirmed diagnosis of gastroesophageal reflux disease (GERD) based on upper gastrointestinal endoscopy and 24-hour ambulatory pH monitoring,
3. Completion of the Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) scale in both the preoperative and postoperative periods.

Exclusion criteria included:

- Previous upper gastrointestinal or antireflux surgery,
- Severe comorbidities (e.g., advanced cardiopulmonary disease, malignancy),
- Documented psychiatric or cognitive disorders affecting the ability to respond to the questionnaire,
- Incomplete or missing preoperative or postoperative follow-up data.

Eligible patients were identified via electronic medical records. All procedures were performed by the same surgical team using a standardized technique.

This study was approved by the Ethics Committee of Non-Interventional Clinical Research, Faculty of Medicine, Kocaeli University (Date: 22.08.2024, Decision No: KÜ GOKAEK 2024/13.04). All patients provided written informed consent prior to inclusion in the study. The study adhered to the ethical standards of the Declaration of Helsinki, revised in 2013.

Quality of Life Measurement

Quality of life was evaluated using the Turkish-adapted version of the GERD-HRQL scale. The questionnaire was administered face-to-face by trained personnel both before surgery and during a standardized postoperative follow-up at 6 months**.** The scale consists of 10 items rated from 0 (no symptoms) to 5 (incapacitating symptoms), yielding a maximum score of 50, where higher scores reflect worse symptom burden.

To ensure accuracy, patients were guided through the questionnaire with standardized instructions and clarifications when needed.

A clinically significant improvement was defined as a reduction of ≥50% in the total GERD-HRQL score, in accordance with previous validation studies.

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA).

- Normality of data distribution was assessed using the Shapiro-Wilk test**.**
- For normally distributed variables**,** paired t-tests were used to compare pre- and postoperative scores; for non-normally distributed variables, the Wilcoxon signed-rank test was applied.
- Data are presented as mean ± standard deviation (SD) for normally distributed variables, and median with interquartile range (IQR) for non-parametric data.
- Confidence intervals (95% CI) were calculated for main outcomes.
- Effect sizes (Cohen's d for parametric data, or rank biserial correlation for non-parametric data) were calculated to assess the clinical significance of the observed differences.

A post hoc power analysis indicated that the sample size (n = 300) was sufficient to detect a large effect size (d = 0.8) with a power of 95% at a two-sided alpha of 0.05.

Results

A total of 300 patients who underwent LNF between June 2019 and June 2024 were included in the analysis. The mean age was 44.5 ± 12.3 years (95% CI: 43.1-45.9) and the mean body mass index (BMI) was 27.8 ± 3.5 kg/m² (95% CI: 27.4-28.2). Of the participants, 204 (68%) were male**,** and 96 (32%) were female (Table 1)**.**

Preoperative Symptom Burden

The median preoperative total GERD-HRQL score was 25.0 (IQR: 22.0-27.0), indicating significantly impaired quality of life. The most frequently reported symptoms were:

- Heartburn: 255 patients (85%)
- Regurgitation: 204 patients (68%)
- Chest pain: 156 patients (52%)
- Dysphagia: 135 patients (45%)

Table 1. Demographic and Clinical Characteristics of Patients (n = 300)

Characteristic	Value
Age, years (mean ± SD)	44.5 ± 12.3 (95% CI: 43.1-45.9)
Gender, n (%)	Male: 204 (68%) Female: 96 (32%)
BMI, kg/m² (mean ± SD)	27.8 ± 3.5 (95% CI: 27.4-28.2)
Presence of hiatal hernia, n (%)	98 (32.7%)
Preoperative proton pump inhibitor use	300 (100%)
Smoking history, n (%)	88 (29.3%)
Duration of GERD symptoms (years)	Median: 5.0 (IQR: 3.0-7.0)
Previous foregut surgery	None (Exclusion criterion)

Postoperative Outcomes

Postoperative assessments were conducted at 6 months after surgery.

The mean total GERD-HRQL score decreased from 24.8 ± 4.7 (95% CI: 23.9-25.7) to 6.3 ± 3.1 (95% CI: 5.9-6.7); this reduction was statistically significant ($p < 0.001$) with a very large effect size (Cohen's d = 4.0)**.**

Subscale Symptom Improvements:

- **Heartburn score**: from 12.3 ± 2.8 (95% CI: 11.8-12.8) to 1.8 ± 1.6 (95% CI: 1.5-2.1) → $p < 0.001$**,** 85% reduction**,** d = 4.3
- **Regurgitation score**: from 8.1 ± 2.5 (95% CI: 7.6-8.6) to 2.6 ± 1.9 (95% CI: 2.3-2.9) → $p < 0.001$**,** 68% reduction**,** d = 3.1
- **Chest pain score**: from 6.4 ± 2.7 to 2.2 ± 1.8 → $p < 0.001$**,** d = 2.2
- **Dysphagia score**: from 5.8 ± 2.6 to 1.5 ± 1.3 → $p < 0.001$**,** d = 2.5

A clinically significant improvement, defined as a ≥50% reduction in total GERD-HRQL score, was achieved in 246 patients (82%; 95% CI: 77.6-86.4) (Table 2)**.**

Table 2. Preoperative and Postoperative GERD-HRQL Scores and Symptom Improvements

Symptom	Preoperative (Mean ± SD, 95% CI)	Postoperative (Mean ± SD, 95% CI)	p-value	Effect Size (Cohen's d)	% Reduction
Total GERD-HRQL score	24.8 ± 4.7 (23.9-25.7)	6.3 ± 3.1 (5.9-6.7)	< 0.001	4.0	74.6%
Heartburn	12.3 ± 2.8 (11.8-12.8)	1.8 ± 1.6 (1.5-2.1)	< 0.001	4.3	85.4%
Regurgitation	8.1 ± 2.5 (7.6-8.6)	2.6 ± 1.9 (2.3-2.9)	< 0.001	3.1	67.9%
Chest pain	6.4 ± 2.7 (5.9-6.9)	2.2 ± 1.8 (1.8-2.6)	< 0.001	2.2	65.6%
Dysphagia	5.8 ± 2.6 (5.4-6.2)	1.5 ± 1.3 (1.3-1.7)	< 0.001	2.5	74.1%

Complications

Postoperative complications were mild and self-limiting:

- Transient dysphagia in 15 patients (5%; 95% CI: 2.8-8.2), resolved within 4 weeks without intervention.
- Gas-bloat syndrome or increased flatulence in 24 patients (8%; 95% CI: 5.1-11.7), managed conservatively.

No cases of major complications, readmission, or mortality were recorded.

Patient Satisfaction

Patient satisfaction was assessed using a 5-point Likert scale at 6 months postoperatively. A score of 4 or 5 was considered high satisfaction.

270 patients (90%; 95% CI: 86.2-93.1) reported high satisfaction with the surgical outcome.

Data from 300 patients who underwent LNF between June 2019 and June 2024 were evaluated. The mean age of the patients was 44.5 ± 12.3 years, and the mean body mass index (BMI) was 27.8 ± 3.5 kg/m². Among the participants, 68% were male, and 32% were female.

Preoperative GERD-HRQL scores indicated that patients had significantly impaired quality of life due to severe symptoms. The most commonly reported symptoms were heartburn (85%), regurgitation (68%), chest pain (52%), and dysphagia (45%).

Postoperative assessments revealed that 68% of patients experienced significant symptom improvement based on GERD-HRQL scores. The mean scores decreased from 24.8 to 6.3 ($p<0.001$). Notably, symptoms such as heartburn and regurgitation showed significant reductions.

Additionally, mild postoperative dysphagia was reported in 5% of patients; this condition was generally transient and resolved spontaneously. Overall, 90% of patients reported satisfaction with the surgical outcome, and

significant improvements in GERD-HRQL measures were noted.

Moreover, minimal complications, such as reduced incision size, were observed in a small number of patients (Figure 1).

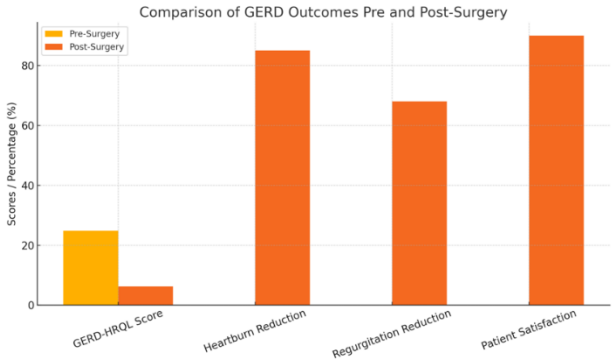

Figure 1. Comparison of preoperative and postoperative GERD outcomes. GERD-HRQL scores decreased significantly, while heartburn, regurgitation, and patient satisfaction improved postoperatively.

The mean GERD-HRQL score significantly decreased from 24.8 (95% CI: 23.9-25.7) to 6.3 (95% CI: 5.9-6.7); p<0.001. Postoperative assessments revealed that 82% of patients (n=246) experienced significant symptom improvement based on GERD-HRQL scores. The mean GERD-HRQL score significantly decreased from 24.8 (95% CI: 23.9-25.7) to 6.3 (95% CI: 5.9-6.7); $p < 0.001$. The mean heartburn score decreased from 12.3 (95% CI: 11.8-12.8) to 1.8 (95% CI: 1.5-2.1); $p < 0.001$**,** representing an 85% reduction. Similarly, the mean regurgitation score decreased from 8.1 (95% CI: 7.6-8.6) to 2.6 (95% CI: 2.3-2.9); $p < 0.001$**,** corresponding to a 68% reduction.

Additionally, mild postoperative dysphagia was reported in 15 patients (5%; 95% CI: 2.8-8.2), which was generally transient and resolved spontaneously. Other gas-related complaints were reported in 8% of patients (n=24; 95% CI: 5.1-11.7), all of which were temporary.

Overall, 270 patients (90%; 95% CI: 86.2-93.1) reported satisfaction with the surgical outcome, and significant improvements in GERD-HRQL measures were noted in most domains.

Discussion

This study demonstrated that laparoscopic Nissen fundoplication (LNF) significantly improved symptom control and health-related quality of life (HRQL) in patients with gastroesophageal reflux disease (GERD). The use of a validated, disease-specific instrument (GERD-HRQL) allowed for objective and standardized measurement of symptom burden and postoperative outcomes. Our results revealed a statistically and clinically significant reduction in total GERD-HRQL scores, particularly for core symptoms such as heartburn and regurgitation, with large effect sizes supporting the procedure's efficacy.

These findings are consistent with prior studies. For instance, Zehetner et al. reported over 85% symptom relief after LNF in a large cohort, comparable to our observed 82% rate of clinically significant improvement. Similarly, Broeders et al. demonstrated durable symptom control and high patient satisfaction over mid-term follow-up after antireflux surgery. Our study adds to this evidence base with a relatively large sample size and a standardized postoperative assessment.

However, unlike some previous studies, our investigation focused exclusively on outcomes at 6 months postoperatively. While this timeframe offers early insight into treatment success, longer-term data are needed to evaluate symptom recurrence, durability of HRQL gains, and potential late complications such as gas-bloat syndrome or wrap failure.

Complications in our cohort were infrequent and mostly mild. The most common adverse event was transient dysphagia (5%), consistent with the early postoperative adaptation phase frequently reported in other LNF series. Importantly, all cases resolved spontaneously. Our results suggest that careful surgical technique, standardized patient selection, and structured postoperative care contribute to minimizing adverse events. Still, individualized surgical approaches (e.g., partial wrap in patients with motility disorders) may further optimize outcomes in select populations.

One strength of this study is its use of prospectively collected, patient-reported outcomes with a validated scale administered face-to-face to ensure comprehension. Additionally, our sample size (n = 300) provides statistical power and reliability. However, several limitations must be acknowledged. First, the study was conducted at a single center, limiting generalizability. Second, the absence of a control group (e.g., medical management or different surgical techniques) restricts comparative interpretation. Third, we did not include multivariate analyses to evaluate the influence of age, BMI, hiatal hernia, or symptom duration on surgical outcomes. Finally, follow-up was limited to 6 months, and long-term recurrence or satisfaction trends remain unknown.

Future studies should include multicenter designs, longer follow-up periods, and subgroup analyses based on demographic or anatomical variables. In addition, randomized comparisons of total versus partial fundoplication or laparoscopic versus robotic approaches would provide further insight into the optimal surgical strategy for GERD.

In conclusion, LNF is a safe and effective treatment for GERD that significantly improves health-related quality of life. The GERD-HRQL scale remains a practical and robust tool for capturing patient-centered outcomes. While our findings are promising, long-term, prospective, and controlled studies are warranted to validate and extend these results.

This study is limited by its single-center design, lack of a control group, and relatively short follow-up period. Additionally, potential confounders such as esophageal motility or lifestyle factors were not assessed

Limitations

This study has several limitations that should be acknowledged. First, it was conducted at a single tertiary care center, which may limit the generalizability of the findings to broader or more diverse populations. Second, the absence of a comparison group (e.g., patients managed with medical therapy or alternative surgical techniques) restricts the ability to assess the relative efficacy of LNF. Third, although the data were prospectively collected, the analysis was retrospective in nature, which may introduce selection or reporting biases.

Additionally, the follow-up period was limited to six months, which does not allow for assessment of long-term outcomes such as symptom recurrence, durability of symptom relief, or late-onset complications. Furthermore, potential confounding factors such as esophageal motility, the presence and size of hiatal hernia, or patient adherence to postoperative dietary modifications were not analyzed. Finally, no multivariate or subgroup analyses were performed to identify predictors of surgical success or dissatisfaction.

Future research should focus on multicenter, prospective trials with longer follow-up, inclusion of control groups, and more comprehensive statistical modeling to strengthen the evidence base and inform individualized treatment strategies for GERD.

Compliance with Ethical Standards

This study was conducted in accordance with the ethical standards of the Declaration of Helsinki (2013 revision). Ethical approval was obtained from the Ethics Committee of Non-Interventional Clinical Research, Faculty of Medicine, Kocaeli University (Date: 22.08.2024, Decision No: KÜ GOKAEK 2024/13.04). Written informed consent was obtained from all participants.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

Author Contributions

MFO, TS: Concept and design; MFO: Data collection; MFO, TS: Analysis and interpretation; MFO: Manuscript writing; NZC: Critical revision. All authors read and approved the final version of the manuscript.

Financial Disclosure

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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