



Clinical Outcome and Recurrence of Open versus Laparoscopic Nissen Fundoplication in the Republic of Kazakhstan during 2010-2021

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What's Known

- Intra- and postoperative complications and surgical outcomes of open Nissen fundoplication (ONF) are higher than laparoscopic Nissen fundoplication (LNF) surgery.
- Redo fundoplication is commonly performed in the case of recurrent gastroesophageal reflux disease (GERD).

What's New

- Post-operative complications were 2.7-fold higher in ONF than in LNF surgery. The rate of redo fundoplication was the same after failed primary LNF and ONF.
- Risk factors associated with recurrent GERD were obesity and male sex. LNF surgical outcomes are associated with high quality of life and patient satisfaction.

Abstract

Background: Surgical treatment of recurrent gastroesophageal reflux disease (GERD) negatively affects patients' quality of life (QoL). Determination of risk factors is essential when considering a surgical approach. The present study aimed to evaluate short-term and long-term outcomes of primary laparoscopic Nissen fundoplication (LNF) and open Nissen fundoplication (ONF), as well as the risks of laparoscopic redo fundoplication.

Methods: A retrospective cohort observational study was conducted from 2010 to 2021 at the National Research Center of Surgery (Almaty, Kazakhstan). Depending on the type of primary GERD surgical correction, 475 patients were stratified into two groups, namely LNF (n=117) and ONF (n=358). The outcomes and associated complications of LNF and ONF surgeries were assessed. The odds ratio of recurrent GERD in terms of risk factors was analyzed as well as post-intervention QoL.

Results: Postoperative complications in ONF surgery were 2.7-fold higher than in LNF (P=0.0001). Moreover, intra-operative complications were higher with ONF surgery (7.7%) than with LNF (1.4%) (P=0.002). In cases with persistent clinical manifestations, the rate of redo fundoplication was the same after failed primary LNF and ONF. The risk factors associated with recurrent GERD, leading to redo fundoplication, were obesity (OR=2.16, P=0.473) and male sex (OR=3.0, P=0.272). One-year after LNF, 88.7% of the patients were satisfied with the outcome of the surgery.

Conclusion: Recurrent symptoms of GERD and the rate of redo fundoplication were associated with obesity and the male sex. Obesity was the main risk factor, necessitating stringent selection of patients for surgical management of the disease.

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Introduction

Gastroesophageal reflux disease (GERD) is the most common disease of the gastrointestinal tract among the Kazakh population, with a varying prevalence from 40.5 to 67.6% depending on the region in Kazakhstan. The prevalence of GERD in the world also varies depending on the geographical area, e.g., North America (8.1-27.8%), South America (23.0%), Europe (8.8-25.9%), East Asia (2.5-7.8%), West Asia (8.7-33.1%), and Australia (11.6%).^{1, 2}

The main causes of GERD are esophageal motility disorders, anatomical features, obesity, age, and sex. These factors affect the morbidity and recurrence of GERD symptoms after initial anti-reflux surgery.^{3,4} Patients with complicated GERD may not respond to conservative therapy, and thus surgical treatment is considered.⁵ Laparoscopic surgery is the gold standard in patients with drug-resistant forms of GERD. Laparoscopic Nissen fundoplication (LNF) is a classical procedure for the treatment of GERD. Although this procedure is shown to be safe and effective, there are reports of disease recurrence after surgery.^{6,7} In addition, the associated postoperative complications (e.g., dysphagia, fundoplication cuff insufficiency, stenosis of peptic ulcers, hernia)^{8,9} do not fully justify a repeat procedure. Therefore, the choice of surgical treatment for GERD requires the identification of patient-specific parameters such as clinical characteristics, type of esophagitis, and the presence of ulcers, stricture, Barrett's esophagus, acid/bile reflux, and obesity.^{5,7,10} The rate of GERD recurrence after LNF ranges from 3% to 30% and is associated with recurrent reflux or erosive esophagitis, with 4% to 25% of patients requiring re-intervention.

Given the above, the present study aimed to evaluate the surgical outcome of ONF and LNF in terms of GERD recurrence rate and the associated risk factors, as well as the effect on quality of life (QoL).

Materials and Methods

A retrospective cohort observational study was conducted from 2010 to 2021 at the Department of Gastrointestinal Tract and Endocrine Surgery, National Scientific Center of Surgery (Almaty, Kazakhstan). The sample size was calculated based on the urban population of Almaty (1,700,000 people) and the high prevalence of GERD among its adult population (1,100,000 people). Accordingly, a sample size of 475 adult patients (confidence level: 95%, margin of error: 5%) was calculated. The patients were recruited from clinics in urban areas of Almaty with the support of local medical staff. The exclusion criteria were morbid obesity, scleroderma, lung disease, neoplasms, esophageal motility disorder, diseases causing GERD or altering the natural course of esophageal motility, benign or malignant gastroduodenal diseases, and caustic injury. Pregnant women and those with cognitive impairment or mental illness were also excluded. Depending on the type of primary surgical correction of GERD, the patients were stratified into two groups, namely

LNF (n=117) and open Nissen fundoplication (ONF) (n=358).

The GERD health-related quality of life (GERD-HRQL) questionnaire was used to assess the QoL of the patients before and after anti-reflux surgery. Similar to the original version of GERD-HRQL, the Russian version also consists of ten questions. Each item was scored on a five-point scale, namely 0: No symptoms; 1: Noticeable, but not bothersome; 2: Noticeable, bothersome, but not every day; 3: Bothersome daily; 4: Bothersome and affect daily activities; and 5: Incapacitating to do daily activities. The validity of the GERD-HRQL questionnaire was confirmed with Cronbach's alpha coefficient for the total items ($\alpha=0.694$) and each item ($\alpha=0.77$). Psychometric properties of the Russian version of the GERD-HRQL questionnaire were examined by Ionova and colleagues.¹¹ They confirmed acceptable reliability, validity, and sensitivity of the questionnaire. Based on Spearman's correlation coefficient, a high positive correlation between questions 2, 4, 8, and 9 ($r=0.79-0.86$, $P<0.05$) was reported. A significantly high correlation between questions 1, 3, 5, and 6 ($r=0.91-1.0$, $P<0.05$) was also reported. However, with respect to question 7 ("Do you find it difficult to swallow?"), they reported a weak positive correlation ($r=0.542$, $P<0.05$). In addition, using a test-retest interval of 10 to 14 days, they reported a statistically significant high correlation ($r=0.917$, $P<0.001$) in the total score of the questionnaire.

Overweight and obesity were evaluated using body mass index (BMI) in line with the classifications recommended by the World Health Organization. Further evaluation of the patients included a poly positional radiography examination of the esophagus and stomach using a contrast solution, endoscopy of the upper gastrointestinal tract, and morphological examination of biopsy specimens. Indications for surgical treatment included ineffectiveness of conservative treatment; exacerbation of GERD combined with hiatal hernia (HH) of any size; the presence of extraesophageal manifestations of GERD, cardiac, bronchopulmonary, and other diseases; the presence of complicated GERD (Barrett's esophagus, peptic esophageal ulcers, esophageal stenosis); and the presence of concomitant abdominal surgical pathology (gallstones, gastric and duodenal ulcers, anterior abdominal hernias). Demographic characteristics of the patients were age, sex, overweight, and obesity status. Clinical features included GERD complications, diagnosis, and radiological and endoscopic examinations (tables 1 and 2).

Table 1: Main characteristics of patients after open and laparoscopic Nissen fundoplication surgeries

Characteristics	ONF (n=117)	LNF (n=358)	Chi square	t statistic	P value	
Age (years)	54.93±2.00	56.24±10.60	-	1.11	0.265	
Sex (n, %)	Male	44 (9.26%)	118 (24.84%)	4.68 ^β	-	0.031*
	Female	73 (1.47%)	240 (50.53%)	56.18 ^β	-	0.0001*
Overweight and obesity (n, %; mean±SD)	Overweight	43 (36.75%)	130 (36.31%)	0.00	-	0.962
		27.85±0.20	28.67±0.10	-	38.82 ^α	0.0004*
	Obese class 1	39 (33.33%)	90 (25.14%)	0.91	-	0.34
		32.19±2.90	31.10±0.10	-	-3.61 ^α	0.0001*
	Obese class 2	2 (1.71%)	29 (8.10)	0.11	-	0.746
		35.60±0.03	36.65±0.62	-	2.55 ^α	0.016*
BMI (Kg/m ²)	28.08±0.53	28.25±4.09	-	0.53	0.599	
Duration of GERD (years)	3.51±1.40	3.50±1.10	-	0.00	1.000	
Days of hospitalization	9.45±4.31	5.72±2.80	-	-10.89 ^α	0.0001*	
Complicated GERD	Hiatal hernia	92 (78.63%)	299 (83.52%)	1.16	-	0.282
	Esophageal stenosis	6 (5.13%)	16 (4.47%)	0.00	-	0.954
	Barrett's esophagus	1 (0.85%)	10 (2.79%)	0.01	-	0.909
	Peptic ulcers	3 (2.56%)	10 (2.79%)	0.00	-	0.986

GERD: Gastroesophageal reflux disease; ONL: Open Nissen fundoplication; LNF: Laparoscopic Nissen fundoplication; α: The value relative to the degree of freedom corresponds to a significance level <0.05; β: The observed frequency distribution is significantly different from its expected frequency distribution; *Statistically significant difference P≤0.05.

Table 2: Comparative radiological and laparoscopic semiotics of patients after open and laparoscopic Nissen fundoplication

Indicator	ONF (n=117)	LNF (n=358)	OR	P value
Radiological semiotics				
Gastroesophageal reflux	19 (16.24%)	62 (17.32%)	0.93 ^β	0.7787
Short esophagus	51 (43.59%)	227 (63.41%)	0.44 ^β	0.0002*
Axial sliding hiatal hernia	65 (55.56%)	253 (70.67%)	0.52 ^β	0.003*
Paraesophageal hiatal hernia	1 (0.85%)	21 (5.86%)	0.14 ^β	0.055*
Esophageal stricture	1 (0.85%)	11 (3.07%)	0.27 ^β	0.215
Esophageal diverticulum	1 (0.85%)	3 (0.84%)	1.02 ^α	0.986
Chronic duodenitis	48 (41.03%)	233 (65.08%)	0.37 ^β	0.0001*
Endoscopic semiotics				
Gastroesophageal reflux	65 (55.56%)	231 (64.53%)	0.69 ^β	0.083
Short esophagus	9 (7.69%)	43 (12.01%)	0.61 ^β	0.198
Hiatal hernia	96 (82.05%)	300 (83.80%)	0.88 ^β	0.660
Peptic esophageal ulcer and erosive esophagitis	30 (25.64%)	82 (22.90%)	1.16 ^γ	0.545
Barrett's esophagus	2 (1.71%)	9 (2.51%)	0.67 ^β	0.618
Esophageal stricture	7 (5.98%)	27 (7.54%)	0.78 ^β	0.571
Candidiasis	1 (0.85%)	2 (0.56%)	1.53 ^γ	0.728
Degree of esophageal affection				
Grade A: One or more mucosal tears ≤5 mm that does not cross the tops of 2 mucosal folds	3 (2.56%)	32 (8.94%)	0.27 ^β	0.032*
Grade B: One or more mucosal tears >5 mm that do not cross the tops of 2 mucosal folds	3 (2.56%)	31 (8.66%)	0.28 ^β	0.037*
Grade C: One or more mucosal tears that cross ≥2 mucosal folds and involve <75% of the esophageal circumference	31 (26.50%)	76 (21.23%)	1.34 ^γ	0.237
Grade D: One or more mucosal tears involving ≥75% of the esophageal circumference	12 (10.26%)	24 (6.70%)	1.59 ^γ	0.211

ONF: Open Nissen fundoplication; LNF: Laparoscopic Nissen fundoplication; OR: Odds ratio; α: OR=1 means that the odds are equal in both groups; β: OR<1 means that the event has an inverse relationship and chance to occur in the second group; γ: OR>1 means that the event is directly related and has a chance of occurring in the first group; *z test statistical significance P≤0.05.

Diagnosis and treatment of patients with GERD were performed according to the clinical protocol in a hospital setting as recommended by the Ministry of Healthcare of the Republic of Kazakhstan. The study protocol was conducted

in accordance with the ethical principles of the Declaration of Helsinki and the code of practice for the public health and healthcare system of the Republic of Kazakhstan (7 July 2020, number: 360-VI 3PK). The study was approved by the

Ethics Committee of JSC National Scientific Center, Republic of Kazakhstan (IRB-02 dated August 31, 2022). The participants were informed of the confidentiality of the provided information, and written informed consent was subsequently obtained.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics software version 17.0 (IBM SPSS Inc., Chicago, IL, USA). Numerical variables were expressed as mean \pm SD and categorical variables as numbers and percentages. Nonparametric statistics were performed for dataset analysis. Between-group comparisons were assessed for numerical variables, and the Chi square test and Fisher's exact test were used for categorical variables. $P\leq 0.05$ was considered statistically significant. Analysis of main risk factors for recurrent GERD and the corresponding causal relationship was evaluated by calculating the odds ratio (OR).

Results

A total of 475 patients were included in the study, of which 162 (34.1%) were men, and 313 (65.9%) were women ($P=0.0001$). The average age of the patients was 56 ± 5.0 years, ranging from 19 to 85 years. The average BMI was 28.4 ± 5.1 Kg/m², corresponding to the overweight category 25-30 Kg/m². Of the patients who underwent fundoplication, 168 (35.4%) were overweight and obese (table 1).

The results of clinical investigations (endoscopy, radiography, and histological examinations) showed that the groups were homogeneous (table 2).

The average follow-up of the patients was 3.1 ± 2.8 years ranging from five months to 11 years. The duration of follow-up in the ONF group (6.2 ± 3.3 years) was longer than the LNF group (2.3 ± 1.9 years) (t test: 15.76, $P=0.0001$). Patients with GERD received symptomatic and pathogenetic therapies before surgical correction. The duration of symptomatic therapy (range: three months to 15 years) in the ONF and LNF groups was 3.5 ± 0.07 and 3.5 ± 0.14 years, respectively. The average surgery time, including 177 additional procedures, was 118 ± 18 minutes. The surgery time in the LNF group was 140.5 ± 50.0 minutes, and in the ONF group was 128.1 ± 57.5 minutes (t test: 2.24, $P=0.025$). The laparoscopic redo fundoplication surgery time was 182 ± 65 minutes. The average postoperative hospitalization was 5.0 ± 3.2 days (range: 1 to 48 days).

LNF was performed on patients with complicated GERD in combination with gullet bougienage under endoscopic examination. There were 16 (4.5%) patients with esophageal stenosis, 299 (83.5%) with HH, 9 (7.7%) with esophagoplasty, and 7 (6.0%) with peptic esophageal stricture. ONF was combined with the surgical placement of a gastrostomy tube (table 1, figure 1).

Among patients with peptic esophageal ulcer and erosive esophagitis ($n=30$), Barrett's esophagus ($n=2$), and esophageal stricture ($n=7$) with endoscopic evidence of peptic esophageal stenosis, a total of 20 (17.1%) patients underwent ONF in combination with bougienage sessions. In 2 (1.7%) patients, a gastrostomy tube was inserted with a decompensated peptic esophageal stricture. Furthermore, 7 (6.0%) patients with esophageal hiatus underwent plastic surgery. Moreover, 11 (2.3%) patients

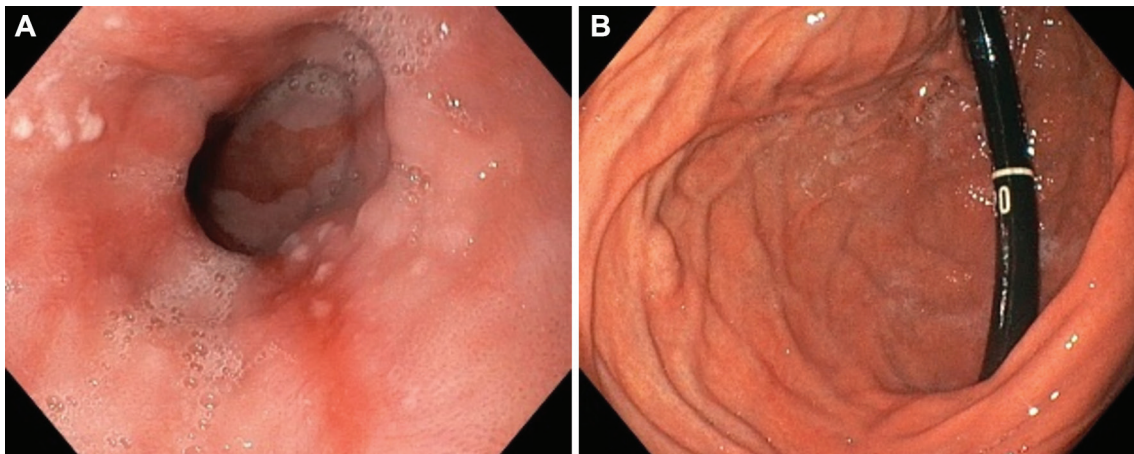


Figure 1: A sample case of a patient born in 1960 with Barrett's esophagus, incompetence of the gastric cardia, subtotal hernia, and endogastritis. (A) Esophagus is unobstructed, the mucous membrane is pink and smooth, and there are three segments of intestinal metaplasia in the form of flame-shaped Barrett's esophagus without endoscopic signs of dysplasia. The width of the circular segment is 5.0 cm, and the length of the longest segment from the edge of gastric folds is 10.0 cm. (B) Z-line is indistinct and blurred. Hiatal hernia is approximately 8.5 \times 9.0 cm in size. The gastric mucosa is pink and smooth. Mucosal folds are medium and fully straightened.

with Barrett's esophagus underwent ONF or LNF. Postoperatively, all these patients were prescribed antisecretory drugs (i.e., proton pump inhibitors) on a long-term basis. Of the 8 (2.2%) patients who underwent autoesophagoplasty, 3 (0.8%) patients with Barrett's esophagus had high-grade dysplasia–esophageal bypass–colo anastomosis, and 4 (1.1%) had meta-esophagogastroplasty (figure 2).

During follow-up, postoperative complications occurred in 78 (12.6%) patients. The development of complications after ONF and LNF in terms of risk factors is presented in table 3.

The GERD-HRQL questionnaire was completed by 126 patients before fundoplication (total score: 3,332 points, average score: 26.4±7.8 points). Of these, the response of 11 (8.7%) patients on the outcome of GERD conservative therapy was neutral, and 115 (91.3%) were not satisfied. However, one month after the intervention, all patients completed the questionnaire, and 159 (33.5%) patients were satisfied, of which 19 (90.4%) of the 21 (13.2%) patients underwent ONF, and 130 (94%) of the 138 (86.8%) patients underwent LNF surgeries. Of the satisfied patients, 122 (76.7%) complained of bloating, 115 (72.3%) of heartburn, and 126

(79.2%) of reflux. The sensitivity, specificity, and test accuracy for bloating were 8.2%, 86.5%, and 26.4%, respectively. These values for heartburn were 11.3%, 91.9%, and 33.3%, respectively. Reflux had a sensitivity of 4.8%, specificity of 87.9%, test accuracy of 22.0%, and disease prevalence of 79.25%. One-year after LNF, out of 71 patients, 63 (88.7%) were satisfied with the outcome of the surgery (total score=84 points, mean score=1.4±4.1 points; P=0.221). GERD recurrence was observed in 8 (11.3%) patients (total score=94 points, mean score= 15.7±3.7 points). A redo fundoplication was performed in 22 (4.6%) patients after failed primary LNF or with persistent clinical manifestations of GERD after ONF. The redo fundoplication risk in both groups was similar (OR=1.2, P=0.768). There were 3 (0.6%) patients with fatal outcomes, of which 1 (0.85%) was in the ONF group and 2 (0.55%) in the LNF group. There was no statistically significant difference in fatal outcomes between the groups (P=0.980).

Discussion

The prevalence of GERD is not dependent on the geographical area or the sex of patients.

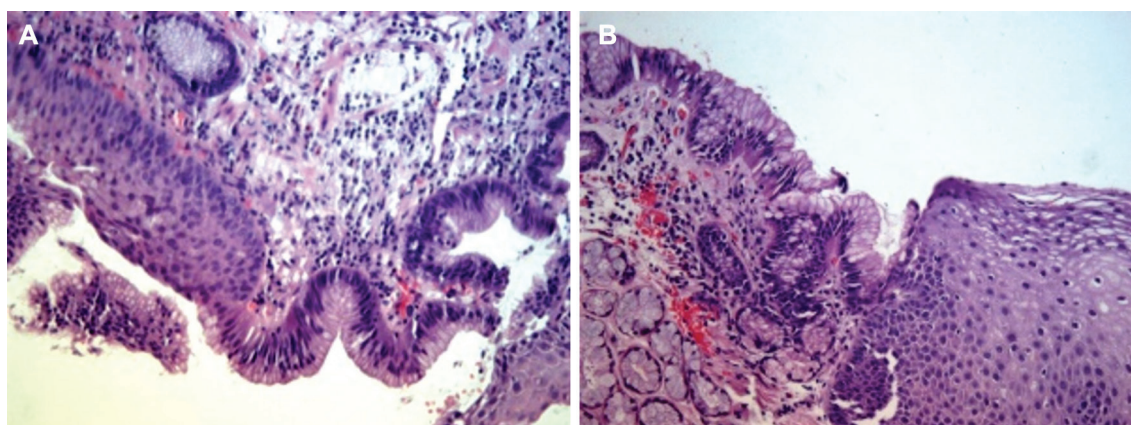


Figure 2: A sample case of a patient who was born in 1954. (A) Multilayer metaplastic epithelium is represented by 4×8 layers of basally arranged cells and the surface layer of columnar mucinous epithelium. (B) Metaplasia transition of the stratified squamous epithelium into the cylindrical cell. Urine specific gravity ×100.

Table 3: The risk of complications after open Nissen fundoplication and laparoscopic Nissen fundoplication

Parameters	ONF (n=117)	LNF (n=358)	OR	P value
Complications	33 (28.21%)	45 (12.57%)	2.73 ^y	0.0001 ^z
Intra-operative	9 (7.69%)	5 (1.40%)	5.88 ^y	0.002 ^z
Postoperative (early)	7 (5.98%)	10 (2.79%)	2.21 ^y	0.115
Postoperative (long-term)	5 (4.27%)	15 (4.19%)	1.02 ^a	0.969
Recurrent gastroesophageal reflux	6 (5.13%)	11 (3.07%)	1.71 ^y	0.304
Hiatal hernia	5 (4.27%)	11 (3.07%)	1.41 ^y	0.534
Esophageal peptic ulcer and erosive esophagitis	5 (4.27%)	4 (1.12%)	3.95 ^y	0.043 ^z
Esophageal stricture	1 (0.85%)	4 (1.12%)	0.76 ^b	0.809

ONF: Open Nissen fundoplication; LNF: Laparoscopic Nissen fundoplication; OR: Odds ratio; α : OR=1 means that the odds are equal in both groups; β : OR<1 means that the event has an inverse relationship and the chance to occur in the second group; γ : OR>1 means that the event is directly related and has a chance of occurring in the first group; ^z: z-test statistical significance; P≤0.05 was considered statistically significant.

We found that it was mainly associated with risk factors such as overweight and obesity. In our study, the majority of patients (71.8%) had elevated BMI. Age was also associated with the clinical manifestation of GERD. Some studies reported other risk factors including male sex (OR=3.05), tobacco smoking (OR=2.64), alcohol consumption (OR=1.99), consumption of non-steroidal anti-inflammatory drugs (OR=1.99), and the presence of HH (OR=1.55).^{12, 13} Our results showed overweight and obesity as risk factors after ONF surgery (OR=1.66, P=0.529). Stratification of data showed that after primary ONF, obesity class 1 increased the risk of redo fundoplication by a factor of 2 (OR=2.16, P=0.473). Besides, the risk of developing recurrent GERD was directly associated with the sex of patients, such that male patients had a three-fold higher recurrence rate compared to female patients (OR=3.0, P=0.272).

The frequency of postoperative complications (e.g., persistent dysphagia) after Nissen and Nissen-Rosetti fundoplication are low and typically managed by conservative treatment. However, in laparoscopic fundoplication, there are intra-operative complications (bleeding from the surgery site, rupture of stomach wall), postoperative complications (4.5% to 12.5% of the cases), and esophageal stricture (up to 30% of the cases).^{5, 10, 14, 15} In our study, the difference in the frequency of intra-operative complications between ONF and LNF was not statistically significant. Intra-operative complications in ONF included splenic decapsulation in 4 (3.4%) patients, the need for splenectomy due to ruptured spleen in 3 (2.6%) patients, and esophageal perforation during surgery in 2 (1.7%) patients. Whereas in LNF, the main intra-operative complication was an injury causing pneumothorax in the mediastinal pleura. Postoperative complications (e.g., transient dysphagia) in LNF patients were by a factor of two higher than in ONF patients. Dysphagia is usually treated by one or two sessions of pneumatic dilation. In addition, myocardial ischemia was observed in 2 (0.4%) patients, pneumonia in 1 (0.2%), exudative pleurisy in 3 (0.6%), and intra-abdominal bleeding in 1 (0.2%). Late postoperative complications (5 years) after the intervention were esophagitis in 17 (3.6%) patients, esophageal stricture in 9 (1.9%), and HH in 16 (3.4%).

Based on the results of the GERD-HRQL questionnaire, previous studies reported QoL satisfaction after LNF in 78.4-93.1% of patients.^{11, 13} Recurrence of reflux esophagitis after fundoplication was reported in 5.8-43% of patients. Complaints of heartburn, regurgitation,

or food reflux back up from the stomach into the esophagus were reported in 80% to 86% of patients. However, a redo fundoplication was only recommended for severe complications (46% of patients) due to the upper esophageal sphincter, slipping or loosening of the fundoplication cuff, and in rare cases the occurrence of paraesophageal hernia.^{4, 16} After one month of follow-up, our results showed QoL satisfaction with ONF in 19 (90.4%) and LNF in 130 (94.2%) of the patients (P=0.525). However, after one year, QoL satisfaction with LNF reduced to 88.7% and complaints related to dyspepsia to 11.3%; possibly due to non-adherence to the conservative treatment protocol.

In the present study, the OR for recurrent GERD leading to a redo fundoplication was comparable in both ONF and LNF groups. This is probably because a redo fundoplication does not often produce positive results, and disease symptoms and endoscopic features of esophagitis persist. Therefore, a stringent selection of patients for a redo fundoplication is recommended. It has been reported that HH affects the relationship between obesity and GERD,^{17, 18} and HH in combination with shortened esophagus often leads to GERD recurrence after the intervention.^{11, 14, 19} Our results showed a direct relationship between recurrent GERD and a redo fundoplication after primary ONF. Moreover, based on endoscopic results, there was an inverse relationship between primary ONF and esophageal stricture. Several studies reported very low peri-operative mortality rates in anti-reflux surgery (0.1% to 0.2%).^{10, 20, 21} In line with previous studies,^{22, 23} our results showed that 0.6% of postoperative mortalities were associated with poor pre-morbid conditions leading to stroke and pulmonary embolism.

Overall, considering risk factors such as obesity, further studies are recommended to evaluate an individualized approach for the surgical management of patients with GERD. In addition, postoperative QoL assessment should be actively performed to compare patients' clinical features and QoL assessments.

Conclusion

Recurrent symptoms of GERD and the rate of a redo fundoplication were not associated with laparoscopic and open approaches of the Nissen fundoplication. They were most likely associated with risk factors such as obesity and male sex. The rate of complications after ONF surgery was higher than LNF, mainly due to intra-operative complications and esophagitis. In the long term, the QoL of patients who had undergone LNF

improved significantly. Given that obesity is the main risk factor for recurrent symptoms of GERD, a more stringent selection of patients for surgical management of the disease is required.

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Authors' Contribution

B.B: Study conception and design, surgeries, revising discussion section of the manuscript. S.Z: Study design, surgeries, data analysis, and interpretation, revising discussion section of the manuscript. A.S: Data acquisition, analysis, and interpretation; surgeries, revising results section of the manuscript. N.O: Data collection, surgeries, drafting, revising results section, and final approval of the manuscript. N.I, Kh.K, K.K: Data collection. Y.Y: Data collection, medical diagnoses, surgical pathologic evaluations. G.I: Study conception and design, overall responsibility of the study, data analysis and interpretation, final approval of the manuscript. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest: None declared.

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