

# Laparoscopic Nissen fundoplication: a five-year single-center clinical experience and results

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**Abstract. – OBJECTIVE:** The current surgical approach in the treatment of hiatal hernia with gastroesophageal reflux disease is known as hernioplasty together with antireflux surgical procedures. Among the antireflux surgical treatment procedures, the most applied approach is the laparoscopic Nissen fundoplication. In this study, we aimed to examine the results and effectiveness of laparoscopic Nissen fundoplication and to share our clinical experiences.

**PATIENTS AND METHODS:** Patients who underwent laparoscopic Nissen fundoplication operation between January 2017 and January 2022 in the general surgery clinic of a tertiary healthcare center were included in the study. The clinical data, preoperative, operative, and postoperative findings and results of the cases were investigated.

**RESULTS:** The mean age of the patients was  $46.2 \pm 14.7$  years, and the female/male ratio was 1.5/1. According to the Clavien-Dindo classification system, 9.9% of the patients had grade I, and 18.3% grade II complications. The patients were followed up for a mean of  $32.6 \pm 14.8$  months. During the follow-up, reoperation was planned in 5.6% of the patients due to recurrence.

**CONCLUSIONS:** Laparoscopic Nissen fundoplication is a well-defined technique. It is a safe and effective surgical method with appropriate patient selection.

## Key Words:

Laparoscopic Nissen fundoplication, Hiatal hernia, Esophagitis, Endoscopy, Gastroesophageal reflux disease.

## Introduction

Gastroesophageal reflux disease is a very common entity in Western societies. Hiatal hernia is a type of herniation in which intra-abdominal organs, especially the stomach, slip from the enlarged or defective diaphragmatic opening to the thoracic cavity<sup>1</sup>. It can be counted as an indepen-

dent risk factor for esophageal exposure to acidic gastric contents and is associated with gastroesophageal reflux disease<sup>2</sup>. The current surgical approach in the treatment of hiatal hernia can be counted as antireflux surgical procedures together with cruroraphy for diaphragmatic defect<sup>3</sup>. Laparoscopic surgical interventions in antireflux surgical procedures have become a standard treatment today due to both their technical advantages and their safe and effective application<sup>4</sup>. Among the antireflux surgical treatment procedures, the most applied approach is the laparoscopic Nissen fundoplication<sup>5</sup>.

Literature on antireflux surgery have been gaining momentum in recent years. However, there is some controversies on this issue. There are differences of opinion, especially in selecting patients who are candidates for surgical treatment. The aim of this study is to inform clinicians in the selection of candidates for antireflux surgery, to discuss the results and effectiveness of laparoscopic Nissen fundoplication in hiatal hernia patients with gastroesophageal reflux symptoms and to share our clinical experience.

## Patients and Methods

Ethical approvals were obtained from the Ethics Committee of Gulhane Training and Research Hospital (approval No: 2022/99). Patients who underwent Laparoscopic Nissen fundoplication surgery between January 2017 and January 2022 at the tertiary healthcare center general surgery clinic were included in the study. The data of the patients were analyzed retrospectively from patient files and electronic hospital archive system. Patients' age, gender, comorbidities, American Society of Anesthesiologists (ASA) scores, body mass index (BMI) results, smoking-alcohol habitus, preoperative and postoperative endoscopy results, preoperative laboratory test results,

operative findings, postoperative findings, Clavien-Dindo Classification System results for complications were recorded and analyzed.

### Statistical Analysis

Statistical analyses were performed by using the SPSS version 24.0 package program (IBM, Armonk, NY, USA). The conformity of the variables to the normal distribution was examined using visual (histogram and probability graphs) and analytical methods (Kolmogorov Smirnov, Shapiro-Wilk test). Descriptive statistics were expressed as mean and standard deviation in normally distributed numerical data, median and minimum-maximum values in non-normally distributed data, and numbers and percentages in nominal data.  $p < 0.05$  was considered statistically significant.

## Results

The mean age of the included seventy-one patients was  $46.2 \pm 14.7$  years (20-82 years) and the female/male ratio was 1.5/1. The ASA score was "I" in 25.4% (n=18) of the patients, "II" in 67.6% (n=48) and "III" in 7% (n=5). The mean BMI of the patients was  $27.0 \pm 3.6$  kg/m<sup>2</sup>. 53.5% (n=38) of the patients were smoking and 26.8% (n=19) of the patients were using alcohol. 42.3% (n=30) had comorbid disease. The most common comorbid diseases were hypertension (25.4%), cardiovascular disease (18.3%) and diabetes mellitus (16.9%) (Table I).

Median defect diameter was 2.5 cm (1-4 cm). Recurrence was observed in 7% (n=5) of the patients. However, 5.6% (n=4) required reoperation. pH monitoring was performed in 70.4% (n=50) of them. Cholecystectomy was performed in 11.3% (n=8) of the patients and endoscopic balloon dilatation was performed in 12.7% (n=9) of the patients. According to the Clavien-Dindo Classification System, 9.9% (n=7) grade I complications and 18.3% (n=13) grade II complications were observed. Bleeding was observed in 8.5% (n=6) of the patients, wound infection was observed in 4.2% (n=3), and ileus was observed in 2.8% (n=2). In preoperative endoscopy, hiatal hernia was observed in 7% (n=5) of the patients, and hiatal hernia and esophagitis were observed in 93% (n=66) of the patients. In the endoscopy performed at the postoperative 6th month, 15.5% (n=11) of the patients had esophagitis, 12.7% (n=9) achalasia, 4.2% (n=3) hiatal hernia and esophagitis. Also, hiatal hernia was observed in 1.4% (n=1) and 66.2% (n=47) had normal endoscopy. The patients were followed for a mean of  $32.6 \pm 14.8$  months. During the follow-up, reoperation was planned in 5.6% (n=4) of the patients due to recurrence. While 19.7% (n=14) of the patients stayed in the intensive care unit (ICU), the median length of stay in the ICU was one day (1-2 days), and the median hospital stay was three days (2-7 days). No mortality was observed in the follow-ups (Table II).

Median CRP (C-Reactive Protein) level of the patients was 4.4 mg/dl (0.1-32.4 mg/dl), lymphocyte count  $1.2 \times 10^3/\mu\text{L}$  ( $0.5-2.8 \times 10^3/\mu\text{L}$ ),

**Table I.** Demographic and clinical features of the patients.

Features		Distributions
Age (years)	Average $\pm$ SD	$46.2 \pm 14.7$
Gender	n (%)	
Female		43 (60.6)
Male		28 (39.4)
ASA	n (%)	
I		18 (25.4)
II		48 (67.6)
III		5 (7.0)
BMI (kg/m <sup>2</sup> )	Average $\pm$ SD	$27.0 \pm 3.6$
Smoking habitus	n (%)	38 (53.5)
Alcohol habitus	n (%)	19 (26.8)
Comorbid disease	n (%)	30 (42.3)
Hypertension		18 (25.4)
Cardiovascular diseases		13 (18.3)
Diabetes mellitus		12 (16.9)

ASA: American Society of Anesthesiologists, BMI: body-mass index, SD: standard deviation.

**Table II.** Surgical features of patients.

Features		Distributions
Defect diameter (cm)	Median (min-max)	2.5 (1.0-4.0)
Reoperation	n (%)	4 (5.6)
pH monitoring	n (%)	50 (70.4)
Cholecystectomy	n (%)	8 (11.3)
Endoscopic balloon dilatation	n (%)	9 (12.7)
Operation time (minutes)	Median (min-max)	130 (100-185)
Clavien-Dindo Classification	n (%)	
Grade I		7 (9.9)
Grade II		13 (18.3)
Postoperative complications	n (%)	
None		60 (84.5)
Presence		11 (15.5)
Bleeding		6 (8.5)
Surgical site infection		3 (4.2)
Ileus		2 (2.8)
Endoscopy (preoperative)	n (%)	
Hiatal hernia + esophagitis	n (%)	66 (93.0)
Hiatal hernia	n (%)	5 (7.0)
Endoscopy (postoperative 6th month)	n (%)	
Normal		47 (66.2)
Esophagitis		11 (15.5)
Achalasia		9 (12.7)
Hiatal hernia + esophagitis		3 (4.2)
Hiatal hernia		1 (1.4)
Follow-up time (months)	Average ± SD	32.6 ± 14.8
Follow-up	n (%)	
Recurrence (-)		67 (94.4)
Recurrence (+) Operation (+)		4 (5.6)
Length of hospital stay (days)	Median (min-max)	3 (2-7)
ICU (+)	n (%)	14 (19.7)
ICU length of stay (days)	Median (min-max)	1 (1-2)
Mortality	n (%)	0

ASA: American Society of Anesthesiologists, BMI: body-mass index, SD: standard deviation.

blood urea nitrogen level was 33 mg/dl (9-42 mg/dl), mean leukocyte count  $7.7 \pm 2.4 \times 10^3/\mu\text{L}$ , neutrophil count  $5.8 \pm 2.1 \times 10^3/\mu\text{L}$ , platelet count  $299 \pm 64 \times 10^3/\mu\text{L}$ , albumin level was  $4.1 \pm 0.5$  mg/dl, hemoglobin level was  $13.0 \pm 1.2$  g/dl, and creatinine level was  $0.81 \pm 0.17$  mg/dl (Table III).

**Table III.** Laboratory results and distributions of the patients in the preoperative period.

Features		Distributions
CRP (mg/dl)	Median (min-max)	4.4 (0.1-32.4)
Leukocytes ( $10^3/\mu\text{L}$ )	Average ± SD	$7.7 \pm 2.4$
Neutrophils ( $10^3/\mu\text{L}$ )	Average ± SD	$5.8 \pm 2.1$
Lymphocytes ( $10^3/\mu\text{L}$ )	Median (min-max)	1.2 (0.5-2.8)
Platelets ( $10^3/\mu\text{L}$ )	Average ± SD	$299 \pm 64$
Albumin (mg/dL)	Average ± SD	$4.1 \pm 0.5$
Hemoglobin (g/dL)	Average ± SD	$13.0 \pm 1.2$
Hematocrit (%)	Average ± SD	$37.8 \pm 3.0$
Creatinine (mg/dL)	Average ± SD	$0.81 \pm 0.17$
Blood urea nitrogen (mg/dL)	Median (min-max)	33 (9-42)

CRP: C-Reactive Protein, SD: standard deviation, Min: minimum, Max: maximum.

## Discussion

With the definition of minimally invasive techniques and the dizzying speed in biomedical fields, laparoscopy has gradually expanded its application area in general surgery practice since the early 1980s. Although the frequency of surgical procedures decreases with the use of proton pump inhibitors in gastroesophageal reflux disease, surgical requirements may continue as a result of endoscopic and pH manometric examinations in cases such as accompanying hiatal hernia and severe esophagitis<sup>6</sup>. However, vagal nerve surgery and its modifications, known as additional surgical interventions, have decreased significantly. Laparoscopic antireflux surgery can be defined as the laparoscopic application of open surgical fundoplication techniques. It can also be applied robotically<sup>7</sup>. There are well-known types of fundoplication, such as Nissen, Toupet, and Dor, and are differentiated according to the gradation of gastric wrapping. At the present time, laparoscopic Nissen fundoplication has been described as a safe and effective method<sup>8</sup>. We also observed that laparoscopic Nissen fundoplication is preferred in this study in our clinical practice.

Karabacak and Kozan<sup>9</sup> performed laparoscopic Nissen fundoplication and suture cruroplasty in a series of 32 patients with persistent gastroesophageal reflux and hiatal hernia and reported that the results of these techniques were successful with appropriate patient selection. In this study, in addition to laparoscopic Nissen fundoplication, cruroplasty was used as a standard technique in hiatal hernia cases.

In their study, Sfara and Dumitrascu<sup>10</sup> reported that age, gender, comorbidities and BMI were also effective on postoperative recurrence as well as the increase in defect diameter in hiatal hernia. In addition, Koch et al<sup>11</sup> defined hiatal hernias with a defect diameter larger than 5 cm as large hiatus hernias. On the other hand, Frantzides et al<sup>12</sup> recommended the use of prosthetic material in cases with large defect diameter. In this study, however, we observed that the average hiatal hernia defect diameter was 2.5 cm and cruroplasty was applied as an additional procedure for all cases.

In the literature, complications such as bleeding, pneumothorax, gastroesophageal leak can be seen in the early period after laparoscopic Nissen fundoplication, as well as complications such as surgical site infection and wound dehiscence. It is known that medical treatment and follow-up

may be sufficient after such complications, as well as early reoperation or interventional procedures may be required<sup>13</sup>. In this study, grade I and II complications were observed according to the Clavien-Dindo classification, and they were managed with medical follow-up and treatment, and no postoperative early interventional procedure or reoperation was required.

It is known that recurrence may be detected after laparoscopic Nissen fundoplication and reoperation may be required. It is stated in the literature that it can reach up to 18%<sup>14</sup>. In this study, this rate was found to be 5.6%.

It has been reported that laparoscopic Nissen fundoplication can be followed-up with a single-day hospitalization in experienced centers. In addition, it has been stated that this fast treatment process has a positive effect on clinical results and even shortens the operation times significantly with increasing experience<sup>15</sup>. However, in the literature, it is commonly reported that the duration of hospitalization is more than two days<sup>15</sup>. In this study, it was seen that the median hospital stay was three days, and the operation time was 130 minutes on average.

In the long-term results, dysphagia and dyspepsia are symptoms that may occur later as a result of conditions such as stenosis, stricture, esophagitis and achalasia in general. It can be managed with medical and endoscopic treatments, and the need for re-surgical indications may occur<sup>16</sup>. There are studies<sup>17</sup> in the literature revealing that these long-term results can improve for 5-10 years. In this study, the patients were controlled endoscopically at the postoperative 6<sup>th</sup> month and their findings were revealed. There was also a mean follow-up period of 32.6 months.

In patients who are candidates for antireflux surgery, pH monitoring has a very important diagnostic role in cases unresponsive to proton pump inhibitors. It is also recommended in the diagnostic algorithm. The most applied technique in this patient group, with a success rate of over 80%, it is a laparoscopic Nissen fundoplication with a full wrap (360°)<sup>18</sup>. In this study, it is seen that 70.4% of the patients underwent pH monitoring.

Nissen fundoplication is a surgery that can also be performed robotically, and there are similar results with laparoscopic surgery in the literature. It has been stated that robotic surgery is not superior to laparoscopy, but multi-center randomized controlled studies are needed in this object<sup>19</sup>. In this study, all cases were performed laparoscopically in line with experience and technical possibilities.

No mortality was observed in this study, and surgery-related mortality is reported as 0.01% in the literature<sup>20</sup>.

## Conclusions

Laparoscopic Nissen fundoplication is a well-defined technique and is the most widely used antireflux surgical treatment worldwide. It is a reliable and effective surgical method with appropriate patient selection. However, there are various controversies in the literature in terms of patient selection for antireflux surgery. As studies with larger case series are added to the literature, the discussions about the ideal patient selection for antireflux surgery will also be concluded.

## Conflict of Interest

The Authors declare that they have no conflict of interests.

## Funding

No funding.

## Data Availability

The data of the study will be shared with those who want to access the data.

## Ethics Approval

Ethical approval was obtained from the Ethics Committee of Gulhane Training and Research Hospital, in Ankara. The research adhered to the tenets of the Declaration of Helsinki.

## Informed Consent

According to the local Ethical Guidelines, the need for patient consent was waived for data analysis due to the retrospective nature of the study, and the patients' anonymity was secured. However, informed consent was obtained from the patients for surgical and medical treatments.

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