

Laparoscopic Nissen fundoplication: Long-term clinical study

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Original
Article

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ABSTRACT

Background: Gastroesophageal reflux disease (GERD) is one of the most common benign medical conditions of the stomach and esophagus.

Aim: To review the cases of laparoscopic Nissen fundoplication carried out at our hospital and to analyze the prognostic factors that influenced surgical outcomes.

Patients and Methods: This was a retrospective study of the patients who underwent laparoscopic Nissen fundoplication in the period between January 2017 and December 2021 at Gastrointestinal Surgical Center, Mansoura University, Egypt.

Results: 70.9% of patients have no intraoperative difficulties, while 18.8% have a large hiatus hernia, 5.5% adhesions, 2.4% gastric volvulus, and 1.8% large left lobe. Intraoperative complications were found to be minimal, with 95.8% having no complications. The mean hospital stay ranged from 1 to 4 days, with one case causing vomiting. 56.6% of cases did not use proton pump inhibitor, while 22% used it, and 21.4% used it intermittently. Sixteen cases needed redosurgery, with 18.8% due to dysphagia and 81.2% due to disrupted and migrated wrap. The mean GERD quality of life score was 9.86 ± 11.37 .

Conclusion: Nissen fundoplication may be a better option for GERD patients, minimizing symptoms like dysphagia, heartburn, and regurgitation, with no postoperative complications and a positive correlation between patient satisfaction.

Key Words: Gastroesophageal reflux disease, laparoscopic Nissen fundoplication, outcome.

Received: 30 August 2024, **Accepted:** 15 October 2024, **Published:** 1 January 2025

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ISSN: 1110-1121, January 2025, Vol. 44, No. 1: 359-364, © The Egyptian Journal of Surgery

INTRODUCTION

Gastroesophageal reflux disease (GERD) is one of the most common benign medical conditions of the stomach and esophagus. GERD is defined as abnormal distal esophageal exposure to acid causing annoying symptoms. Most patients who present to their family doctor with GERD symptoms (i.e. heartburn and regurgitation) are never formally diagnosed, and usually, they are managed with medical treatment, specifically proton pump inhibitors (PPIs)^[1].

When persistent, life quality affecting symptoms in spite of maximal PPI therapy, a formal diagnostic assessment should be achieved. This evaluation includes esophageal pH monitoring, esophageal manometry, upper gastrointestinal contrast studies, and esophagogastroduodenoscopy. For patients who show increased distal esophageal acid exposure and persistent symptoms despite maximal medical treatment, antireflux surgery should be highly recommended. In fact, patients who experience no improvement in their symptoms with PPI use may not have GERD; surgeons must carefully consider alternative causes before offering surgical treatment^[2].

Considerably, the diagnosis of GERD is made clinically based on the presence of typical GERD symptoms and improvement in those symptoms with PPI therapy. Although, when patients are referred to a surgeon for antireflux surgery, four tests are helpful to establish the diagnosis: ambulatory pH monitoring confirms the presence of elevated distal esophageal acid exposure, esophageal manometry identifies esophageal motility disorders that may affect the type of antireflux operation performed. Esophagogastroduodenoscopy can identify the competence of LES and gastroesophageal mucosal injuries (e.g. erosive esophagitis and Barrett's esophagus). Oral contrast studies provide the surgeon with detailed anatomy of the esophagus and stomach^[3].

Surgical treatment should be offered to patients who have failed medical treatment and those who have intractable regurgitation complicated GERD or an extra-esophageal manifestation related to GERD^[4,5].

This study aimed to review the cases of laparoscopic Nissen fundoplication carried out at our hospital and to analyze the prognostic factors that influenced surgical outcome.

PATIENTS AND METHODS:

This was a retrospective study of the patients who underwent laparoscopic Nissen fundoplication in the period between January 2017 and December 2021 at Gastrointestinal Surgical Center, Mansoura University, Egypt.

Inclusion criteria: patients aged 20–70 years with typical GERD symptoms, dominated by heartburn and acid regurgitation, were eligible for inclusion. The diagnosis of GERD was verified by increased esophageal acid exposure on 24-h ambulatory PH monitoring and/or a classification of esophagitis by upper gastrointestinal tract endoscopy and with a significant decrease of lower esophageal sphincter pressure by esophageal manometric study.

Exclusion criteria: patients were not recruited in our study when any of the following criteria were recorded: contraindication for laparoscopic surgery such as the American Society of Anesthesiologists III or IV, advanced liver cirrhosis, severe bleeding tendency, severe cardiopulmonary illness, history of upper abdominal surgery, pregnancy, BMI above 40 kg/m², previous antireflux surgery, major psychiatric illness, esophageal motility disorders like achalasia or lower esophageal spasm and patient's refusal to participate in the trial.

Ethical consideration

Informed written consent was obtained from all patients before the operation after a complete explanation of the benefits and complications of each procedure. Besides, the study was approved by the Intuitional Review Board (IRB) of Mansoura University.

Methods

All patients were subjected to the following.

Preoperative workup

All patients were assessed preoperatively for demographic data, ambulatory PH monitoring to detect Demester score and pathological reflux, upper gastrointestinal tract endoscopy for detection of esophageal erosions and grading of reflux, Esophageal motility study to asses esophageal body motility and lower esophageal sphincter pressure and to exclude esophageal motility disorders and Laboratory studies including: routine blood testing and abdominal ultrasound examination

Operative technique

The operative technique was standardized for all patients. Third-generation cephalosporin was administered intravenously at induction of anesthesia before trocar insertion. All procedures were done under general anesthesia.

Laparoscopic Nissen fundoplication

The patient was placed in a lithotomy position and reversed Trendelenburg position, then a pneumoperitoneum was created and five trocars were inserted. The procedure began with an incision of the gastrohepatic ligament, exposing the right crus of the hiatus. Dissection continued to develop the plane between the esophagus and the right crus, and the peritoneal reflection and phreno-esophageal ligament were divided at the anterior aspect of the esophagus. Circumferential dissection was continued towards the left crus, releasing it from the esophagus and creating a retroesophageal window. A tape was passed around the lower esophagus and posterior vagus to provide traction. The esophagus was dissected through the hiatus into the mediastinum, aiming for at least 4 cm of intraabdominal esophageal. The fundus was mobilized using ultrasonic scissors to create a tension-free wrap. The posterior crural repair was performed using nonabsorbable interrupted sutures, and a “shoe-shine” maneuver was performed to ensure the wrap was not under tension. Three sutures were placed, creating a fundoplication high in the esophagus, and the wrap was not placed into the stomach.

Postoperative period

Patients were allowed to drink clear liquids on the night of the operative day and were discharged the next day if they were free from complications. The follow-up period was at least 4 years after the operation, either by attending the GISC outpatient clinic or by phone. Postoperative outcomes, such as dysphagia, gas bloat, heartburn, and reflux symptoms, were assessed subjectively, and GERD-QOL questionnaires were obtained after 4 years. Persistent symptoms of dysphagia or reflux recurrence were investigated using barium, endoscopy, or motility studies.

Statistical analysis

Data analysis was performed using SPSS software, version 25 (SPSS Inc., PASW statistics for Windows, version 25. SPSS Inc., Chicago, Illinois, USA). Qualitative data were described using numbers and percents. Quantitative data were described using median (minimum and maximum) for nonnormally distributed data and mean±SD for normally distributed data after testing normality using the Kolmogorov–Smirnov test. The significance of the obtained results was judged at the less than or equal to 0.05 level.

(1) χ^2 , Monte Carlo tests were used to compare qualitative data between groups as appropriate.

(2) Mann–Whitney U and Kruskal–Wallis test were used to compare two studied groups and more than two studied groups, respectively, for nonnormally distributed data.

(3) One-way analysis of variance test was used to compare more than two independent groups with the post-hoc Tukey test to detect pair-wise comparison.

(4) Spearman's rank-order correlation is used to determine the strength and direction of a linear relationship between two nonnormally distributed continuous variables and/or ordinal variables.

RESULTS:

The mean age of studied cases is 47.52 ± 12.32 years ranging from 20 to 70 years, 48.5% are females and 51.5% males. Mean BMI of studied cases is 30.65 ± 5.65 kg/m² ranging from 17 to 47 kg/m². Among studied cases; 18.8% are hypertensive, 0.6% type I diabetes mellitus (DM), and 4.2% type II DM. As regard smoking history; 81.2% nonsmokers, 7.9% active smokers, and 10.9% ex-smokers (Table 1).

Median operative time among studied cases is 90 min, ranging from 40 to 360 min. About 70.9% have no intraoperative difficulties, 18.8% large hiatus hernia, 5.5% adhesions, 2.4% gastric volvulus, and 1.8% large left lobe. As regards, intraoperative complications, 95.8% have no complications, 3.6% (six cases) pleural injury and 0.6% short gastric versus bleeding (one case) (Table 3).

The mean length of hospital stay is 1.18 ± 0.49 ranging from 1 to 4 days. Postoperative complication was detected in one case in the form of vomiting only in the early postoperative period and managed medically (Table 4).

Among 165 studied cases, two (1.2%) cases lost follow-up, four (2.4%) cases died, and 159 (96.4%) cases completed the study (Table 5).

After 4 years of follow-up; 42.8% of studied cases have heartburn with the mean score is 0.72 ± 0.98 ranging from 0 to 3, 37.7% of studied cases have regurgitation with the mean score is 0.65 ± 0.93 ranging from 0 to 3, 22.6% of studied cases have dysphagia in the early postoperative period with the mean score is 0.47 ± 0.92 ranging from 0 to 3 and 18.9% have gas bloat with mean score is 0.55 ± 1.23 ranging from 0 to 5. All patients who suffered from gas bloat were managed medically, except 1.9% of patients with a score 5, who were managed surgically due to tight wrap (Table 6).

56.6% of studied cases do not use PPI, 22% use PPI for residual GERD symptoms, and 21.4% intermittent use. Among the studied cases, 16 (10.1%) cases need redosurgery and for causes of redosurgery are as follows; three (18.8%) cases due to dysphagia and 13 (81.2%) cases due to disrupted and migrated wrap (Table 7).

The mean GERD quality of life score is 9.86 ± 11.37 ranging from 0 to 42. As regard patient satisfaction, 76.1% are satisfied, 20.8% are unsatisfied, and 3.1% are neutral (Table 8).

Table 1: Demographic characteristics, BMI, and medical history of studied cases

	N=165	%
Age/years		
Mean \pm SD	47.52 \pm 12.32	
Minimum–maximum	20–70	
Sex		
Male	85	51.5
Female	80	48.5
BMI (kg/m ²)		
Mean \pm SD	30.65 \pm 5.65	
Minimum–maximum	17–47	
Hypertension	31	18.8
Diabetes		
No	157	95.2
Type I	1	0.6
Type II	7	4.2
Smoker		
No	134	81.2
Active smoker	13	7.9
Ex-smoker	18	10.9

Table 2: Demester score % among studied cases

	Total number=165	
	Median (minimum–maximum)	Mean \pm SD
Demester score %	20 (0.2–202)	24.28 \pm 23.5

Table 3: Intraoperative findings among studied cases

	N=165	%
Intraoperative time (min)		
Median (minimum–maximum)	90 (40–360)	70.9
Mean \pm SD	112.6 \pm 48.3	1.8
Intraoperative difficulties	117	5.5
No	3	18.8
Large left lobe	9	2.4
Adhesions	31	
Large HH	4	
Gastric volvulus		
Intraoperative complications		
No	158	95.8
Short gastric vs. bleeding	1	0.6
Pleural injury	6	3.6
Complication management	N=7	
Controlled by sealing device	1	14
Follow up	4	58
Repair of pleural injury	2	28

Table 4: Length of hospital stay and incidence of postoperative complications among studied cases

	N=165	%
Hospital stay (days)		
1	142	86.1
2	17	10.3
3	5	3.0
4	1	0.6
Mean±SD	1.18±0.49	
Median (minimum–maximum)	1 (1–4)	
Postoperative complications		
No	164	99.4
Vomiting	1	0.6

Table 5: Follow-up findings after 4 years

	N=165	%
Follow up 4 years		
Lost follow-up	2	1.2
Died	4	2.4
Complete	159	96.4

Table 6: Clinical findings score after 4 years of follow-up

	N=159	%
Heartburn score		
0	90	56.6
1	38	23.9
2	16	10.1
3	15	9.4
Mean±SD	0.72±0.98	
Median (minimum–maximum)	0 (0–3)	
Regurgitation score		
0	95	59.7
1	36	22.6
2	17	10.7
3	11	6.9
Mean±SD	0.65±0.93	
Median (minimum–maximum)	0 (0–3)	
Dysphagia score		
0	123	77.4
1	5	3.1
2	23	14.5
3	8	5.0
Mean±SD	0.47±0.92	
Median (minimum–maximum)	0 (0–3)	
GAS bloat	30	18.9

Gas bloat score

0	128	80.5
1	2	1.3
2	13	8.2
3	7	4.4
4	6	3.8
5	3	1.9
Mean±SD	0.55±1.23	
Median (minimum–maximum)	0 (0–5)	

Table 7: Incidence of proton pump inhibitors use and need for redosurgery among studied cases

	N=159	%
PPI		
No	90	56.6
Yes	35	22.0
Intermittent	34	21.4
Redosurgery		
No	143	89.9
Yes	16	10.1
Redo causes		
Dysphagia	3	18.8
Disrupted and migrated wrap	13	81.2

Table 8: Quality of life score and patient satisfaction among studied cases

	N=159	%
GERD-QOL score		
Mean±SD	9.86±11.37	
Median (minimum–maximum)	6 (0–42)	
Satisfaction		
Satisfied	121	76.1
Neutral	5	3.1
Unsatisfied	33	20.8

DISCUSSION

Regarding to demographic characteristics, BMI and medical history of studied cases, our results demonstrates that mean age of studied cases was 47.52±12.32 years ranging from 20 to 70 years, 48.5% was females and 51.5% males, the mean BMI of studied cases was 30.41±5.15 kg/m² ranging from 17 to 40 kg/m², 18.8% was hypertensive, 0.6% type I DM and 4.2% type II DM. As regard smoking history, 81.2% were nonsmokers, 7.9% were active smokers, and 10.9% were ex-smokers.

In agreement with Park *et al.*^[6], who aimed to identify quantitative measurement parameters that can accurately predict the resolution of reflux symptoms after fundoplication, including high-resolution esophageal manometry finding and they the mean age was 48.3±17.2 years, with 49.3% (N=75) being men and 50.7% (N=77) women, the mean BMI was 23.1±3.6 kg/m².

Concerning the Demester score % and operative time among studied cases, our findings showed that the median Demester score was 20, ranging from 0.2 to 202, and the mean was 24.28±23.5 while the median operative time among studied cases was 90, ranging from 40 to 360 min and the mean was 112.67±48.29.

In consistent with our results, Park *et al.*^[7] found that the average duration of surgery was 117.8±37.2 min range from 75 to 270 min.

Also, in accordance with Vidal *et al.*^[8], showed that the mean Demester score was 30±4.

Concerning the length of hospital stay and incidence of postoperative complications among studied cases, our results revealed that the mean length of hospital stay was 1.18±0.49 ranging from 1 to 4 days. Postoperative complication was detected in one case in the form of vomiting.

As well, agreed with Anvari and Allen^[9] showed that the mean postoperative stay was 2.8±1.7 days.

Concerning clinical findings score after 4 years of follow-up, our results found that 42.8% of studied cases have heartburn with the mean score is 0.72±0.98 ranging from 0 to 3, 37.7% of studied cases have regurgitation with the mean score was 0.65±0.93 ranging from 0 to 3, 22.6% of studied cases have dysphagia with the mean score was 0.47±0.92 ranging from 0 to 3 and 18.9% have gas bloat with the mean score was 0.55±1.23 ranging from 0 to 5.

In accordance with our results, Lee *et al.*^[10] aimed to compare long-term GERD-related outcomes following different fundoplication procedures, and they reported that the incidence of heartburn for patients follow-up who received Nissen was 30.5%, the incidence of dysphagia was 29.4%, the incidence of postoperative regurgitation was 28.3%.

Regarding comparison of clinical findings between baseline and follow-up, our findings showed that there was a statistically significant change in clinical symptom frequency after follow-up as compared to baseline with the following distribution (heartburn frequency changed from 93.9% at baseline to 42.8% at follow up). From 73.3% regurgitation at baseline to

37.7% at follow-up and change of dysphagia frequency from 7.9% at baseline to 22.6% at follow-up.

Also, agreed with Bammer *et al.*^[11] revealed that heartburn, regurgitation and dysphagia at 5–8 years after laparoscopic surgery were significantly improved compared to before surgery. This proved that the laparoscopic Nissen fundoplication provides an excellent antireflux barrier. However, patients reported a high incidence of gas bloat and diarrhea.

Concerning the incidence of PPI use and the need for redosurgery among studied cases, our results found that 56.6% of studied cases do not use PPI, 22% use PPI, and 21.4% intermittent use. Among the studied cases, 16 cases needed redosurgery (10.1%) and the causes of redosurgery were as follows; three (18.8%) cases due to dysphagia and 13 (81.2%) cases due to disrupted and migrated wrap.

In supporting our results, Park *et al.*^[6] showed that 32 (24%) patients did not respond to PPI before surgery, fair response was 88 (66.2%) patients, and an excellent response was 13 (9.8%) patients.

Regarding the quality of life score and patient satisfaction among studied cases, our results revealed that the mean GERD quality of life score was 9.86±11.37 ranging from 0 to 42. As regard patient satisfaction, 76.1% are satisfied, 20.8% unsatisfied, and 3.1% are neutral.

There was a statistically significant positive correlation between GERD quality of life and patient satisfaction among studied cases with *P value* less than 0.001.

In supporting our results, Anvari *et al.*^[9] found that 86% reported high satisfaction with surgery, and 89% said that they would have the surgery again. This suggests that if partial satisfaction with surgery was also ascertained, the satisfaction percentage would be higher. Satisfaction with surgery remains high even in patients who have required redo-fundoplication for recurrence.

Also, Bammer *et al.*^[11] agreed that 93% were satisfied, 2% were unsure, and 5% were not satisfied with their decision to have surgery. At more than 5 years, overall well-being showed significant improvement compared to before surgery with *P value* less than 0.001.

CONCLUSION

We concluded from our study that the present review presents high certainty evidence that Nissen fundoplication may be preferable with respect to minimizing GERD

symptoms, such as dysphagia, heartburn, and regurgitation and other unwanted side effects and there were no postoperative complications in 164 patients except only one case in the form of vomiting while there was statistically significant positive correlation between GERD quality of life patient satisfaction among studied cases.

CONFLICT OF INTEREST

There are no conflicts of interest.

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