



Received for publication: August 05, 2019

Accepted: September 20, 2019

Research article

A combination of laparoscopic Nissen fundoplication and laparoscopic gastric plication for gastric esophageal reflux disease and morbid obesity

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Abstract

Introduction. The gastroesophageal reflux disease (GERD) is common in obesity due to the increased intra-abdominal pressure. This study retrospectively analyzed the combination (LNFGP) of laparoscopic gastric plication (LGP) and laparoscopic Nissen fundoplication (LNF) applied to patients with obesity and GERD.

Materials and Methods. The study included patients operated on between January 1st, 2013 and January 1st, 2016. The body mass index (BMI) of the patients was evaluated both preoperatively and postoperatively. The preoperative and postoperative degrees of esophagitis were compared using upper gastrointestinal tract (UGI tract) endoscopy. Additionally, postoperative complications and mortality were evaluated.

Results. In this study, resistance and morbid obesity were evaluated for the 123 patients who underwent combined LNF and LGP operation (due to the co-existence of GERD) with the medical treatment. A statistically significant decrease was observed in the BMI after one-year follow-up ($p < 0.001$). Compared to the preoperative period, an improvement was observed in the degree of endoscopic esophagitis at 12 months postoperatively ($p < 0.001$).

Conclusions. In case of the co-existence of morbid obesity and GERD, combined LNF and LGP operation is a good option for the treatment of obesity as well as for obesity-related comorbidities, such as GERD.

Keywords : laparoscopic, morbid obesity, nissen, plication

Highlights ✓ The LNFGP combination in patients with morbid obesity and GERD may be a good alternative for the simultaneous treatment of both obesity and obesity-related comorbidities.

To cite this article: Toprak SS, Gultekin Y. A combination of laparoscopic Nissen fundoplication and laparoscopic gastric plication for gastric esophageal reflux disease and morbid obesity. *J Clin Invest Surg.* 2019; 4(2): 81-87. DOI: 10.25083/2559.5555/4.2/81.87



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Introduction

Almost 1.7 billion people experience health problems due to obesity worldwide. Approximately 25% of the population, especially in developed societies, encounter this problem. Diseases such as sleep apnea, hypertension, diabetes mellitus, coronary artery disease and gastroesophageal reflux disease (GERD) are closely associated with obesity (1-3). Obesity is the most important risk factor for GERD and the incidence of hiatal hernia is three times higher in such individuals than in people with a normal body weight (4-6). Intra-abdominal pressure is increased in obesity. Lower esophageal sphincter (LES) pressure is decreased and gastric emptying is delayed secondary to the increased intra-abdominal pressure. All these changes trigger esophageal exposure to gastric acid and GERD initiation (7, 8). Obesity is believed to be the primary cause of the reflux disease. Therefore, the treatment for obesity is considered the basic approach in treating GERD (8).

Laparoscopic Nissen fundoplication (LNF) is the most preferable method in the surgical treatment of the gastroesophageal reflux disease. In the early 1990s, a rapid increase was noted in the number of LNF procedures with the introduction of laparoscopy (9, 10). On the other hand, laparoscopic sleeve gastrectomy (LSG), Roux-en-Y gastric bypass (RYGB) and gastric banding were the common methods used in the surgical treatment of obesity. Specifically, LSG and RYGB are still the most frequently preferable methods in obesity surgery (11, 12). Gastric plication was first introduced in the surgical approach of morbid obesity in 1981. This method, which did not receive attention at first, has been standing out in recent years (13).

This study retrospectively evaluated patients who underwent the combination of LFP and LNF (LNFPG) due to GERD and morbid obesity.

Materials and Methods

Patients who underwent LNFPG due to GERD and morbid obesity between January 1st, 2013 and January 1st, 2016 were retrospectively evaluated. Each patient was preoperatively informed both in writing and verbally about the indications and the results of the operation. Moreover, all patients were given a written informed consent. The study was conducted in accordance with the principles of the Declaration of Helsinki. The creation of the Database was approved by the Ethics Committee.

Data collection

Preoperative and postoperative BMI values of the patients were obtained from the patients' medical records

and the recorded data. The degrees of esophagitis were established according to the reports of upper gastrointestinal tract (UGI tract) endoscopy performed preoperatively and postoperatively at one and 12 months, respectively. The intraoperative and postoperative details of the patients were obtained from the patients' medical records and the hospital database.

Non-life threatening complications such as wound site infection, nausea and vomiting lasting less than a week and atelectasis, which were resolved by means of a medical treatment, were considered minor complications. Intra-abdominal abscess, leakage, transfusion-required hemorrhage, pneumonia, acute respiratory distress syndrome, nausea and vomiting lasting more than one week and dysphagia lasting more than one month were considered major complications.

Endoscopy

In our clinic, upper GI tract endoscopy is performed on a routine basis both preoperatively and postoperatively at one and 12 months respectively to all patients scheduled for operation due to morbid obesity and GERD. The presence of hiatal hernia is examined and the assessment of esophagitis is made in patients undergoing upper GI tract endoscopy. The presence of 2 or more-cm gastric rugal folds above the diaphragmatic crura is considered sufficient to define hiatal hernia during the upper GI tract endoscopy. Hetzel grading for esophagitis is used to evaluate endoscopic esophagitis in our laboratory (Table 1).

Table 1. The Hetzel grading system for reflux esophagitis

Grade	
Grade 0	No mucosal abnormalities
Grade I	No macroscopic erosions but erythema, hyperaemia or mucosal friability
Grade II	Superficial erosions, involving <10 % of the mucosal surface of the last 5 cm of esophageal squamous mucosa
Grade III	Superficial erosions or ulceration involving 10-50% of the mucosal surface of the last 5 cm of esophageal squamous mucosa
Grade IV	Deep peptic ulceration anywhere in the esophagus or confluent erosion of >50% the mucosal surface of the last 5 cm of esophageal squamous mucosa

The surgical treatment

Patients, in whom a 6-month medical treatment had failed, who still complained of GERD and who had a BMI ≥ 35 kg/m², were selected for the combination of laparoscopic gastric plication and LNF.

The surgical technique

LNFGP operations were performed in our clinic under general anesthesia and at an intra-abdominal pressure of 12 mmHg, under normal conditions. Trocars with a 10-mm diameter were introduced in the umbilicus, to the left subcostal region on the midclavicular line and to the right subcostal region on the midclavicular line (for the liver retractor). Trocars with a 5-mm diameter were introduced in the subxiphoid region and the left subcostal region on the mid-axillary line. The greater curvature was freed using Covidien® ligature starting from a distance of 4-6 cm from the pylorus and the left crus of the diaphragm was exposed. The left lobe of the liver was retracted upwards and to the lateral site, followed by the dissection of the gastro hepatic ligament and the exposure of the lesser curvature of the stomach. The peritoneum over the right diaphragmatic crural muscle was entered and the crura were made visible. In cases of hiatal hernia, the aperture between the crura was approximated using a silk suture of 1.0-26 mm and two or three stiches. The oro-gastric tube was withdrawn and a 42 F bougie was placed by the anesthesiologist and Nissen fundoplication was performed. For the gastric plication, single sutures were placed using 1.0-26 mm silk sutures starting at the point that was 4-6 cm proximal to the pylorus up to the fundus. The sutures were placed at a 2.5 cm distance and the plication was performed at the greater curvature pointed towards the inside of the stomach.

All the analyses were performed with IBM SPSS Statistics for Windows software (version 20.0. Armonk, NY: IBM Corp). The categorical variables were represented by frequencies and percentages, and the numerical variables were represented by mean \pm standard deviation. The normality assumptions were checked using histogram, boxplots and Kolmogorov-Smirnov test. The repeated measures of ANOVA were implemented to detect the differences between BMI values of the preoperative and postoperative evaluations of patients at 6 and 12 months respectively, thus confirming that the parametric assumptions were met. Pairwise comparisons were made with Bonferroni correction test. A non-parametric Friedman test was carried out to compare the measures of the degrees of esophagitis through endoscopy for the preoperative and the postoperative evaluation on the first and 12th month, respectively. Post hoc analysis with Wilcoxon signed-rank tests was utilized to reveal which

time points were different from one other. P values below 0.05 were considered statistically significant.

Results

The study included 123 patients, 49 males and 74 females. The mean age was 36.7 ± 9.5 years. While hiatal hernia was detected endoscopically in 44.7% of the patients prior to surgery, it was not detected endoscopically in any of the patients postoperatively. Before surgery, erosive esophagitis was 95.1%. 1st and 2nd degree esophagitis on the 12th postoperative month was 25.2% and 4.1%, respectively. The preoperative BMI of the patients was 39.3 ± 2.8 kg/m². The BMI on the 6th and 12th postoperative month was 32.1 ± 2.9 kg/m² and 27.6 ± 2.6 kg/m², respectively (Table 2).

Table 2. Change in body mass index: Repeated Measures of ANOVA results for preoperative 6th, and 12th months of postoperative.

Parameter	Mean \pm SD			Time	
	Preoperatively	6th Month of postoperatively	12th Month of postoperatively	F	p
BMI	39.26 \pm 2.73***	32.06 \pm 2.98***	27.62 \pm 2.63***	1814.11	<0.001

The mean preoperative and the 6th and 12th postoperative month BMI values were analyzed and it was found that the preoperative BMI value decreased in time by the 6th and 12th postoperative months (Figure 1).

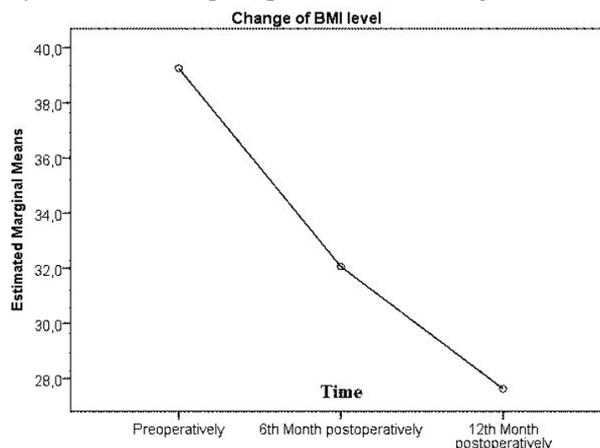


Figure 1. Changes in the mean of BMI according to the operation time points

In order to identify whether there was a significant difference between them, the results of the Bonferroni-adjusted pairwise comparison were further analyzed. Based on these results, the difference between the mean BMI values at different time points (preoperatively, 6th postoperative month and 12th postoperative month) were statistically significant (p<0.001).

In order to compare the degree of esophagitis preoperatively and on the 1st and 12th postoperative month, Friedman test was performed and a significant chi-square value ($\chi^2 = 204.96$, p < 0.001) was obtained.

The mean esophagitis degree and frequency at each time point are given in Figure 2. While the mean degree of preoperative esophagitis was 2.56, it was 2.33 on the 1st postoperative month and 1.11 on the 12th postoperative month. No significant difference was detected between the degree of preoperative esophagitis and the 1st

postoperative month esophagitis ($p \geq 0.05$). However, the difference between the degree of esophagitis on the 12th postoperative month and preoperative esophagitis and 1st postoperative month respectively was statistically significant (diff1 = 1.44, diff2 = 1.21; $p < 0.001$ for each, respectively).

Related-Samples Friedman's Two-Way Analysis of Variance by Ranks

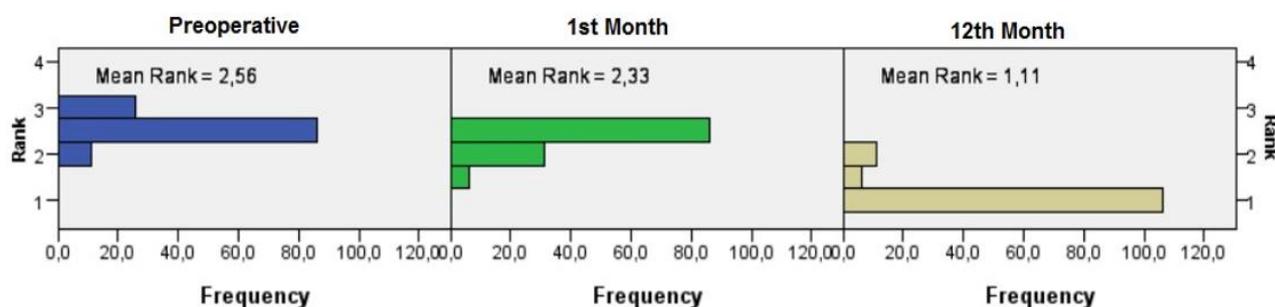


Figure 2. Distribution of esophagitis grades

All patients continued to receive medical treatment for gastroesophageal reflux for two postoperative weeks. 12 patients (9.75%) required medication for gastroesophageal reflux intermittently for one year. The mean duration of the hospital stay was 3.8 ± 1.7 days. The mean duration of the operation was 88.2 ± 11.4 minutes. There were no mortalities in the subject group. The required amount of weight loss was not achieved for three subjects after the one-year follow up. Subtotal gastrectomy was performed in two patients as a result of necrosis that developed in the suture line. The patients were discharged after the reoperation without any complications. One patient developed intra-abdominal abscess and subsequently underwent another operation to drain the abscess. Four patients complained of dysphagia that lasted for more than a month. One patient underwent endoscopic dilation for dysphagia. Another patient who had had nausea and vomiting symptoms for two months was hospitalized and received medical treatment. A total of 16 patients experienced minor complications such as atelectasis, short-term nausea/vomiting (less than a week), and dysphagia.

Discussions

Obesity is the most important factor for GERD (7). Intra-abdominal pressure is increased in obesity. Increased intra-abdominal pressure is associated with conditions such as GERD, erosive esophagitis and esophageal adenocarcinoma (14). The standard surgical treatment for GERD is LNF when medical treatment means are unresponsive. Several studies have demonstrated the efficacy and long-term success of LNF in GERD (9, 15, 16).

Obese patients are expected to experience a high rate of complications and insufficiency following LNF due to the increased intra-abdominal pressure and other comorbid causes. Morbid obesity is known to cause many additional comorbidities and it has also been demonstrated to have adverse outcomes following LNF. In a study by Perez et al., the recurrence of reflux was reported to be more frequent following LNF in obese patients than in individuals with a normal weight. Tekin et al. reported a similar result in their publication (17, 18). The treatment of obesity in cases of GERD accompanying morbid obesity will positively affect the long-term results of GERD and it will as well as result in the removal or decrease of other comorbidities associated with morbid obesity (19). Weight loss can also be observed following LNF. However, the LNF procedure alone is inadequate for weight loss, as reported by Frazzoni et al. in 2014 (9). Therefore, the LNF procedure, when performed alone in case of obesity and GERD, may not be efficient or adequate for long-term success. Besides, GERD-related adverse outcomes may also occur in bariatric surgery procedures performed to treat morbid obesity. LSG is a commonly used method for bariatric surgery and it leads to efficient weight loss, which has been demonstrated by several clinical studies (16, 20, 21). However, a change in the His angle and dysfunction in the LES pressure occur following LSG. Prior studies have reported a newly formed GERD following LSG in 8.6-47% of the cases. Therefore, sleeve gastrectomy is not an appropriate option in patients with GERD and morbid obesity (19). In gastric banding, which is another surgical option for morbid obesity treatment, a large area of intra-abdominal pressure is developed and hence, LES pressure

increases accordingly. However, the long-term development of esophageal dilation causes the worsening of the postoperative GERD. Therefore, the gastric banding method is also inappropriate for the morbid obese patients with GERD (19, 22). RYGB, one of the restrictive bariatric surgical methods, is the bariatric surgery type with the widest use. The results associated with GERD following RYGB are generally positive. A study with 55 cases did not reveal the aggravation of GERD following RYGB in any patient and established the improvement of 96% of the patients. This is the reason for the preference of RYGB in patients with morbid obesity and GERD (23). However, RYGB surgery includes anastomoses and anastomotic leakage can occur in 1-2% of the cases. Besides, the reported rate of general complications is up to 40% in such operations. The selection of RYGB by both the surgeons and the patients as the preferable method is negatively affected by all the causes stated above (24).

As a result, combined operations have become a current issue in the resolution of the two pathological conditions in patients with morbid obesity and GERD. The study by Khan et al. (2016), which evaluated the effect of the treatment of obesity on GERD, pointed out that there are numerically inadequate studies on combined operations in morbid obesity and GERD. Furthermore, the authors have emphasized the low number of cases of such studies (19). In 2007, Fedenko et al. published a study on combined operation about the combination of sleeve gastrectomy and Nissen fundoplication in three cases. As a result of the study, the authors reported an adequate weight loss during the follow-up of 5-7 months and no signs of esophagitis at the postoperative upper GI tract endoscopy (25). In turn, Khazzaka and Sarkis combined mediogastric plication and laparoscopic fundoplication in 16 obese patients with GERD. They concluded that total healing was achieved in GERD and an adequate weight loss was ensured at the end of the first year (26). In 2014, Lee et al. published a combination study of LNF and LGP which included 25 patients. In that study, the mean preoperative BMI of the patients was 37.4 ± 5.1 kg/m². In turn, the postoperative 12th month BMI was 30.8 kg/m². The duration of the operation and the hospital stay were 145.6 ± 23.5 minutes and 1.4 ± 1.5 days, respectively. Postoperatively, only 16% of the patients had intermittent reflux symptoms; however, anti-acid treatment was not required. Preoperatively, 80% of the patients had erosive esophagitis, while only 20% of the patients had A-degree esophagitis at the postoperative evaluation. The authors reported that this method is satisfactory in terms of the anti-reflux effects and weight loss (10). In the present study, which involved a similar

procedure, the mean preoperative BMI was 39.3 ± 2.8 kg/m², while the mean BMI on the 12th postoperative month was 27.0 ± 2.5 kg/m². The present study established a higher decrease in BMI with regard to weight loss. The mean duration of the operation was also shorter, while the duration of the hospital stay was longer. In the present study, esophagitis was present in 95.1% of the cases preoperatively, while 25.2% and 4.1% of the patients had degree 1 and degree 2 esophagitis, respectively on the 12th postoperative month.

There was no increase in the rate of intraoperative or postoperative complications in the combined operations compared to LNF alone and LGP alone. Dallemagne et al. evaluated the efficacy and the results of fundoplication in 100 cases. The reflux symptom recurrence was observed in three patients and reoperation was required in one patient due to resistant dysphagia (27). In the study by Pessaux et al., which involved laparoscopic fundoplication in 1,470 patients, the rate of conversion to open surgery was 6.5% and reoperation due to clinical recurrence was 5.6%. The mean duration of the hospital stay was reported to be 4.6 days (28). All the LNFGP operations performed as a combination were completed laparoscopically in the present study. Although the duration of our follow-up is shorter, four patients developed short-term dysphagia. No case required reoperation due to dysphagia or clinical recurrence. It was observed that the hospitalization period of the patients who had received a combined operation was no longer (3.8 ± 1.7 days) than the hospitalization period of the patients who had only undergone LNF. Talebpour et al. have conducted a research that evaluated 800 LGP patients. They determined that 1% of the patients required reoperation due to several reasons such as micro perforation or obstruction. This study indicated the operation duration to be 72 (49-152) minutes (29). Kourkoulos et al. evaluated the effects of the LGP operation in case of morbid obesity. They found the incidences of minor complications, major complications and reoperation to be 10.7%, 4.4%, and 3%, respectively (30). 3 of our patients (2.43%) required reoperation after the LNFGP combined operation. Our reoperation rate was consistent with the study of Kourkoulos et al. The duration of our LNFGP operations was determined at 88.2 ± 11.4 minutes. This was not significantly longer than the duration of LGP operation alone. In our study, the major and minor complication rates were 6.5% (8 patients) and 11.3% (16 patients) respectively. The complication rates were not significantly different from the results obtained by Kourkoulos et al.

Conclusions

For morbid obesity patients with accompanying GERD, the LNFGP combined operation is used to treat both morbid obesity and diseases that are comorbid with morbid obesity (such as GERD). Moreover, LNFGP positively influences the long-term results of LNF in GERD. In addition, the LNFGP combination does not determine a clinically significant increase in complication and mortality rates. However, there are not enough studies or subjects on this topic. The limitations of this study are that it only reports short-term results and it depends on retrospective analyses. We believe that studies with more subjects and more prospective evaluations are needed to clarify this topic.

Conflict of interest disclosure

There are no known conflicts of interest in the publication of this article. The manuscript was read and approved by all authors.

Compliance with ethical standards

Any aspect of the work covered in this manuscript has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

Abbreviations

- GERD: Gastroesophageal reflux disease
 BMI: Body mass index
 GI tract: Gastrointestinal tract
 LES: Lower esophageal sphincter
 LGP: Laparoscopic gastric plication
 LNF: laparoscopic Nissen fundoplication
 LNFGP: The combination of laparoscopic gastric plication and laparoscopic Nissen fundoplication
 UGI tract: Upper gastrointestinal tract
 LSG: Laparoscopic sleeve gastrectomy
 RYGB: Roux-en-Y gastric bypass

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