

The Value of Combination of Laparoscopic Nissen's Fundoplication with Laparoscopic Greater Curvature Plication in Obese Patient with Gastroesophageal Reflux Disease

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Introduction: Gastroesophageal reflux disease (GERD) and obesity are commonly associated. Resistant GERD is mainly treated surgically with laparoscopic antireflux surgery, including laparoscopic Nissen fundoplication (LNF). Bariatric surgery has been recognized as the only definitive treatment for sustained weight loss. A recent combination of LNF and gastric plication has been proposed for the treatment of GERD and obesity in one setting.

Aim of work: This study aimed to present our experience in performing combined LNF and laparoscopic greater curve plication (LGCP) for patients with obesity and associated GERD.

Patients and methods: This is a prospective non-randomized cohort study that included patients who underwent LNF with LGCP for the treatment of obesity and GERD. The patients were followed up for 6 months postoperatively, during which they underwent clinical assessment of the weight loss, upper GIT endoscopy, and GERD-Health Related Quality of Life (GERD-HRQL) questionnaire assessment.

Results: This study included 24 patients who were eligible for the study. Perioperative adverse events were encountered in two patients. One case indicated surgical intervention (4.17%). There were no mortality cases. At the 6-month follow-up, the mean amount of weight loss was 25.7 ± 13.3 kg, and the mean percentage of total weight loss was 22.49 ± 0.12 . There was statistically significant postoperative improvement in the postoperative endoscopic findings and GERD-HRQL scores ($p < 0.001$).

Conclusion: This study shows promising short-term efficacy of combined LNF and LGCP for the treatment of obesity with associated GERD. There are still concerns regarding the standardization of plication techniques.

Key words: Obesity, gastroesophageal reflux disease (GERD), laparoscopic greater curve plication (LGCP), laparoscopic Nissen fundoplication (LNF), weight loss, GERD control.

Introduction

Gastric contents may occasionally reflux into the esophagus. If this physiological phenomenon is manifested as regurgitation, heartburn, and/or signs of mucosal irritation, then this denotes the development of gastroesophageal reflux disease (GERD).¹

GERD is one of the most commonly encountered disorders in daily practice.² It affects about one-third of the general population. This percentage is stated to increase up to 70% in patients with morbid obesity.³⁻⁵

The occurrence of GERD in patients with obesity was believed to be mainly the consequence of a large amount of abdominal fat and elevated intra-abdominal pressure. Currently, it is assumed that obesity may be associated with dysfunction of the lower esophageal sphincter (LES), with a reduction of the LES pressure and an increase in the frequency of transient LES relaxation. This may also be combined with disturbances in gastroesophageal motility and delayed esophageal and gastric emptying.^{6,7}

In resistant cases, GERD is mainly treated surgically with laparoscopic antireflux surgery (LARS).^{8,9} Laparoscopic Nissen fundoplication (LNF) was first

performed in 1992.¹⁰ Since then, it has gained growing popularity. LNF has shown successful long-term symptomatic relief in more than 80% of patients.^{11,12}

As for obesity, bariatric surgery has been recognized as the only definitive treatment for sustained weight loss and comorbidity resolution.^{13,14} There has been continuous improvement in iniatric procedures and the evolution of new ones. One of the newly evolved bariatric procedures is laparoscopic greater curvature plication (LGCP).¹⁵ This procedure entails the reduction of the stomach volume through folding the greater curve of the stomach into itself, with fixation using one or more rows of stitches, with a resultant restrictive effect.¹⁵ Since it was introduced, LGCP has gained increasing interest among bariatric surgeons. LGCP has shown safety and efficacy in several studies.¹⁶⁻¹⁸

Recently, a combination of LNF and gastric plication has been proposed for the treatment of GERD and obesity in one setting.¹⁹ The literature addressing this combination is scarce.

Therefore, this study aimed to present our experience in performing combined LNF and LGCP for patients with obesity and associated GERD.

Patients and methods

This is a prospective non-randomized cohort study that was performed in the surgical departments of our institution, and included patients who underwent LNF with LGCP for the treatment of obesity and GERD. The study was approved by the Institutional Research Ethics Committee and performed as per the Declaration of Helsinki.

The adult patients who were recruited to the surgery department with obesity were checked for being candidates for bariatric surgery as per the 1991 NIH consensus,²⁰ and the International Federation for the Surgery of Obesity (IFSO).²¹ Only patients with a BMI greater than 30 with one or more associated co-morbidities or a BMI greater than 35 with or without comorbidities were considered suitable candidates for our technique. From our experience with gastric plication, we excluded patients with a BMI greater than 45 to achieve adequate excess weight loss. Patients who were candidates for surgery were assessed for GERD, and those who were found to have a history of GERD symptoms that are resistant to the antireflux medications were informed about the study. Those who accepted to participate after a dedicated discussion with the surgeon underwent a pH study and were eligible for the study if a GERD diagnosis was confirmed. The included patients underwent preoperative clinical examination, including full history taking, multidisciplinary physical evaluation, laboratory tests, abdominal ultrasound, barium swallow and meal, and upper GIT endoscopy. Written informed consent was obtained from the included patients before surgery.

The study patients were asked to fill out the GERD-Health Related Quality of Life (GERD-HRQL) questionnaire to estimate their GERD severity preoperatively and at postoperative follow-up.²³

The surgical technique

The patient was positioned in a reversed Trendelenburg position, and the surgery was performed with the standard five-port laparoscopic technique. After pneumoperitoneum was created, the greater curvature was mobilized, and devascularization was done using the Covidien® Ligasure device, starting 3–4 cm from the pyloric ring and reaching the angle of His with a full release of the phrenoesophageal ligament. The right crural dissection was achieved by opening the pars flaccida of the gastro-hepatic ligament. The right phreno-esophageal membrane was opened to

expose the right crural fibers. A retro-esophageal window was made, taking care to avoid injury to the posterior vagus nerve. Esophageal mobilization was performed to attain an esophageal length in the abdominal cavity of 3–5 cm with special care to avoid injury to both the vagi and pleura. In cases where a hiatus hernia was found, repair was done after esophageal mobilization (**Fig. 1**).

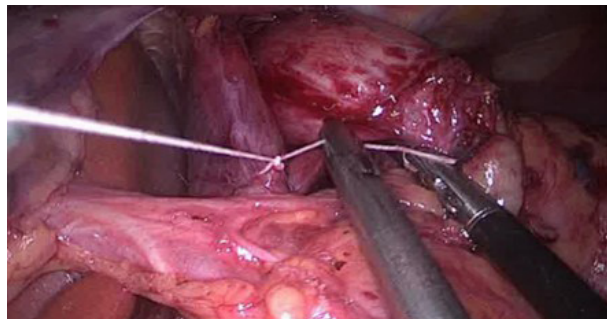


Fig 1: Hiatal hernia repair after the esophageal mobilization.

The crural approximation was done using 2/0 ethibond sutures, and the wrap was created after passing the calibration tube through a 50 Fr bougie to ensure standardization and precision in the surgical process.

The posterior portion of the fundus was bypassed by the esophagus posteriorly from left to right. Meanwhile, the anterior portion of the gastric fundus was grasped about 2 cm proximal to the greater curve and about 3 cm distal to the gastroesophageal junction. We ensured that the anterior and posterior portions of the fundus were grasped equidistant from the greater curve to avoid inserting the gastric body into the wrap. Using 2/0 ethoibond sutures, three seromuscular sutures were performed at the anterior fundus, esophagus, and posterior fundus. (**Fig. 2**).

After that, gastric plication was performed over a 36 Fr bougie in a similar manner. The plication was done from just caudal to the wrap using a running seromuscular suture line of 2/0 non-absorbable Covidien® V.LOC 45cm length. The first layer of plication was done by forming serial horizontal suture lines, taking multiple posterior wall bites, greater curvature, and then multiple anterior wall bites. The space between the horizontal lines was adjusted to 1–1.5 cm until reaching 5–7 cm from the pylorus, then a second running suture line was applied over the first layer to avoid the outpunching with a 0.5–1 cm distance between the serial horizontal bites. (**Fig. 3**).

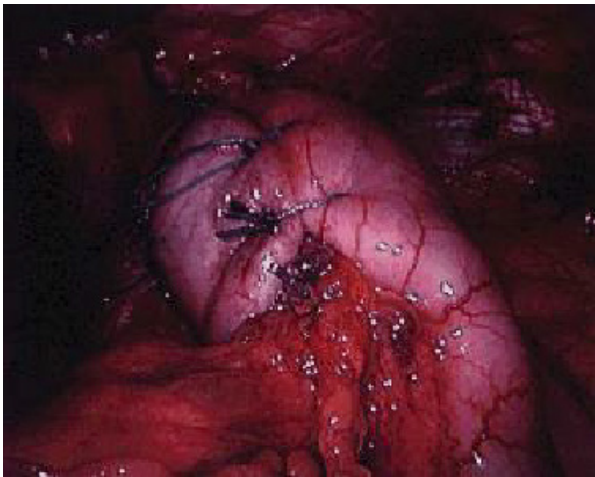


Fig 2: Nissen Fundoplication.



Fig 3: The end of the procedure after plication of the greater curvature.

A methylene blue leak test was performed to ensure no leakage. The perioperative events and the operative time were recorded.

Proton pump inhibitors were prescribed for 3 months postoperatively and continued if the symptoms persisted until the follow-up time. The patients were followed up until the postoperative 6th month, during which they were subjected to clinical assessment of weight loss, upper GIT endoscopy, and GERD-HRQL questionnaire assessment. Endoscopic assessment was done by an independent endoscopist. The total body weight loss (TWL%) was calculated as standardized.²⁴

Study outcomes

The primary outcomes were the TWL% and the degree of esophagitis as shown in the endoscopic assessment. The secondary outcomes were the perioperative complications and the GERD-HRQL assessment at the 6-month follow-up.

Statistical analysis

The patients' data was analyzed using SPSS statistical software (IBM Corp., Armonk, NY, USA), version 28. Comparing the postoperative numerical data to the corresponding preoperative values was done using the paired samples t test or Wilcoxon signed rank test according to the data normality, while the McNemar test was used to compare the

categorical data. A p-value less than 0.05 was considered statistically significant.

Results

This study included 24 non-randomly selected morbidly obese patients who underwent the combined LGCP and Nissen fundoplication technique. The allocation of patients to this operation depended on the choice of the patient after discussion with the surgeon. The patients' ages ranged from 26 to 53 years, with a mean of 35.5 ± 6.91 years. Females constituted a higher percentage ($n = 17, 70.8\%$). The mean preoperative weight was 111.9 ± 17.7 kg, and the mean preoperative BMI was 39.95 ± 3.03 kg/m² (**Table 1**).

The endoscopic assessment revealed that 15 patients (62.5%) had grade A esophagitis, while 9 patients (37.5%) had grade B. The preoperative GERD-HQRL assessment demonstrated that the patients had sub scores ranging from 9 to 27, with a median of 22, in the items assessing heart burn; sub scores ranging from 0 to 6, with a median of 0, in the items assessing dysphagia; and sub scores ranging from 2 to 9, with a median of 6, in the remaining items (Assessing gas bloating and response to treatment). The final total score ranged from 15 to 51, with a median of 35 (**Table 2**).

The operation time ranged from 85 to 120 minutes, with a mean of 94.21 ± 9.25 minutes. The patients' mean hospital stay length was 3 ± 1.5 days. Perioperative adverse events were encountered in two patients, of whom one case indicated surgical intervention. There were no mortality cases (**Table 1**).

One patient developed persistent vomiting that did not respond to medical treatment on day 20 postoperatively. An upper endoscopy was done and revealed an accumulation of food remnants that were retained in both the fundoplication wrap and the stomach. The endoscopy failed to pass freely through the gastric lumen. The patient was vitally stable and readmitted for parenteral fluid, intravenous proton pump inhibitors (PPIs), and intravenous antiemetics. However, there was no clinical improvement. The patient was re-operated upon to undo the gastric plication and preserve Nissen's fundoplication, and she was discharged uneventfully.

Another case of dysphagia to solid and semi-solid food developed in the second month postoperatively, with accepted tolerance to oral fluids in the range of 80–120 cc daily. Computed tomography with oral gastrograffin imaging revealed no pathological abnormalities, but upper endoscopic assessment showed severe gastritis. The patient was managed conservatively and improved on medical treatment (Intravenous fluids, PPIs, and antacid drugs). After

10 days of hospital admission, she was discharged with no significant complaints.

At the 6-month follow-up, the mean BMI was significantly reduced to $30.39 \pm 7.51 \text{ kg/m}^2$ ($p < 0.001$). The mean amount of weight loss was $25.7 \pm 13.3 \text{ kg}$, and the mean TWL% was 22.49 ± 0.12 .

The endoscopic assessment revealed that 5 patients (20.83%) had grade A esophagitis, and the remaining patients had normal examinations. There was a statistically significant improvement compared to the preoperative findings ($p < 0.001$). The postoperative GERD-HQRL assessment demonstrated that the

patients had scores ranging from 5 to 15, with a median of 5 in the items assessing heart burn; scores ranging from 4 to 6, with a median of 4 in the items assessing dysphagia; and scores ranging from 0 to 5, with a median of 2 in the remaining items. The final total score ranged from 9 to 34, with a median of 16. There were statistically significant postoperative reductions in the heart burn ($p < 0.001$) and regurgitation scores ($p < 0.001$), whereas there were statistically significant higher dysphagia scores ($p < 0.001$) compared to the preoperative values. The total postoperative score was significantly lower compared to the preoperative one, denoting an overall significant improvement (**Table 2**).

Table 1: Baseline demographic data and operative events of the study patients

		Study patients (n=24)	
		Mean \pm SD	Range
Age (year)		35.5 \pm 6.91	26 - 53
Baseline weight (Kg)		111.9 \pm 17.7	95 - 146
Baseline BMI (Kg/m²)		39.95 \pm 3.03	35 - 44.1
Total Surgery time (min.)		94.21 \pm 9.25 \uparrow	85 - 120
		Count	%
Sex	Male	7	29.2%
	Female	17	70.8%
Early Postoperative Adverse Events			
Yes		2	8.33%
No		22	91.67%
Required surgical intervention			
Yes		1	4.167%
No		23	95.83%
Mortality Rate			
Yes		0	0.0%
No		24	100%

Table 2: GERD-HRQL and endoscopic assessment preoperatively and postoperatively

	Study patients (n=24)		
	Preoperative N = 24	6-month postoperative N = 24	p-value
	Median (range)	Median (range)	
GERD-HRQL (Heart Burn)	22 (9 - 27)	5 (5 - 15)	<0.001* ^a
GERD-HRQL (dysphagia)	0 (0 - 6)	4 (4 - 6)	<0.001* ^a
GERD- HRQL (Remaining items)	6 (2 - 9)	2 (0 - 5)	<0.001* ^a
GERD-HRQL (Total score)	35 (15 - 51)	16 (9 - 35)	<0.001* ^a
	Count (%)	Count (%)	
Endoscopic findings			
Grade A esophagitis	15 (62.5)	5 (20.38)	
Grade B esophagitis	9 (37.5)	0 (0)	<0.001* ^b
None		19 (79.62)	

a: Wilcoxon signed rank paired test, b: McNemar test, *: statistically significant.

Discussion

Obesity has been described as a major risk factor for GERD. Both obesity and GERD are serious health and social problems. This has prompted several attempts to find the best therapeutic options.

This study aimed to investigate a relatively recently proposed combination of anti-reflux surgery (LNF) and bariatric surgery (LGCP). The present study revealed that this combination resulted in significant GERD improvement and satisfactory weight loss with a relatively low complication rate.

The combination of LNF and gastric plication was first described by Khazzaka and Sarkis in 2011 and published in 2013.¹⁹ The authors declared that this technique offered a mean weight loss of 10 kilograms while providing reasonable control of GERD after one year of surgery. Our study provided a higher amount of weight loss at the 6-month follow-up, which may be attributed to variation in the patients' baseline criteria. Khazzaka and Sarkis's study was conducted on 16 patients with a baseline BMI ranging from 32–35 kg/m², which is obviously lower than the baseline BMI of the current study's patients and likely partially explains the higher amount of weight loss despite a shorter time of follow-up. Another reason could be the difference in plication technique, where we performed a greater curvature plication compared to the mediogastric plication performed by Khazzaka and Sarkis.¹⁹ In this context, Brethauer,²⁵ observed that greater curvature plication provided a better weight-loss outcome than mediogastric plication.

In 2014, Lee et al.²⁶ replaced the mediogastric plication with the greater curve side plication and reported a weight loss outcome that was close to what was found in the present study since they described a reduction of the mean BMI from 37.4 kg/m² at baseline to 31.5 kg/m² at the 6-month follow-up. They also reported reasonable control of the GERD condition, but at the expense of an 8% procedure-related major complications rate.

In 2016, Ospanov et al.²⁷ compared combining LNF and LGCP to LNF alone and reported the superiority of combined procedures in terms of better GERD control, as estimated by PH monitoring and GERD-HRQL assessment, besides the weight loss benefit of LGCP. They reported a lower rate of major perioperative complications (3.6%), similar to the rate of 4.17% that was found in the current study.

One year later, Ivano et al.²⁸ reported that LNF with LGCP led to a reduction of the mean DeMeester scores from 28.7 to 2.8 3 months after the surgery in 16 patients. This was accompanied by a satisfactory rate of weight loss.

In 2018, Talha and Ibrahim,²⁹ presented their experience with 18 patients who underwent LNF combined with mid-gastric plication. They observed a significant improvement in endoscopic findings and GERD-HRQL at 6 months compared to the preoperative findings.

Finally, the latest experience with this combination was published in 2019 by Toprak and Gultekin.³⁰ They reported a statistically significant reduction in the BMI and the esophagitis grade at the 12-month follow-up.

It is worth noting that the GERD-HRQL in this study revealed higher postoperative dysphagia-related sub-scores. This is consistent with the previously established fact that dysphagia is relatively common after anti-reflux surgery, with 8%–35% of patients experiencing persistent dysphagia 12 months after the operation.³¹ However, the median dysphagia-related sub score was 4 (The sub scores denoting dysphagia severity range from 0 to 10), denoting a mild to moderate condition. Moreover, this did not affect the total GERD-HRQL satisfaction score, which showed significant improvement. None of the studies that investigated the effect of combined procedures on GERD-HRQL specified the effect on dysphagia.^{27,29}

The present study is limited by the relatively small sample size and the short-term follow-up. However, it presents our experience with a scarcely performed technique. Further larger studies with long-term follow-up are warranted to resolve the procedure-related unanswered questions.

Conclusion

This study shows the promising short-term efficacy of combined LNF and LGCP for the treatment of obesity with associated GERD. There are still concerns regarding the standardization of plication techniques.

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