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# Laparoscopic surgical treatment of severe obesity combined with gastroesophageal reflux disease: a pilot randomized two-arm controlled clinical study

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**ABSTRACT**

Obesity and gastroesophageal reflux disease (GERD) are serious medical, social, and economic problems of modern society. A pilot randomized two-arm controlled clinical study was conducted to compare laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication (LFN+LGP) versus only Nissen fundoplication (LFN). The study included 114 patients with GERD with a body mass index of 30.0–39.9 kg/m2. The following indices were used to assess efficacy: 24-hour pH-metry with calculation of the DeMeester index, percentage of excess weight loss (EWL%), and patients' quality of life, for which the Bariatric Analysis and Reporting Outcome System with the Moorehead-Ardelt Quality of Life Questionnaire II scoring key was used. Postoperative evaluation of quality of life and the dynamics of key GERD symptoms was conducted with the GERD Health-Related Quality of Life questionnaire. All operations were performed laparoscopically. No significant difference was noted in the antireflux function after surgery between the two groups. The bariatric effect (EWL% after 12 months) was better in the LFN+LGP group (45.26 ± 5.80 %) than in the LFN group (18.43 ± 4.60 %) ($p < 0.0001$).

**KEYWORDS**
gastroesophageal reflux disease, obesity, Nissen fundoplication, greater curvature placation

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## Introduction

The World Health Organization (WHO) officially declared "the threat of global obesity" for the first time in 1997 (World Health Organisation, 1997). Today, WHO experts conclude that the disease has quickly spread beyond the territory of the United States and Western Europe, covering Eastern Europe,

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Latin America, the Middle East, and the developing world, thus turning into pandemic disease (Branca, Nikogosian & Lobstein, 2007a; Parfilova & Karimova, 2016).

According to the WHO, the number of obese people is expected to increase two-fold by 2025 as compared with 2000. The European Office estimated that in 2010, about 150 million (20 %) of the adult population in Europe were obese and that 30–80 % of adults in other countries were overweight (Branca, Nikogosian & Lobstein, 2007b; Chan, 2011). As claimed by the WHO, an average of 24.4 % of the employable population of Kazakhstan is obese (World Health Organisation, 2015). In 2005, Dent et al. pointed out a similar global trend for the prevalence of gastroesophageal reflux disease (GERD), which, like obesity, is constantly increasing and now affects up to 40 % of the population (Dent et al., 2005).

The body mass index (BMI) itself is a strong predictor of overall mortality. A progressive increase in mortality is noted above a BMI of 22.5–25.0 kg/m2. This is mainly due to metabolic and vascular disease (Whitlock et al., 2009). Indeed, the prevalence of the metabolic comorbidities that contribute to atherosclerosis appears to increase significantly with an increasing BMI (Bays, Chapman & Grandy, 2007; Nguyen et al., 2008). In parallel with this trend in obesity is the perception that the prevalence of GERD has increased as well, currently affecting 8–26 % of the population in the Western world (Neumayer et al., 2005; Corley, Kubo & Zhao, 2007; El-Serag et al., 2007).

The prevalence of GERD is markedly higher in overweight and obese individuals than in those with a normal BMI (El-Serag et al., 2005; Hampel, Abraham & El-Serag, 2005). In 2009, for example, Ayazi et al. (2009) showed that an increase in BMI increases the probability of heartburn and regurgitation. The researchers identified a logical pattern showing that obese patients experience the previously discussed symptoms of GERD three times more often than do people of normal weight.

The association between the relative risk of death and a high BMI has been established (Freedman et al., 2006). Unfortunately, however, there are different opinions regarding a single-step treatment of GERD and obesity. Some scientists consider that gastric bypass provides the best outcomes, and others believe that only crurorаphy or fundoplication is sufficient. The absence of any generally accepted recommendations regarding surgical treatment makes this an important clinical issue.

## Aim of the Study

The aim of this study was to evaluate the antireflux and bariatric effects of fundoplication by floppy Nissen fundoplication combined with gastroplication.

## Research questions

The overarching research question of this study was as follows:

Is laparoscopic surgery safe?

## Method

This was a pilot randomized two-arm controlled clinical study involving 114 patients diagnosed with GERD and first- or second-degree associated obesity. All were patients randomly divided in two groups: 56 patients underwent plication

of the greater gastric curvature combined with Nissen fundoplication (LFN+LGP group), and 58 patients underwent standard Nissen fundoplication (LFN group).

These patients underwent surgeries from 2010 to 2015. We performed a comparative analysis using statistical methods to determine the correlative relationship and outcomes of the selected single-step method of treatment.

Only patients with typical GERD symptoms, esophagitis, and hiatal hernias treated with proton pump inhibitors for at least 2 months before surgery were invited to participate in the study. Patients were admitted to the study only after they had been properly instructed and had provided written informed consent.

All necessary ethical and governance approvals were obtained from the Ethics Committee of the Astana Medical University (No. 3 15.01.2010).

### *Patient inclusion criteria*

The patient inclusion criteria were as follows: age of >18 years, the presence of diet-induced (primary) obesity of type one and two according to either a gynoid or android pattern of fat deposition (BMI, 30.0–39.9 kg/m2), and the presence of GERD with simultaneous antireflux and bariatric treatment. Patients of both sexes were included. Finally, 114 patients were enrolled.

### *Patient exclusion criteria*

The patient exclusion criteria were as follows: refusal to undergo the operation and/or participate in the ongoing study at any stage of the study; laparoscopic operations that required conversion to open operations; diseases of other organs and systems, the treatment of which could affect the course of GERD; BMI of <30.0 or >39.9 kg/m2; the presence of a large diaphragmatic hernia; the presence of second-degree esophageal shortening; a history of an operation in the cardioesophageal area; a history of an operation in the abdominal cavity; and the need for other simultaneous operations.

### *Barium X-ray test*

This test plays a crucial role in the diagnosis of GERD and traditionally begins with chest and stomach X-ray examination. The patient positioning during examination of the stomach was vertical and then horizontal with rotation in different directions. The postoperative stomach volume, shape, and contrast evacuation period were determined using contrast-enhanced multiple-view X-ray examination. Therefore, barium swallowing was an essential part of this examination (Mattioli et al., 2003).

### *Esophagogastroscopy before and 6–12 months after the operation*

Endoscopic methods help to specify the diagnosis by evaluation of the mucous membrane and identification of the border between the mucous membranes of the esophagus and stomach.

### *24-hour monitoring of pH of lower third part of esophagus after surgery*

The pH of different levels of the gut and stomach was measured during the first 24 hours postoperatively and ranged from 4.0 to 7.0. The results were stored on an external memory drive and printed. This analysis was a more

specific method with which to confirm the diagnosis of nonerosive esophageal reflux, particularly for patients without exact endoscopic or histological evidence of the disease (Mattiolo et al., 1991).

BMI was used as a measure of relative size based on the mass and height of an individual.

### *DeMeester evaluation*

This evaluation reflects the pH gastroesophageal transition for 1–24 months after surgery. It was used to evaluate the daily pH levels by taking into account exposure to the acidic environment in the esophagus throughout the entire investigation period as well as in the vertical and horizontal body positions. The original scoring system proposed by Johnson and DeMeester (Johnson & Demeester, 1974) examined six variables (percent total time that the pH was <4, percent upright time that the pH was <4, percent recumbent time that the pH was <4, number of reflux episodes, number of reflux episodes with a pH of <4 for 5 minutes, and duration of the longest single acid exposure episode). A composite score was then calculated according to a formula based on the deviation of each of these variables from normal values.

### *Bariatric efficiency as evaluated by excess weight loss*

The body mass was measured using the percent of excess weight loss (EWL%) by standard methodology 1, 3, 6, 12, 18, and 24 months after surgery as follows:

EWL% = [EWL (kg) / original EBW (kg)] × 100 %

Original EBW = body mass of patient during checkup (kg) − ideal body mass (kg)

Brock's formulas:

Male ideal weight = (height in cm − 100) × 1.15

Female ideal weight = (height in cm − 100) × 1.15

## Data, Analysis, and Results

### *Bariatric Analysis and Reporting Outcome System (BAROS) with Moorehead-Ardelt Quality of Life Questionnaire II scoring key*

The BAROS analysis of outcomes after bariatric surgery is based on three major components including weight loss, improvement in comorbidities related to obesity, and quality of life (QoL) assessment. Points are added or subtracted according to changes in these domains. Points are deducted for complications or reoperations. The total number of points defines the five outcome groups (failure, fair, good, very good, and excellent). Weight loss is analyzed by the total EWL%. In the present study, QoL was evaluated with the Moorehead–Ardelt Quality of Life Questionnaire II, which ranges from −3 to 3 points (Mattiolo et al., 1991; Myers et al., 2006). According to this questionnaire scoring key, QoL is considered very poor from −3.0 to −2.1 points, poor from −2.0 to −1.0 point, fair from −1.0 to 1.0 point, good from 1.1 to 2.0 points, and very good from 2.1 to 3.0 points (Myers et al., 2006).

### GERD Health-Related Quality of Life assessment

Before and after the surgeries, all patients completed surveys using the GERD Health-Related Quality of Life (GERD-HRQL) questionnaire to determine QoL and dynamics of key GERD symptoms.

### Operative procedure

A 32- to 34-Fr calibration bougie (probe) was placed in the lumen of the esophagus and stomach (Ch/Fr scale). The operation comprised the following main steps:

1. Examination of the abdomen and evaluation for the presence of a hiatal hernia
2. Mobilization of the greater curvature of the stomach
3. Extraction of the diaphragmatic crus and identification and preservation of both vagus nerves
4. Mobilization of the abdominal esophagus with creation of a retroesophageal window
5. Suturing of the crus (crurorаphy) of the diaphragm (hiatoplasty)
6. Creation of a fundoplication cuff around the esophagus by the Nissen method
7. Gastroplication by dipping the mobilized greater curvature into the stomach lumen below the fundoplication cuff, shaping the stomach in the form of a tube

Mobilization of the greater curvature of the stomach began 4–6 cm above the pyloric sphincter and continued to the His angle, as shown in Figure 1.

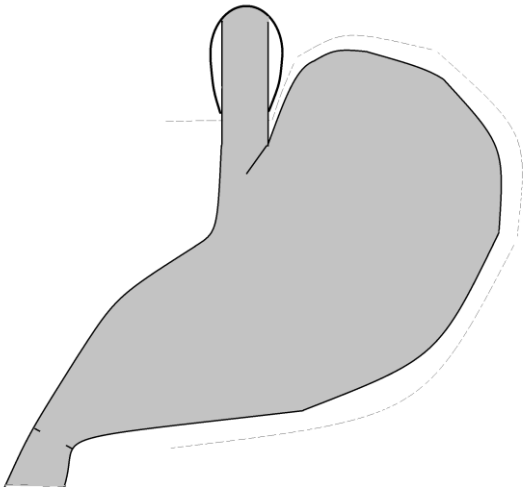

**Figure 1.** Mobilization scheme of the greater curvature of the stomach. Arrows indicate the levels of the beginning and completion of the mobilization.

An important step of the operation was complete mobilization of the greater curvature of the stomach to the left crus of the diaphragm. At the same time, the short gastric vessels were crossed and the stomach was fused with the spleen and left diaphragm crus. During mobilization, damage to the stomach wall was

avoided to prevent necrosis inside the invaginated fold. Clipping of vessels was usually unnecessary when ultrasonic shears were used.

The next stage of the operation was dissection of the liver and gastric ligament using ultrasonic shears. The ligament was dissected from its thin caudal portion (pars flaccida) to its dense cranial part (pars densa), exposing the right crus of the diaphragm.

To facilitate the dissection and isolation of anatomical structures in the esophageal hiatus, we used a bendy metal retractor to post ligatures (known as a "Goldfinger"). This was carried out behind the esophagus from the right to left diaphragm crus. Moreover, the velum rear part of diaphragm–esophageal membrane (phrenoesophageal membrane) was clearly observed and later dissected using electrocoagulation. Next, we attached a tape-like ribbon (strip) of fabric material to the fixing cut of the working part of the instrument and through a ring made of surgical polyester sutures, size 1/0.

The esophageal hiatus was well visualized when the webbing in the caudal direction was pulled out. The traction of the esophagus pulled down the seam between the esophagus and the surrounding tissues in the area of the retromediastinal fiber that was dissected earlier. At this stage, the right (rear) and left (front) vagal nerves were identified and any possible damage was avoided. Additionally, transhiatal retromediastinoscopic dissection of the esophagus close to the esophagus was rapidly performed to avoid probable damage to the left and right pleural sheets. The seams formed by periesophagitis from important anatomical structures (major blood vessels, nerves, and pleura) were clearly distinguished using laparoscopic imaging.

During selection of the diaphragmatic crus, excluding the risk of damage to the above-mentioned structures, the left gastric artery and lower diaphragmatic arteries extending directly from the celiac trunk were taken into account due to anatomical proximity.

The next stage of the operation was hiatoplasty. Suturing of the legs of the diaphragm was performed without net prosthetic devices in all patients. Two-way suturing of the legs of the diaphragm was applied in patients with larger hiatal hernias. This involved not only the obligatory rear but also the front suturing with capture of the diaphragm.

Therefore, the fundoplication cuff around the esophagus was formed according to the floppy Nissen method in patients of the LFN+LGP group, who underwent the proposed simultaneous antireflux great curvature gastric plication. This implied crossing of the short gastric vessels and the formation of a circular cuff with a length and width of no more than 2 cm with no fabric tension.

Gastroplication was performed in one of two ways: either by using one row of separate units made of nonabsorbable sutures (Ethibond 2/0) with 1-cm intervals between the stitches, or by using one row of separate units of absorbable sutures (Vicryl 2/0) and a second row represented by a continuous seam of nonabsorbable suture (Ethibond 2/0). The largest part of the antrum retains its shape and volume to enable smooth evacuation of food from the reduced stomach. The remaining part of the stomach is formed as a tube. Figure 2 shows a schematic representation of the final view of the completed antireflux great curvature gastric plication.

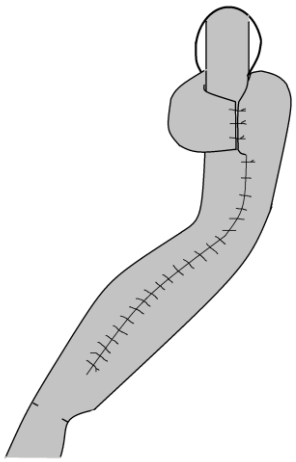

**Figure 2.** Completed antireflux great curvature gastric plication and fundoplication as floppy Nissen

We used a 32- to 34-Fr. bougie to calibrate the size of the stomach tube (Figure 3).

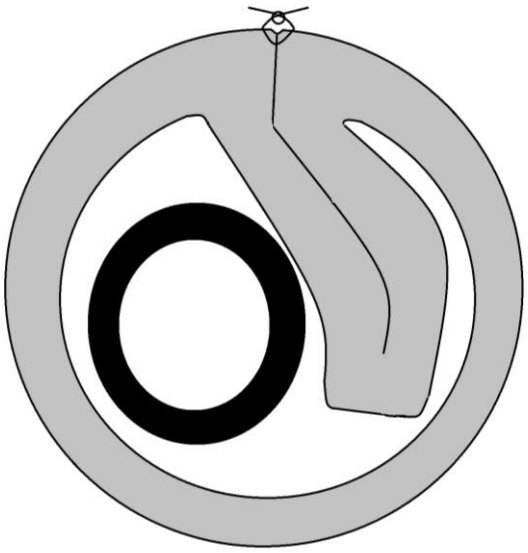

**Figure 3.** Cross-sectional view of calibration bougie and invaginated fold of great curvature in the lumen of the stomach tube.

## *Statistical analysis*

Student's t-test and the chi-squared test were used for statistical analysis.

The difference in the operative durations between the two groups was statistically significant. The longer average duration of the surgery in the patients of the LFN+LGP group is explained by the addition of plication of the greater gastric curvature, which was performed simultaneously with the standard Nissen fundoplication (Table 1).

**Table 1.** Operative data

| Indices | Groups | | |
|---|---|---|---|
| | LFN+LGP (n = 56) | LFN (n = 58) | p value |
| Average duration of operation (min) | 96.46 ± 17.25 | 59.83 ± 16.11 | <0.0001 |
| Postoperative complications (n) | 2 | 2 | |
| Average hospital stay (days) | 4.291 ± 0.530 | 4.100 ± 0.980 | NS |
| Fatal outcomes | - | - | |

Data is presented as mean ± standard deviation.

LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only

There were no fatal outcomes in this investigation, which emphasizes the safety of the laparoscopic surgeries. No suppurative or thromboembolic complications were identified. The probability of complications was analyzed according to the methodology used in the operation and using a contingency table (Table 2).

**Table 2.** Complications in each group of patients

| Group | Complications | No complications | $x^2$ | p |
|---|---|---|---|---|
| LFN+LGP, n = 56 | 2 | 54 | 0.001 | p = 0.9 |
| LFN, n = 58 | 2 | 56 | | (p > 0.05) |

LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only

As seen in Table 2, the two groups of patients did not differ in the probability of complications, and both procedures were relatively safe. Table 3 shows the types of complications.

**Table 3.** Complication types

| Complication | Number | |
|---|---|---|
| Groups of patients | LFN+LGP | LFN |
| Marginal injury of spleen by nontraumatic needle | 1 | 0 |
| Postoperative hemorrhage from short gastric vessels | 1 | 0 |
| Pneumothorax during operation, atelectasis | 0 | 1 |
| Stricture of esophagus at the level of the tight fundoplication cuff | 0 | 1 |
| Total | 2 | 2 |

LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only

An intraoperative complication occurred in one (1.8 %) patient in the LFN+LGP group. This complication was a marginal injury of the spleen by a nontraumatic needle fixed in a needle holder. Hemorrhage was stopped by electrocoagulation with additional wound closure by fibrin glue. In the early

postoperative period, no complications occurred in this group. One (1.8 %) patient from the LFN+LGP group developed a postoperative complication in the form of hemorrhage from short gastric vessels; the hemorrhage required re-laparoscopy for treatment.

During the intraoperative and early postoperative period, one (1.7 %) patient in the LFN group developed postoperative pneumothorax; therefore, a drainage tube was placed in the pleural cavity. One case of esophageal stricture at the level of the tight fundoplication cuff was detected 7 weeks postoperatively. Laparoscopic separation of the tight fundoplication cuff, junction of the short gastric vessels, and fundoplication by the floppy Nissen method were performed to resolve the issue.

Erosive esophagitis was not detected among the remaining patients in both groups, which implies elimination of reflux esophagitis and complete healing of the defects in the mucous membrane of the esophagus (Table 4).

**Table 4.** Distribution of groups before and after operations by degree of esophagitis

| Indices | Groups | |
|---|---|---|
| | LFN+LGP | LFN |
| Before operation | n = 56 | n = 58 |
| No esophagitis | 0.0 | 0.0 |
| A | 32.1 | 34.4 |
| B | 37.5 | 37.9 |
| C | 23.2 | 19.0 |
| D | 7.1 | 8.6 |
| 6 months after operation | n = 48 | n = 46 |
| No esophagitis | 87.5 | 82.6 |
| A | 12.5 | 17.4 |
| B | 0.0 | 0.0 |
| C | 0.0 | 0.0 |
| D | 0.0 | 0.0 |
| 12 months after operation | n = 45 | n = 48 |
| No esophagitis | 88.9 | 89.5 |
| A | 11.1 | 10.4 |
| B | 0.0 | 0.0 |
| C | 0.0 | 0.0 |
| D | 0.0 | 0.0 |

Data are presented as %.

LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only

The DeMeester generalized index reflecting the pH at the gastroesophageal junction was 10.50 (2.05) ± 0.52 in the LFN+LGP group and 11.30 (1.48) ± 0.38 in the LFN group (Table 5). Notably, along with the substantial antireflux effect in both groups, the differences were not statistically significant ($p > 0.05$).

**Table 5.** Data on 24-hour pH measurement before operation and 1 year after operation

| | | Before operation | | After operation | | p-value (comparison before and after operation) | |
|---|---|---|---|---|---|---|---|
| | | LFN+LGP (n = 15) | LFN (n = 15) | LFN+LGP (n = 15) | LFN (n = 8) | | |
| Indices | Standard | *1* | *2* | *3* | *4* | *1 and 3* | *2 and 4* |
| % time with pH <4, general | <4.5 | 6.0 (1.36) ± 0.35 | 5.97 (1.37) ± 0.35 | 3.47 (1.22) ± 0.31 | 3.3 (1.04) ± 0.27 | p > 0.05 | p > 0.05 |
| | | p > 0.05 | | p > 0.05 | | | |
| % time with pH <4, standing position | <8.4 | 6.0 (0.92) ± 0.23 | 5.85 (1.0) ± 0.25 | 4.2 (1.89) ± 0.48 | 4.2 (1.45) ± 0.37 | p > 0.05 | p > 0.05 |
| | | p > 0.05 | | p > 0.05 | | | |
| % time with pH <4, lying position | <3.5 | 4.06 (1.03) ± 0.26 | 3.77 (0.87) ± 0.22 | 1.44 (0.49) ± 0.12 | 1.88 (0.78) ± 0.20 | p > 0.05 | p > 0.05 |
| | | p > 0.05 | | p > 0.05 | | | |
| Total number of GER with pH <4 | <46.9 | 22.7 (1.16) ± 0.30 | 22.1 (3.04) ± 0.78 | 20.8 (5.19) ± 1.34 | 18.8 (6.08) ± 1.57 | p < 0.05 | p > 0.05 |
| | | p < 0.05 | | p > 0.05 | | | |
| Number of GER >5 min | <3.5 | 3.66 (0.97) ± 0.25 | 4.64 (2.2) ± 0.56 | 1.93 (0.96) ± 0.24 | 2.23 (1.1) ± 0.28 | p < 0.05 | p > 0.05 |
| | | p < 0.05 | | p > 0.05 | | | |
| Longest reflux (min) | <20.0 | 13.4 (1.05) ± 0.27 | 15.4 (3.22) ± 0.83 | 10.2 (5.3) ± 1.37 | 12.5 (4.61) ± 1.19 | p < 0.05 | p > 0.05 |
| | | p < 0.05 | | p > 0.05 | | | |
| DeMeester index | <14.72 | 17.4 (1.87) ± 0.48 | 18.3 (3.09) ± 0.79 | 10.5 (2.05) ± 0.52 | 11.3 (1.48) ± 0.38 | p > 0.05 | p > 0.05 |
| | | p > 0.05 | | p > 0.05 | | | |

LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only; GER, gastroesophageal reflux episodes

Moreover, we evaluated the results of antireflux surgery by taking the patients' subjective feelings and complaints into account. For this purpose, postoperative data were analyzed using the GERD-HRQL (Table 6).

QoL, quality of life; GERD-HRQL, Gastroesophageal Reflux Disease–Health-Related Quality of Life; LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only; SEM, standard error of the mean; SD, standard deviation

Functional results were obtained for both groups of patients. The majority of patients with a hiatal hernia were cured of their typical and atypical symptoms of GERD. At the same time, the GERD-HRQL revealed certain differences in generalized indicators (the best result was 0 and the worst result was 50). As can be seen in Table 6, the number of patients with heartburn decreased. Patients' satisfaction regarding GERD consequences improved from 0 % to 79 % in the LFN+LGP group and from 0 % to 82 % ($p > 0.05$) in the LFN group.

**Table 6.** Results of QoL assessment of patients based on GERD-HRQL questionnaire

| Criterion | Examination period | | | | | |
|---|---|---|---|---|---|---|
| | Before operation | | | After operation | | |
| | LFN+LGP n = 56 | LFN n = 58 | p-value | LFN+LGP n = 55 | LFN n = 56 | p-value |
| GERD – HRQL scores | | | | | | |
| Mean (SEM) | 15.1 (5.8) ± 0.8 | 14.46 (6.4) ± 0.85 | p > 0.05 | 2.0 (3.05) ± 0.40 | 2.1 (3.1) ± 0.41 | p > 0.05 |
| Median (range) | 14.0 (4-36) | 12.0 (6-34) | | 0.0 (0-10) | 1.0 (0-11) | |
| Heartburn sub score | | | | | | |
| mean (SD | 2.73 (0.8) ± 0.11 | 2.91 (0.6) ± 0.08 | p < 0.05 | 0.39 (0.7) ± 0.09 | 0.22 (0.53) ± 0.07 | p < 0.05 |
| Median (range) | 2.91 (1-5) | 2.91 (1-4) | | 0.0 (0-3) | 0.0 (0-3) | |
| Satisfaction index | | | | | | |
| *n* (%) satisfied | 0/56 (0%) | 0/58 (0 %) | p > 0.05 | 43/55 (79%) | 46/56 (82%) | p > 0.05 |
| *n* (%) neutral | 5/56 (9%) | 10/58 (17%) | | 9/55 (16%) | 6/56 (11%) | |
| *n* (%) dissatisfied | 51/56 (91%) | 48/58 (83%) | | 3/55 (5%) | 4/56 (7%) | |

## *Bariatric effect of performed operations*

Table 7 shows the bariatric effect of the operations performed in this study. The average EWL% after 12 months was 45.26 ± 5.80 % in the LFN+LGP group and 18.43 ± 4.60 % in the LFN group ($p < 0.0001$). The average examination period was 12 months.

**Table 7.** Percent excess weight loss

| Groups | EWL% after 12 months | t | p-value |
|---|---|---|---|
| LFN+LGP (n = 49) | 45.26 ± 5.80 % | 25.04 | <0.0001 |
| LFN (n = 47) | 18.43 ± 4.60 % | | |

EWL%, percent excess weight loss; LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only;

The efficacy of the bariatric operations was considered to be excellent if the EWL% was >75.0 %, good if the EWL% ranged from 50.0 % to 74.9 %, satisfactory if the EWL% ranged from 25.0 % to 49.9 %, and unsatisfactory if the EWL% was <24.9 % or a repeated operation was required. Consequently, the results for the LFN+LGP group were considered good and those for the LFN group were considered unsatisfactory.

The BMI before surgery in the LFN+LGP and LFN groups was 36.60 ± 2.41 and 35.20 ± 2.03 kg/m2, respectively, and the difference between the groups was not statistically significant ($p < 0.05$). However, as shown in Table 8, the difference became significant after the operation.

**Table 8.** BMI before and after operation

| Index | BMI kg/m$^2$ (M ± σ) | | | |
|---|---|---|---|---|
| | Before treatment | After treatment | t | p-value |
| LFN+LGP | 36.6 ± 2.41 (n = 56) | 30.9 ± 1.53 ( n =49) | 14.11 | <0.0001 |
| LFN | 35.2 ± 2.03 (n = 58) | 32.31 ± 1.95 ( n =47) | 7.185 | <0.0001 |
| Difference between LFN+LGP and LFN | t = 3.435 p = 0.0008 | t = 3.8 p = 0.0003 | - | - |

BMI, body mass index; LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only

Notably, in contrast to the patients in the LFN group, the data for the patients in the LFN+LGP group were outside the values corresponding to second-degree obesity.

## *Dynamics of comorbidities*

Various patients' clinical data were used in this analysis, particularly regression of the numbers of preoperative complaints and pathological conditions associated with severe obesity.

Ninety-seven patients (85 %; 51 in the LFN+LGP group and 46 in the LFN group) had additional pathologies that were associated with obesity:

- 19 (20.0 %) patients had type II pancreatic diabetes
- 40 (41.0 %) patients had arterial hypertension
- 8 (8.3 %) patients had coronary heart disease
- 44 (44.0 %) patients had exchange-dystrophic polyarthritis
- 37 (38.3 %) patients had hypercholesterinemia
- 22 (22.6 %) patients had varicose veins of the lower extremities
- 4 (4.1 %) patients had thyroid disease

Overall, 51 patients in the LFN+LGP group had 50 associated pathologies, and 46 patients in the LFN group had 44 associated pathologies (Table 9).

**Table 9.** Results of comorbidity management

| Type of associated pathology | LFN+LGP (n = 51) | | | LFN (n = 46) | | |
|---|---|---|---|---|---|---|
| | B.O. | A.O. | | B.O. | A.O. | |
| | | N | I | | N | I |
| Type II PD | 5 | 2 | 3 | 5 | 4 | 1 |
| AH | 10 | 5 | 5 | 6 | 3 | 3 |
| CHD | 3 | 1 | 2 | 2 | 1 | 1 |
| EDP | 6 | 1 | 5 | 4 | 3 | 1 |
| HCE | 12 | 1 | 11 | 15 | 11 | 4 |
| VVE | 12 | 5 | 7 | 10 | 3 | 7 |
| TD | 2 | 2 | 0 | 2 | 2 | 0 |
| **Total** | **50** | **17** | **33** | **44** | **27** | **17** |

Comparison of A.O. results of LFN+LGP to LFN group: $x^2 = 7.038$; $p = 0.008$ ($p < 0.005$)

B.O., before operation; A.O., after operation; N, no changes; I, improvement of condition; PD, pancreatic diabetes; AH, arterial hypertension; CHD, coronary heart disease; EDP, exchange-dystrophic polyarthritis; HCE, hypercholesterinemia; VVE, varicose veins of the lower extremities; TD, thyroid disease

The patients' condition with regards to associated diseases was evaluated 1 year after treatment. Generally, the results for the LFN+LGP group were considered to be good. The most significant changes were noted in the frequency of metabolic syndrome, which disappeared or improved in 91.6 % of patients. Substantial changes were also seen in the frequency of arterial hypertension, back and knee pain, type II pancreatic diabetes, and depression; about half of these associated diseases improved or resolved. Significant differences between the two groups (66.0 % of patients in the LFN+LGP group exhibited improvement, and 38.6 % in the LFN group exhibited improvement) can be justified by the decrease in the BMI in the LFN+LGP group.

### *Changes in QoL*

QoL in the LFN+LGP group improved from −1.20 ± 0.96 (range, −2.30 to 1.00) to 1.20 ± 0.41 (range, 0.00–2.00), and this improvement was statistically significant. These parameters for the LFN group were as follows: the preoperative QoL was −0.97 ± 0.97 (range, −2.10 to 1.00) and increased to 0.89 ± 0.46 (range, 0.00–1.50) ($p < 0.0001$).

### *BAROS assessment*

The average BAROS score was 3.90 ± 0.76 in the LFN+LGP group and 1.90 ± 0.53 in the LFN group ($p < 0.0001$). These data indicate that the QoL was good in the LFN+LGP group and satisfactory in the LFN group.

## Discussion and Conclusion

GERD itself is now recognized as an obesity-related comorbidity. Indeed, the importance of the relationship between excess visceral adiposity and GERD is demonstrated by the greater correlation of GERD with waist circumference and the waist-to-hip ratio (markers of central obesity) than that of GERD with BMI (Corley, Kubo & Zhao, 2007). However, the prevalence of GERD, even in the setting of severe obesity, is <50 % (Prachand, Ward & Alverdy, 2010).

The proposed method of simultaneous laparoscopic surgical management of GERD combined with first- and second-degree obesity is based on gastroplication of the greater curvature of the stomach, originally proposed and developed by the Iranian surgical team Talebpour et al. (Talebpour et al., 2012). In our study, the average EWL% after 12 months was 45.26 ± 5.80 % and 18.43 ± 4.60 % in the LFN+LGP and LFN groups, respectively. Our results are equal to those reported by other researchers, including those of Fried et al. (Fried et al., 2012) and Skrekas et al. (Skrekas, Antiochos & Stafyla, 2011). The relatively low bariatric effect of laparoscopic fundoplication in our study is similar to that described by Neumayer in 2005 (Neumayer et al., 2005). Laparoscopic fundoplication cannot be recommended as a target bariatric operation.

All operations were performed laparoscopically. No deaths or severe complications were observed in either group. The average hospital stay in the LFN+LGP and LFN groups was 4.30 ± 0.53 vs. 4.10 ± 0.98 days, with no significant difference. Table 10 shows the patients' general information.

**Table 10.** General characteristics of examined patients

| Parameters | Groups | |
|---|---|---|
| | LFN+LGP (n = 56) | LFN (n = 58) |
| Male (n) | 7 | 24 |
| Female (n) | 49 | 34 |
| Age (years) | 43.80 ± 9.70 | 46.32 ± 9.90 |
| BMI (kg/m$^2$) | 36.60 ± 2.41 | 35.20 ± 2.03 |
| Height (m) | 1.65 ± 0.07 | 1.64 ± 0.07 |
| Weight (kg) | 100.5 ± 10.5 | 95.7 ± 8.9 |

Data are presented as mean ± standard deviation.

LFN+LGP, laparoscopic plication of the greater gastric curvature combined with Nissen fundoplication; LFN, Nissen fundoplication only; BMI, body mass index

Laparoscopic floppy Nissen fundoplication combined with great curvature plication improved the treatment of obesity with GERD.

## Implications and Recommendations

Investigation of the antireflux function of surgical treatments in this study showed a practical similarity of the results in both groups, which supports further application of LFN+LGP for simultaneous management of GERD and morbid obesity.

There are no common approaches to simultaneous surgical treatment of GERD and morbid obesity. However, minimally invasive restrictive operations for morbid obesity are justified for clinical practice because of the low incidence of complications and acceptable bariatric results. We believe that the proposed restrictive procedure (LFN+LGP) is easily accessible, safe, and technically feasible for surgeons experienced in laparoscopic antireflux surgery and standard laparoscopic fundoplication. Therefore, we are confident that this method can be widely used to perform simultaneous treatment of GERD and morbid obesity.

## Trial registration

ISRCTN registry: ISRCTN58550318 (DOI 10.1186/ISRCTN58550318)

Laparoscopic surgery for severe obesity combined with gastroesophageal reflux disease

Presented at the 23rd International Congress of the European Association for Endoscopic Surgery (EAES). Incorporating the annual RAES congress "Breaking the frontiers of minimal invasive surgery" (Scientific Program Bucharest 4–6 June 2015).

P359 - LAPAROSCOPIC NISSEN FUNDOPLICATION COMBINED WITH GREAT CURVATURE PLICATION IMPROVED THE TREATMENT OF

GASTROESOPHAGEAL REFLUX DISEASE IN COMBINATION WITH OBESITY

## Disclosure statement

No potential conflict of interest was reported by the authors.

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## Authors' contributions

O.O. and A.O. designed and conducted the study. O.O. performed the surgeries. A.O., R.F. collected the data, performed the statistical analysis, and helped to draft the manuscript. All authors approved the final manuscript.

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