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Gastric greater curvature plication combined with Nissen fundoplication in the treatment of gastroesophageal reflux disease and obesity

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ABSTRACT

Background and aim: Established anti-reflux procedures such as funduplications are less efficient in obese patients. The aim of this study was to investigate clinical effectiveness of the fundoplication combined with gastric greater curvature plication in the treatment of gastroesophageal reflux disease (GERD) in obese patients.

Materials and methods: During the period from June 2010 to September 2014, patients operated for GERD with BMI from 30 to 39.9 kg/m² were included into the prospective study. Laparoscopic Nissen fundoplication (LNF, n = 58) was performed until February 2013 and later laparoscopic Nissen fundoplication was combined with gastric greater curvature plication (LNFGP, n = 56). The groups were compared according to the control of GERD and weight loss.

Results: In LNF group there were significantly more males, patients had lower BMI and longer duration of GERD symptoms. Duration of surgery was significantly longer in LNFGP group, 96.5 (17.3) min vs. 59.8 (16.1) min ($P < 0.0001$). Postoperative morbidity was similar, 3.6% and 3.4% in LNFGP and LNF groups, respectively ($P = 0.9539$). The average percentage of excess BMI loss after 12 months was 45.3 (5.8) in LNFGP group as compared to 18.4 (4.6) in LNF group ($P < 0.0001$). Significantly more patients experienced remission or improvement of type 2 diabetes mellitus ($P = 0.03$) and hypercholesterolemia ($P = 0.0001$) in LNFGP group. No significant differences between the groups in postoperative DeMeester score, GERD-HRQL mean score, overall satisfaction and healing of esophagitis were observed.

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Conclusions: LNFGP took significantly longer time to perform, but resulted in significantly higher weight reduction and remission/improvement of comorbidities. Both procedures produced similar anti-reflux effect.

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1. Introduction

The prevalence of gastroesophageal reflux disease (GERD) has increased since 1995 and currently 10% to 30% of the adult population in the world experiences at least weekly symptoms such as heartburn and/or regurgitation [1]. One possible explanation for the high prevalence of GERD could be globally increasing rate of obesity, as there is evidence that overweight and obese individuals suffer from GERD more often than individuals with normal BMI [2,3]. Increased intra-abdominal pressure in obese individuals may facilitate development of gastroesophageal reflux as there is an established correlation between GERD and waist circumference. This correlation was found to be even greater than that between GERD and BMI [4]. However, the prevalence of GERD among individuals with severe obesity is about 50% [5], what suggests that severe obesity itself is not sufficient to cause GERD, and that in at least half of severely obese individuals physiological mechanisms that prevent GERD remain reasonably intact. Hiatal hernias are significantly more prevalent among obese patients [6] and are one of the main pathological mechanisms that cause GERD in obese individuals.

The surgical treatment of GERD gives better short and medium term results as compared to medical management [7]. For individuals with obesity and GERD, Roux-en-Y gastric bypass (RYGB) is considered to be a procedure of choice [8]. However, RYGB is a rather complicated surgical intervention with possible long-term nutritional consequences and not all patients, especially with obesity of grade I or II, are willing to undergo such an extensive procedure for their reflux symptoms. An ideal procedure should combine good reflux control and result in weight loss, as weight loss itself has shown to have beneficial effect on reflux control [9]. Reflux control after Nissen fundoplication is comparable to RYGB in obese patients [10], but weight loss is much less. It would be reasonable to suggest restrictive bariatric procedures such as sleeve gastrectomy or adjustable gastric banding for GERD control as metabolic consequences of these interventions are less when compared to RYGB. However, up to 20% of the patients' experiences de novo reflux symptoms after sleeve gastrectomy [11,12] and the popularity of adjustable gastric banding decreases in the world because of high rate of late failures [13].

Recently a combination of Nissen fundoplication with gastric greater curvature plication (GGCP) was suggested for GERD control in obese patients [14]. No studies so far have compared this type of procedure to a Nissen fundoplication alone and thus the aim of the current study was to compare the results of GERD control in obese patients after these two procedures in the prospective trial.

2. Materials and methods

All necessary ethical and governance approvals were obtained from the Ethics Committee of the Medical University of Astana (No. 3, January 15, 2010). Only adult patients with BMI 30–39.9 kg/m² and typical GERD symptoms were eligible for the study. Exclusion criteria were refusal of the patient to participate in the study, short esophagus (it was diagnosed when after extensive mobilization of the esophagus gastroesophageal junction, identified during preoperative endoscopy, could be located less than 1.5 cm below apex of the diaphragmatic hiatus without any tension), giant hiatal hernia and previous surgery in the gastroesophageal region.

The study was performed in the Surgical Departments of Akmola Regional Hospital №2 and National Research Medical Center in Astana, Kazakhstan, during the period from June 2010 to September 2014. A total of 120 consecutive patients with GERD and BMI 30–39.9 kg/m² were available for inclusion. Six patients met exclusion criteria and thus final number of included patients was one hundred fourteen. All patients signed informed consent. The study was divided into two periods. From June 2010 to February 2013, 58 patients were operated on with laparoscopic Nissen gastroplication (LNF) only. During the second period from February 2013 to September 2014, 56 patients underwent laparoscopic Nissen fundoplication combined with gastric greater curvature plication (LNFGP).

2.1. Clinical assessment

All patients had weight and height measured by scales and stadiometer (Fazzini S7350HR, Italy) before operation, 6 and 12 months after operation. Weight outcomes are presented as percentage of excess BMI loss (%EBMIL) and were estimated by the formula: %EBMIL = (BMI loss/[baseline BMI – 25]) × 100 [15].

All patients completed the Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) [16] questionnaire before and 1 year after surgery. The questionnaire included 11 items. Ten items were scored from 0 to 5 and were used to calculate the overall score by simply adding the individual values of the items. The last 11th item represents overall patients' satisfaction.

2.2. Preoperative and postoperative investigations

Esophagogastroduodenoscopy (Evis Exera II Olympus CV-180, Japan) was routinely performed in all patients preoperatively and one year after surgery. The changes in esophageal mucosa

were evaluated and graded according to the Los Angeles classification [17]. Barium meal X-ray test was done preoperatively to all patients in order to diagnose hiatal hernia and to exclude patients with giant hernias. Postoperative investigation was performed only if GERD recurrence was suspected.

The 24-h monitoring of pH in the esophagus was performed preoperatively and on average 7 month after operation for the patients who agreed to undergo this investigation with the portable device (AGM-24PM “Gastroscan-24”, Russia). Patients discontinued acid-reducing medications at least 1 week before planned measurements. After placement of pH electrode the patients were informed to follow their usual life activities. The pH measurements were analyzed and DeMeester score calculated [18].

2.3. Surgical interventions

All operations were done by laparoscopy. Calibration tube of 32-34 Fr. (Sumi, Poland) was placed in the lumen of the esophagus and stomach. Ultrasonic shears (SonoSurg, Olympus, Japan) were used to cut tissues and seal blood vessels. Only fundal part of the stomach was mobilized, if Nissen fundoplication alone was performed. In the case of combined procedure, mobilization of the greater curvature of the stomach was started 4-6 cm above the pyloric sphincter and was performed all the way to the His angle (Fig. 1). All the tissues around left diaphragmatic crus were dissected completely and the presence of hiatal hernia was identified by the inspection of hiatal region. If hiatal hernia was present, as was the case in 95% of our patients, the right diaphragmatic crus was approached through hepatogastric ligament. Meticulous dissection was done in the hiatal region. Anterior and posterior vagal nerves were identified and preserved. Posterior cruroplasty was done with separate sutures. The esophagus was then encircled with fundal part of the stomach and

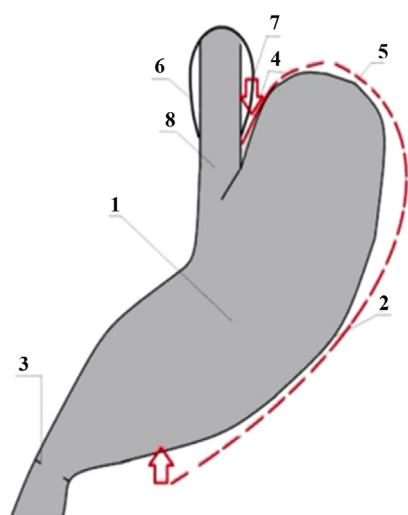


Fig. 1 – Greater curvature mobilization. The arrows indicate the beginning and the completion of the mobilization. The dashed line indicates the direction of mobilization. 1, body of the stomach; 2, greater curvature; 3, pylorus; 4, angle of His; 5, gastric fundus; 6, right diaphragmatic crus; 7, left diaphragmatic crus; 8, gastroesophageal junction.

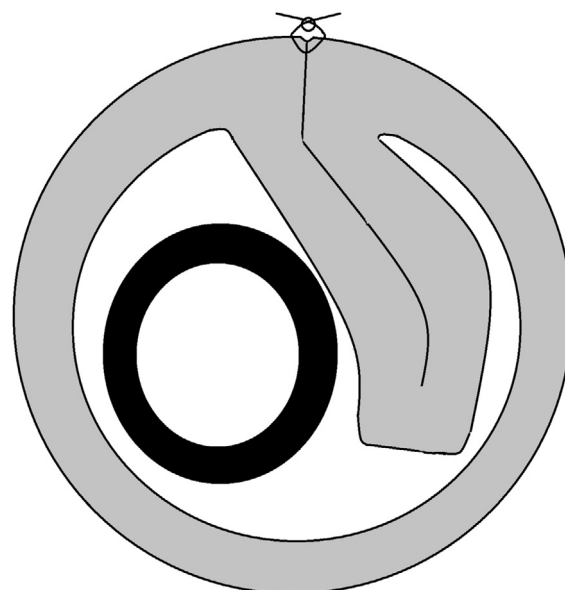


Fig. 2 – Cross-sectional view of calibration tube and invaginated fold in the lumen of the stomach during gastric greater curvature plication.

360 floppy Nissen fundoplication was performed. In all cases non-absorbable seromuscular sutures were used and anterior esophageal wall was included into the stitch. The length of the wrap was less than 2 cm. If gastric greater curvature plication was added to Nissen fundoplication, it was performed by two layers of separate non-absorbable sutures (Ethibond 2/0) placed with 1 cm intervals starting from the fundal part of the stomach and finishing 4-5 cm above pylorus (Figs. 2 and 3).

2.4. Statistical analysis

Continuous variables are presented as mean (standard deviation). Categorical variables are expressed as number (percentage) of patients affected. Shapiro-Wilk test was used to assess normality of the data. Comparison of mean values with Student t test was performed in case of normal distribution. Nonparametric statistics such as Mann-Whitney U test was used to compare continuous variables with abnormal distribution and ordinal variables. Categorical variables were compared by the chi-square test. Significant difference was defined as $P < 0.05$.

3. Results

Patients in LNF group had significantly lower BMI, longer duration of GERD symptoms and more patients were males as compared to LNFGP group (Table 1). As expected, the average duration of surgery was significantly longer in LNFGP group, but there was no difference in average hospital stay, morbidity and mortality between the groups (Table 2). There were no fatal outcomes in this study. Two perioperative complications occurred in each group. In LNFGP group both patients had bleeding. One from superficial injury to the spleen during the

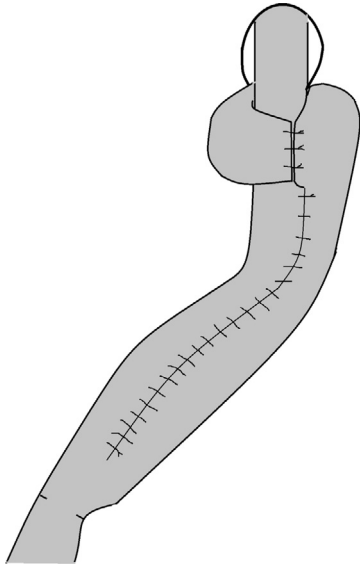


Fig. 3 – Nissen fundoplication combined with gastric great curvature plication.

Table 1 – General characteristics of the study population.

Characteristic	LNFGP (n = 56)	LNF (n = 58)	P
Male/female, n (%)	7/49 (12.5/87.5)	24/34 (41.4/58.6)	0.0006
Age, years	43.8 (9.7)	46.3 (9.9)	0.17
BMI, kg/m ²	36.6 (2.4)	35.2 (2.1)	0.0012
Waist circumference, cm	85.5 (6.3)	87.5 (6.0)	0.0853
Duration of GERD symptoms, years	6.9 (1.9)	7.6 (1.7)	0.04

Values are mean (standard deviation) unless otherwise indicated. BMI, body mass index; GERD, gastroesophageal reflux disease; LNFGP, laparoscopic Nissen fundoplication with gastric greater curvature plication; LNF, laparoscopic Nissen fundoplication.

Table 2 – Perioperative data.

Characteristic	LNFGP (n = 56)	LNF (n = 58)	P
Duration of operation, min	96.5 (17.3)	59.8 (16.1)	<0.0001
Postoperative complications, n (%)	2 (3.6)	2 (3.4)	0.9539
Hospital stay, days	4.3 (0.5)	4.5 (1.0)	0.1159
Mortality, n (%)	0 (0)	0 (0)	1.000

Values are mean (standard deviation) unless otherwise indicated. LNFGP, laparoscopic Nissen fundoplication with gastric greater curvature plication; LNF, laparoscopic Nissen fundoplication.

operation and the bleeding was stopped by bipolar coagulation. The other had postoperative bleeding from short gastric vessels, which was controlled during re-laparoscopy. One patient in LNF group had pneumothorax, which has resolved after placement of chest tube and the other patient had dysphagia due to tight fundoplication. The patient was successfully treated by floppy Nissen re-fundoplication 7 weeks after primary surgery.

There was no difference in acid exposure in the esophagus between the groups either before or after operations (Table 3). However, acid exposure significantly decreased within the groups after operation. DeMeester generalized index decreased from 41.7 to 10.5 ($P < 0.0001$) in the LNFGP group and from 40.7 to 11.3 ($P < 0.0001$) in the LNF group. Similarly, the subjective complaints of the patients evaluated by GERD-HRQL questionnaire significantly improved in both groups after surgery, but there was no difference in the mean score between the groups (Table 4). The prevalence and the grade of esophagitis decreased significantly after surgery in both groups (Table 5). Preoperatively all patients used proton pump inhibitors (PPI) regularly. Four patients in the LNFGP group and 5 in the LNF group used PPI occasionally 1 year after surgery. Moreover, the proportion of patients who were satisfied with GERD control increased from 0% to 79% in the LNFGP group

Table 3 – Data on 24-h pH measurement.

Indices	Before operation		1 year after operation		P (comparison before and after operation)	
	LNFGP (n = 15)	LNF (n = 15)	LNFGP (n = 15)	LNF (n = 8)	1 and 3	2 and 4
	1	2	3	4		
% Time with pH < 4	8.7 (0.7)	8.2 (0.8)	3.5 (1.2)	3.3 (1.0)	<0.0001	<0.0001
P		0.0928		0.7418		
Reflux episodes (pH < 4)/24 h	71.1 (11.7)	63.2 (23.7)	20.8 (5.2)	18.8 (6.1)	<0.0001	<0.0001
P		0.2555		0.6093		
Reflux episodes > 5 min/24 h	8.6 (2.2)	8.0 (0.9)	1.9 (1.0)	2.2 (1.1)	<0.0001	<0.0001
P		0.3879		0.5044		
DeMeester index	41.7 (4.9)	40.7 (3.5)	10.5 (2.1)	11.3 (1.5)	<0.0001	<0.0001
P		0.5510		0.3419		

Values are mean (standard deviation).

Table 4 – Results of GERD-HRQL.

Criterion	Before operation		1 year after operation		P (comparison before and after operation)	
	LFN + LGP (n = 56)	LFN (n = 58)	LFN + LGP (n = 55)	LFN (n = 56)	1 and 3	2 and 4
	1	2	3	4		
GERD-HRQL score	15.1 (5.8)	14.5 (6.4)	2.0 (3.1)	2.1 (3.1)	<0.0001	<0.0001
P	0.5774		0.8625			
Heartburn sub score	2.7 (0.8)	2.9 (0.6)	0.39 (0.7)	0.22 (0.5)	<0.0001	<0.0001
P	0.1759		0.1516			
Satisfaction index, n (%)					<0.0001	<0.0001
Satisfied	0	0	43 (79)	46 (82)		
Neutral	5 (9)	10 (17)	9 (16)	6 (11)		
Dissatisfied	51 (91)	48 (83)	3 (5)	4 (7)		
P	0.42372		0.76418			

Values are mean (standard deviation) unless otherwise indicated.

LNFGP, laparoscopic Nissen fundoplication with gastric greater curvature plication; LNF, laparoscopic Nissen fundoplication.

Table 5 – Degree of esophagitis.

Indices	Before operation		1 year after operation		P (comparison before and after operation)	
	LNFGP (n = 56)	LNF (n = 58)	LNFGP (n = 45)	LNF (n = 48)	1 and 3	2 and 4
	1	2	3	4		
No esophagitis, n (%)	0 (0)	0 (0)	40 (88.9)	43 (89.5)	< 0.0001	<0.0001
A	18 (32.1)	20 (34.4)	5 (11.1)	5 (10.4)		
B	21 (37.5)	22 (37.9)	0	0		
C	13 (23.2)	11 (19.0)	0	0		
D	4 (7.1)	5 (8.6)	0	0		
P	0.78716		0.96012			

LNFGP, laparoscopic Nissen fundoplication with gastric greater curvature plication; LNF, laparoscopic Nissen fundoplication.

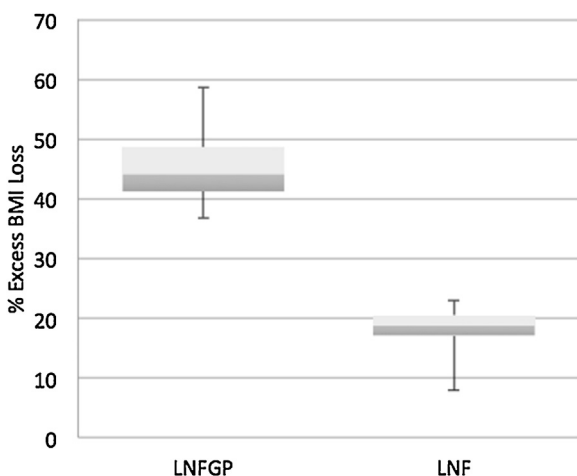


Fig. 4 – Boxplot showing the average percentage of excess BMI loss (%EBMIL) 12 months after surgery in the laparoscopic Nissen fundoplication with gastric greater curvature plication (LNFGP) and laparoscopic Nissen fundoplication (LNF) groups.

($P < 0.0001$), and from 0% to 82% in the LNF group ($P < 0.0001$) (Table 4).

The %EBMIL 12 months after surgery was 45.26 (5.8) and 18.43 (4.6) in LNFGP and LNF groups, respectively ($P < 0.0001$) (Fig. 4). More patients had remission or improvement of their comorbidities associated with obesity in LNFGP group as compared to LNF group (Table 6).

4. Discussion

Nissen fundoplication is a procedure of choice in the treatment of patients with GERD, though some other types of funduplications (Toupet, Dor) were found to produce comparable results [19,20]. The data about long-term effectiveness of Nissen funduplications in patients with obesity and GERD are controversial [21,22]. Therefore, RYGB as a procedure with durable weight loss and anti-reflux effects was proposed for obese individuals with GERD. RYGB reduces severity of reflux symptoms, refluxesophagitis as well as oesophageal acid exposure [23] and 56% of the patients do not need acid reducing medications one-year after surgery [24]. Furthermore, laparoscopic RYGB could be performed as safe as laparoscopic fundoplication with comparable morbidity, mortality and hospital costs [25].

Table 6 – Comorbidity status before and 1 year after operations.

	Type 2 diabetes mellitus			Hypertension			Hyper-cholesterolemia		
	LNFGP (n = 51)	LNF (n = 44)	P	LNFGP (n = 51)	LNF (n = 44)	P	LNFGP (n = 51)	LNF (n = 44)	P
Before operation, n (%)	5 (9.8)	5 (11.4)	0.8011	10 (19.6)	6 (13.6)	0.4381	12 (23.5)	15 (34.1)	0.2558
After operation, n (%)			0.0285			0.3576			0.0001
Remission	2 (40)	0		2 (20)	0		7 (58.3)	0	
Improvement	3 (60)	1 (20)		5 (50)	3 (50)		5 (41.7)	4 (26.7)	
Stable/worse	0	4 (80)		3 (30)	3 (50)		0	11 (73.3)	

LNFGP, laparoscopic Nissen fundoplication with gastric greater curvature plication; LNF, laparoscopic Nissen fundoplication

However, nearly 20% of the patients that did not use anti-acid medications before RYGB start using them one-year after surgery [24]. The reason for this is unknown, but could be partially explained by the presence of untreated hiatal hernias. The intraoperative inspection for a hiatal hernia based on laparoscopic visualization can be misleading. The preoperative upper gastrointestinal contrast studies show that nearly 40% of morbidly obese patients have hiatal hernias [26], but little data exist about the effect of hiatal hernia repair on the long-term outcome of GERD after RYGB [27]. Currently, hiatal hernia repair is not a routine procedure in patients with GERD and obesity undergoing RYGB. Moreover, some patients after RYGB experiences long-term consequences such as nutritional deficiencies, marginal ulcers, internal hernias, dumping and hypoglycemia, which can affect quality of life and needs additional treatment. The patients without metabolic consequences of obesity and with lower BMI maybe willing to undergo the operation that can have a similarly good control of the reflux with less weight loss and consequently less metabolic derangements as in the case with RYGB.

Recently, Nissen fundoplication in combination with GGCP was proposed as a treatment option for patients with GERD and obesity [14,28]. Nissen fundoplication was found to reduce reflux symptoms and acid exposure in the esophagus similarly to RYGB in morbidly obese patients with GERD [10]. GGCP for the treatment of morbid obesity was suggested by Tretbar et al. in 1976 [29] and was thought to be an alternative to more complicated bariatric procedures. It was based on the observation that anti-reflux surgery results in weight loss and the technique was an extension of the fundoplication by invaginating the minor curvature all the way until the "incisura angularis" of the stomach. Wilkinson and Peloso [30] used mesh to reinforce Tretbar plication. However, the use of mesh increased risk for stomach perforation and despite good weight loss results the technique was abandoned. Modern GGCP was developed by Iranian surgeons Talebpour and Amoli [31] who published the results of first 100 patients with %EWL of 60–61% after 12–24 months of follow-up. However, the systemic review of 14 studies with 1450 patients after GGCP have found large variation in %EWL (from 31.8% to 74.4%) after 6 to 24 month follow-up and concluded that it is unclear, if the results are durable [32].

In the present study we compared Nissen fundoplication combined with GGCP to Nissen fundoplication alone. This was a prospective study divided into two periods. Significantly more male patients were operated with Nissen fundoplication alone. Staehelin et al. [33] examined 1650 patients after

laparoscopic fundoplication and found that male patients had less dysphagia, better heartburn control and higher overall satisfaction as compared to female patients. Higher prevalence of male patients in LNF group may have influenced the results of GERD-HRQL score as it is based on subjective patients' complaints. There is little evidence about gender influence on the results of objective investigations such as 24-h pH-metry. Vega et al. [34] have shown that males without GERD or reflux symptoms had significantly more reflux episodes, total reflux time and % time with pH < 4 in the distal esophagus than females. However, in this study endoscopy was not performed to rule out hiatal hernia or silent esophagitis, which could have had direct influence on the obtained results. In our study preoperatively all patients had esophagitis and 95% had hiatal hernia. Moreover, there was no difference in acid exposure between groups measured by 24-h pH-metry. Thus we assumed that groups were comparable regarding GERD status and obesity. Both procedures achieved good reflux control as proved by normalization of DeMeester score, significant decrease in GERD-HRQL mean scores, increase in overall satisfaction and healing of esophagitis in 90% of cases.

In our study Nissen fundoplication combined with GGCP was a safe procedure with low morbidity. In contrast, Lee et al. [14] reported 8% risk of major perioperative complications after this procedure. Two patients in their series needed revision sleeve gastrectomy for leakage and intraabdominal abscess. Only one patient (1.7%) in the present study had serious complication, which needed re-laparoscopy. The % EBMIL of 45.3 was in a range of those reported after usual GGCP [32]. All patients with type 2 diabetes mellitus and hypercholesterolemia, and 70% of patients with hypertension experienced remission or improvement of their comorbidities after combined procedure. However, small number of patients with co-morbidities in both groups prompts cautious evaluation of these results. As GGCP is mainly a restrictive procedure the effect on comorbidities should be attributed to weight loss achieved after this procedure. Patients after Nissen fundoplication also lost weight, however, significantly less as compared to combined procedure. Similar weight loss after Nissen fundoplication was previously reported in the literature [35].

Several limitations of this study should be addressed. First, it was a prospective, but a nonrandomized study. Initially it was planned as a study to explore efficiency of Nissen fundoplication in the treatment of obese patients with GERD. After gaining more experience with GGCP the decision was

taken to extend the study by adding LNFGP group. Such study design may have created a selection bias with higher male prevalence and potentially better clinical results in LNF group. In such case 24 h pH-metry may allow more precise comparison of acid control after the procedures. However, it must be admitted that pH-metry investigations in our study were done only for 25% of patients preoperatively and even less postoperatively. Significant decrease in esophageal acid exposure was found after operations within the groups. However, comparison of acid exposure between the groups, especially due to lower number of patients in LNF group postoperatively, should be evaluated with caution. More data are needed about acid control after combined procedure. GGCP itself may increase intra-gastric pressure and facilitate development of reflux similarly to sleeve gastrectomy. It is still to be proven in future studies that complementary Nissen fundoplication is able to counteract the mechanisms that increase the risk of the reflux after GGCP. Second, the observation time in this study was short. More information is needed about durability of weight loss after combined procedure. Weight regain may have a negative impact on the status of comorbidities and reduce the positive effect of combined procedure. If weight loss will be durable then patients may have a lower intraabdominal pressure and consequently the expected failure rate of anti-reflux procedure may decrease giving some advantage to combined procedure on long-term follow-up. Finally, a new procedure has to be compared to RYGB, which is currently a procedure of choice for obese patients with GERD. Future randomized controlled studies may give a better insight into the role of this novel procedure in the treatment of obese patients, at least with grade I or II obesity.

5. Conclusions

Nissen fundoplication with GGCP took significantly longer time to perform, but resulted in significantly higher weight reduction and remission or improvement of comorbidities. Both procedures produced similar anti-reflux effect.

Conflict of interest

The authors state no conflict of interest.

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