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Randomized controlled trial comparing laparoscopic greater curvature plication versus laparoscopic sleeve gastrectomy

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Abstract
Background Laparoscopic greater curvature plication (LGCP) is a new restrictive bariatric procedure, which has a similar restrictive mechanism like laparoscopic sleeve gastrectomy (LSG) without potential risk of leak. Aim of the study was to compare 2-year outcomes of LSG and LGCP.
Methods Multicenter prospective randomized trial was started in 2010. A total of 54 patients with morbid obesity were allocated either to LGCP group ($n = 25$) or LSG group ($n = 27$). Main exclusion criteria were: ASA > III, age > 75 and BMI > 65 kg/m^2. There were 40 women and 12 men, and the mean age was 42.6 ± 6.8 years (range 35–62). Data on the operation time, complications, hospital stay, body mass index loss, percentage of excess weight loss (%EWL), loss of appetite and improvement in comorbidities were collected during the follow-up examinations.
Results All procedures were completed laparoscopically. The mean operative time was 92.0 ± 15 min for LSG and 73 ± 19 min for LGCP ($p > 0.05$). The mean hospital stay was 4.0 ± 1.9 days in the LSG group and 3.8 ± 1.7 days in LGCP group ($p > 0.05$). One year after surgery, the mean %EWL was 59.5 ± 15.4 % in LSG group and 45.8 ± 17 % in LGCP group ($p > 0.05$). After 2 years, mean %EWL was 78.9 ± 20 % in the LSG group and 42.4 ± 18 % in the LGCP group ($p < 0.01$). After 3 years, mean %EWL was 72.8 ± 22 in the LSG group and only 20.5 ± 23.9 in the LGCP group ($p < 0.01$). Loss of feeling of hunger after 2 years was 25 % in LGCP group and 76.9 % in the LSG group ($p < 0.05$). The comorbidities including diabetes, sleep apnea and hypertension were markedly improved in the both groups after surgery.
Conclusion The short-term outcomes demonstrated equal effectiveness of the both procedures, but 2-year follow-up showed that LGCP is worse than LSG as a restrictive procedure for weight loss.

Keywords Morbid obesity · Laparoscopic greater curvature plication · Laparoscopic sleeve gastrectomy

Bariatric surgery is currently considered to efficiently produce long-term weight loss, improve comorbidities and improve quality of life in morbidly obese patients [1]. Laparoscopic sleeve gastrectomy (LSG) has evolved from the first step of two-step procedure (duodenal switch) initially designed for the super-morbidly obese patients. During the past decade, LSG has enormously grown in popularity worldwide [2, 3]. Numerous studies show similar metabolic improvement and weight reduction after LSG compared to laparoscopic Roux-en-Y gastric bypass (LRYGB) [4–9]. As demonstrated in the literature, two major complications of LSG are staple line leaks and gastric bleeding, with the incidence of 1.2 and 3.6 %,

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respectively [10, 11]. Both complications are difficult to treat.

To reduce serious complications, a novel restrictive technique was introduced: laparoscopic greater curvature plication (LGCP). The mechanism of LGCP is notably similar to that of LSG: Both result in gastric tube formation and elimination of the greater curvature, but LGCP has the advantages of a reversible restrictive technique without gastrectomy and no risk of leakage from the staple line. However, the long-term efficacy is under investigation. There are few studies comparing it with LSG [22, 25].

The primary objective of this prospective randomized study was to compare early and long-term results of LSG and LGCP.

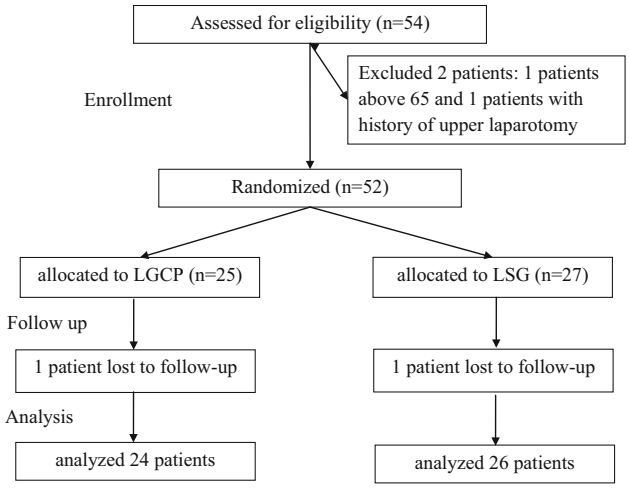

Fig. 1 Diagram of randomized trial

Materials and methods

Patients

Prospective randomized study was conducted in two centers: Odessa National Medical University (Odessa, Ukraine) and Astana Medical University (Astana, Kazakhstan) from January, 2010 to December, 2014. The inclusion criteria were as follows: body mass index (BMI) over 35 kg/m^2, age of 18–75 years and patient's availability for follow-up. The exclusion criteria were: BMI over 65 kg/m^2, age over 75 years, history of supra-umbilical laparotomy, major psychological instability, and patient's unfit for general anesthesia, or American society of anesthesiology (ASA) risk score > III.

Informed consent was obtained from all patients included in the study. The study was approved by the local ethical committee.

A total of 54 patients were enrolled into the study. Two patients were excluded from the study: one patient due to age above 75 years and another because of the history of supraumbilical laparotomy. The randomization was obtained through Random Allocation Software (version 1.0, 2004, Mahmood Saghaei, Isfahan, Iran). The patients were randomized into two groups: LGCP group—25 patients, and LSG group—27 patients (Fig. 1). All patients underwent a multidisciplinary evaluation by physician, psychiatrist and surgeon. Blood tests, abdominal ultrasonography, upper GI endoscopy, barium swallow examination and fat sequencing were performed preoperatively to establish a baseline. The comorbidities were screened pre- and postoperatively. The characteristics of the patients were similar in the two groups (Table 1).

All the patients were followed up at 1, 3, 6, 12, 24 and 36 months postoperatively. Factors analyzed included: operative time, hospital stay, postoperative complications, feeling of hunger, BMI loss (BMIL), percentage of excess weight loss (%EWL) and changes in comorbidities.

Table 1 Population description

Characteristic	LGC patients ($n = 25$)	LSG patients ($n = 27$)	p
Gender, n (%)			
Male—12	5 (20 %)	7 (25.9 %)	NS
Female—40	20 (80 %)	20 (74.1 %)	NS
Age, years	40.5 ± 5.2	44.2 ± 6.8	NS
BMI, kg/m^2	41.6 ± 6.5	45.8 ± 7.2	NS
Comorbidity, n (%)			
Hypertension	5 (20 %)	7 (25.9 %)	NS
Diabetes	2 (8 %)	3 (11 %)	NS
Sleep apnea	4 (16 %)	5 (18.5 %)	NS
Joint pain	2 (8 %)	4 (14.8 %)	NS

Surgical technique

Closed pneumoperitoneum of 12–14 mm Hg was achieved using a Veress needle. Trocar placement was as follows: 10-mm trocar above the umbilicus for the 30° laparoscope; 12-mm trocar on the right at anterior axillary line; 5-mm trocar below the xiphoid for liver retraction; another 5-mm trocar in the midline at the midpoint between xiphoid and umbilicus for suturing and the surgeon's right hand.

Using 5- or 10-mm LigaSure device (Valleylab, Boulder, USA), the omentum and gastroepiploic vessels were dissected from the greater curvature, starting at 4 cm from the pylorus and continuing up to the left crus of the diaphragm and the angle of His. The short gastric vessels, posterior gastric vein and posterior gastric attachments

were carefully divided. A 32-Fr nasogastric tube was inserted and directed toward the pylorus.

Laparoscopic sleeve gastrectomy

Gastric transection started 4 cm proximal to the pylorus using Echelon Flex Endopath with 60 mm green reload (Ethicon, Somerville, USA). The staplers were placed approximately 1 cm from the tube in the direction of the gastroesophageal junction. After completing the transection, bleeding points were secured using 10-mm endoclips or Vicryl 3-0 (Ethicon, Somerville, USA) intracorporal sutures. In every case, we oversewed the staple line, using Ethibond 3-0 (Ethicon, Somerville, USA) continuous suture. The transected stomach was then removed through the right 12-mm port. Air was injected into the stomach, and the staple line was inspected carefully for leaks. Abdominal drain was removed on the third postoperative day after the patient started oral feeding.

Laparoscopic greater curvature plication

After omentum dissection, a row of 8–10 extramucosal interrupted sutures of Ethibond 2-0 (Ethicon, Somerville, USA) sutures was placed just below the angle of His and continued distally to 4 cm of the pylorus over the 32-F gastric tube. The second row of extramucosal running sutures of Ethibond 2-0 (Ethicon, Somerville, USA) was used as reinforcement and to narrow the stomach. No leak test was performed.

Postoperative care

In the LGCP group, proton pump inhibitors (PPI) were administered intravenously during the postoperative period. Patients were discharged once they tolerated a liquid diet without vomiting. Patients were advised to eat soft diet 15 days after surgery and full diet 30 days after surgery. A daily single-dose PPI was prescribed for 30 days. In the LSG group, gastrointestinal radiography was done on the second postoperative day. Patients were allowed to drink clear fluids on the third postoperative day. Patients resumed a normal diet in 3 weeks.

Statistical analysis

Statistical analysis in this study was performed using Statistica 10.0 (StatSoft, Tulsa, USA) software. For continuous variables, descriptive statistics were calculated and were determined as mean ± standard deviation (SD). Chi-square test was used for categorical variables, and Wilcoxon test was used to detect differences in the mean of continuous variables. P values <0.05 were considered significant.

Results

From February, 2010 until December, 2011, a total of 54 patients were assessed for enrollment in the study. Two patients were not included due to age above 75 (1 patient) and history of supra-umbilical laparotomy (one patient). Fifty-two patients were enrolled in the study and randomized to LGCP group (25 patients) and LSG group (27 patients).

In the LGCP group, five patients had hypertension, two patients had type two diabetes mellitus, four patients had obstructive sleep apnea syndrome (OSAS) and two patients had joint pain (Table 1). In the LSG group, seven patients had hypertension, three patients had type two diabetes mellitus, five patients had OSAS and four patients had joint pain. Both groups were comparable in BMI, sex, gender and comorbidities (Table 1).

All procedures were performed laparoscopically without conversions. The mean operative time was 73 ± 19 min (range 65–115 min) in the LGCP group and 92.0 ± 15 min (range 80–128 min) in the LSG group, and the difference was statistically insignificant ($p > 0.05$). No leaks or thromboembolism was observed in either group. Bleeding from staple line developed in one patient after LSG. The patient needed re-laparoscopy and suturing of bleeding vessels. Early episodes of nausea and vomiting, sialorrhea and abdominal pain were recorded in both groups (Table 2). These symptoms resolved spontaneously in 7–10 days in all the cases.

Mean hospital stay was similar in both groups: 3.8 ± 1.7 days (3–7 days) in the LGCP group and 4.0 ± 1.9 days (3–8 days) in the LSG group ($p > 0.05$). A mean follow-up of patients of both groups was 25.5 months (range 13–38 months). There were differences in loss of hunger feeling at 6, 12 and 24 months postoperatively (Table 3).

The BMI and %EWL at 6, 12, 24 and 36 months postoperatively in the two groups are listed in Table 4.

Table 2 Early postoperative complications

Complication	LGCP, *n* (%)	LSG, *n* (%)	*p*
Bleeding	–	1 (3.7 %)	NS
Nausea	4 (16 %)	2 (7.4 %)	NS
Vomiting	2 (8 %)	–	NS
Sialorrhea	5 (20 %)	1 (3.7 %)	NS
Abdominal pain	3 (12 %)	1 (3.7 %)	NS
Total	14 (56 %)	5 (18.5 %)	NS

Table 3 Postoperative loss of hunger feeling

Groups	Loss of feeling of hunger		
	6 months	12 months	24 months
LGCP	13 (54.2 %)	6 (25.0 %)	3 (12.5 %)
LSG	22 (84.6 %)	20 (76.9 %)	18 (69.2 %)
p	<0.05	<0.05	<0.01

In LSG group, patients had a greater %EWL after surgery compared to those in LGCP group. At 1 year after the procedure, %EWL was 45.8 ± 17 % in LGCP group and 59.5 ± 15.4 % in the LSG group ($p > 0.05$). But at 2 and 3 years after procedures, %EWL was significantly higher in LSG group (Table 4). At 2 years after procedures, % EWL was 78.9 ± 20.0 % in LSG group and 42.4 ± 18.0 % in LGCP group ($p < 0.01$). After 3 years, % EWL was 72.8 ± 22.0 % in LSG group and only 20.5 ± 23.9 % in LGCP group ($p < 0.01$).

Gastroesophageal reflux was observed in one patient in each group after 1–2 years postoperatively. No malnutrition was detected in patients of each group after 2 and 3 years. After 6- to 12-month follow-up, the comorbidities such as diabetes mellitus, OSAS, hypertension and joint pain improved in both groups (Table 5). However, in LSG group there were significantly more remissions. The best results of comorbidity improvement or resolution was noticed in hypertension, where 71.4 % of patients after LSG resolved and 28.6 % improved in 1 year.

Table 5 Comorbidity outcomes after 6–12 months

Comorbidity	LGCP, *n* (%)	LSG, *n* (%)	*p*
Hypertension			
Remission	1 (4.2 %)	5 (19.2 %)	<0.05
Improvement	4 (16.7 %)	2 (7.7 %)	NS
Diabetes			
Remission	1 (4.2 %)	2 (7.7 %)	NS
Improvement	1 (4.2 %)	1 (3.8 %)	NS
Sleep apnea			
Remission	1 (4.2 %)	4 (15.4 %)	<0.05
Improvement	3 (12.5 %)	1 (3.8 %)	NS
Joint pain			
Remission	1 (4.2 %)	3 (11.5 %)	NS
Improvement	1 (4.2 %)	1 (3.8 %)	NS

Discussion

Sleeve gastrectomy has gained an enormous popularity as a sole bariatric procedure in the last years [12]. Many publications have documented significant weight loss in spite of differences in many variables such as bougie size, antral resection, stapling flush with the bougie and cuff of tissue left at the gastroesophageal junction [13]. Himpens et al. [8] reported the long-term outcome of LSG, stating that the mean excess weight loss exceeded 50 % after 6 and more years. There was an improvement in comorbidities, including type two diabetes, hypertension and OSAS, in more than 65 % of cases [14].

The rate of complications after LSG varies between authors, with bleeding ranging from 0 to 16 % and gastric leak from 0 to 5.5 % [15, 16]. Leak is considered a major cause of mortality, which ranges from 0 to 1.7 % [3, 7, 10, 11]. In our study, one patient developed bleeding (3.7 %). No leaks were observed. To prevent leaks, we avoided excessively narrowing the sleeve at the incisura and oversewed the staple line, like the other authors [16]. Gastric leak constitutes a major complication, which is difficult to treat. It significantly prolongs hospital stay and may be a cause of mortality [3, 10, 13].

For these reasons, the technique of LGCP was introduced. This procedure is intended to obtain the same results as sleeve gastrectomy, in terms of weight loss, but with lower complication rate than LSG. Although the first gastric plication was performed on animal models in 1960s [17], it was not until 2006 that the first patient results were published by Talebpour [18]. The American society for

Table 4 Differences in BMIL and %EWL between LGCP and LSG groups

Groups	Differences at			
	6 months	12 months	24 months	36 months
LGCP				
BMIL, kg/m^2 ± SD	6.2 ± 1.8	5.8 ± 1.9	5.3 ± 2.0	3.6 ± 2.2
% EWL, mean ± SD	49.8 ± 15.4	45.8 ± 17	42.4 ± 18	20.5 ± 23.9
LSG				
BMIL, kg/m^2 ± SD	6.4 ± 1.7	7.9 ± 2.1	10.2 ± 2.5	9.4 ± 2.7
% EWL, mean ± SD	51.8 ± 13.9	59.5 ± 15.4	78.9 ± 20	72.8 ± 22
p value of BMIL	>0.05	>0.05	<0.05	<0.01
p value of % EWL	>0.05	>0.05	<0.01	<0.01

Metabolic and Bariatric Surgery stated in March, 2011, that gastric plication should be considered an investigational procedure [19], so this procedure should be performed only within protocol studies.

Two systematic reviews of literature were published in 2012. Kourkoulos et al. analyzed 11 articles, with a total of 521 patients included in prospective studies [20]. Abdelbaki et al. analyzed seven articles, with a total of 307 patients treated [21]. Mean follow-up reported for this emerging procedure does not exceed 12 months. Reported %EWL in all studies is around 50 % in 6 months, ranging from 40 to 60 %. An interesting subgroup analysis by Fried et al. considered two groups of patients with preoperative BMI of >40 and <40 [22]. Patients with a preoperative BMI < 40 had significantly greater percentage BMIL at 6 months than patients with a preoperative BMI of >40. This significant difference was no longer existed at 9 months. Different EWL in patients with BMI < 45 or >45 was reported by Skrekas et al. [23]. Percent EWL was significantly higher in the group with BMI < 45, and inadequate weight loss was doubled in patients with BMI > 45 [23]. Results of gastric plication have been compared with results of sleeve gastrectomy in 39 patients by Shen et al. [24]. According to them, weight loss was more significant in the patients after sleeve gastrectomy than after gastric plication in 1 year after surgery. These results were different to other studies [21, 23, 24].

The aim of our randomized study was to compare short- and long-term follow-up results after LGCV and LSG. It was a multicenter study encompassing two clinics: University hospital in Odessa (Ukraine) and University hospital in Astana (Kazakhstan). Fifty-two patients were randomized to two groups: 25 patients underwent LGCP and 27 patients underwent LSG. Preoperative BMI was 41.6 ± 6.5 kg/m^2 in LGCP group and 45.8 ± 7.2 kg/m^2 in LSG group ($p > 0.1$).

Both groups were comparable in BMI, sex, gender and comorbidities. All operations were performed by senior surgeons. Intraoperative and postoperative complications were minimal. No leaks were observed. There was no mortality in both groups. After LSG, one patient had bleeding from staple line and was reoperated. The rate of bleeding in our study was 3.7 %, which is similar to other studies [12, 13, 15].

After LGCP, the most common complications were nausea, vomiting and sialorrhea, and the incidence of these complications in the LGCP group was higher than in the LSG group. Similar results were described by Shen et al. [24]. Strekas et al. [23] reported the overall complication rate 8.8 % after LGCP in 135 patients: micro-leaks from the suture line (two patients), gastric bleeding (two patients) and obstruction (three patients). The same complications were reported in the largest study on the subject that was conducted by Fried et al. [22]. Their results suggested that LGCP cannot eliminate the risk of leaks and gastric hemorrhage. Brethauer et al. [25] analyzed the possible mechanism of postoperative gastric perforation including acute distention of the stomach or severe vomiting, which results in full-thickness tear at the suture line and delayed thermal injury of the stomach that occurred during division of the short gastric vessels. Our experience showed that immaculate surgical technique prevents major complications, such as hemorrhage, leaks and fistula formation.

Our study showed that although the occurrence of such early complications as nausea, vomiting and sialorrhea in the LGCP group was higher than in the LSG group, they were relatively easy to manage. We agree with the opinion of other surgeons [24, 26] that the safety of LGCP is comparable to adjustable gastric banding, which is considered to have lowest incidence of severe complications of all bariatric procedures.

Our follow-up data revealed that the difference in %EWL was not significant between the two groups at 6 months, but at 12, 24 and 36 months there was a significant difference between groups. Short-term follow-up did not show a significant difference in BMIL between the two groups, but after 24–36 months the difference in weight loss was 2–3 times more in LSG group. Ramos et al. [27] reported a series of LGCP in 42 patients who achieve encouraging weight loss. The mean %EWL was about 48 % in 6 months and 60 % EWL in 12 months.

Our study shows similar %EWL in 6 months (49.8 ± 15.4 %), but only 45.8 ± 17 % EWL in 12 months. Such difference in data might be due to the loss of hunger feeling, which significantly differs at short- and long-term follow-up. Our data show that at 6 months, 54.2 % of patients after LGCP had loss of feeling of hunger, but at 12 months it decreased in 25 % of patients only. Differences in loss of feeling of hunger, BMIL and %EWL after 24–36 months were significant (<0.001) between the two procedures.

These differences can be explained by two factors [24]. Firstly, plasma level of ghrelin (the only orexigenic hormone circulating levels of which increase before meals and decrease with feeding) decreases after LSG, due to resection of gastric fundus where ghrelin is produced. In LGCP, which does not include resection of gastric fundus, plasma ghrelin levels may not decrease as sharply as following LSG. Secondly, stomach preservation in LGCP involves the relaxation of the stomach muscular layer and may result in gastric volume enlargement after 6 months. Skrekas et al. [23] found out by endoscopy that in patients with inadequate weight loss, the gastric capacity was noticeably increased in 6 months after LGCP. Our results showed the remarkable improvement in comorbidities in both groups.

At the same time, our results demonstrated that at long-term follow-up, LSG is more effective for decreasing comorbidities. This may be multifactorial due to hormonal alteration [28], BMI loss and decrease in carbohydrate absorption [29] after bariatric surgery.

Conclusion

LGCP is a feasible and safe bariatric procedure for morbidly obese patients. Unlike LSG, LGCP is reversible. At short-term follow-up, LGCP and LSG yield comparable results. However, long-term follow-up demonstrates that LGCP is a less effective procedure for treatment of morbidly obese patients.

Disclosures Drs. V.V. Grubnik, O.B. Ospanov, K.A. Namaeva, O.V. Medvedev and M.S. Kresyun have no conflict of interest or financial ties to disclose.

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