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Original article

Laparoscopic gastric plication versus mini-gastric bypass surgery in the treatment of morbid obesity: A randomized clinical trial

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Abstract

Background: Laparoscopic gastric plication (LGP) is emerging as a safe and effective bariatric procedure. However, there are no reports on the comparison between the efficacy and complications of LGP and laparoscopic mini-gastric bypass (LMGB), which is still an investigational bariatric procedure. The objective of this study was to compare safety and efficacy of LGP and LMGB in the treatment of morbid obesity in a one-year follow-up study.

Methods: Forty patients met the National Institutes of Health criteria and were randomly assigned to receive either LGP (n = 20) or LMGB (n = 20) by a block randomization method. Early and late complications, body mass index (BMI), excess weight loss, and obesity-related co-morbidities were determined at the 1-year follow-up.

Results: Operative time and mean length of hospitalization were shorter in the LGP group (71.0 minutes versus 125.0 minutes, $P < .001$, and 1.6 days versus 5.2 days; $P < .001$, respectively). The mean percentage of excess weight loss (%EWL) at 12 months follow-up was 66.9% in the LMGB group and 60.8% in the LGP group ($P = .34$). Improvement was observed in all co-morbidities in both groups, with the exception of hyperlipidemia, which remained unresolved in 4 patients. Lower incidence of iron deficiency occurred in the LGP group ($P = .035$). Rehospitalization and reoperation were not required in any cases. Considering the cost of instruments used in the LMGB procedure and operative time, LGP saved approximately $2,500 per case compared with LMGB.

Conclusion: Both LGP and LMGB are effective weight loss procedures. LGP proved to be a simpler and less costly procedure compared with LMGB with a lower risk of iron deficiency during a 1-year follow-up study. (Surg Obes Relat Dis 2013;9:914–919.)

Keywords: Morbid obesity; Bariatric surgery; Laparoscopy; Mini-gastric bypass; Gastric plication

Obesity is a major growing health problem in both developing and developed countries. In the United States population over the age of 20, it is estimated that 69% of Americans are obese or overweight, with 8.2% of women and 4.4% of men suffering from morbid obesity [1]. Diet, physical exercise, and medications are not sufficient to provide sustainable and significant clinical results in morbid obesity [2]. At present, bariatric surgery is the only effective alternative treatment with documented, substantial, and sustainable weight loss. Bariatric surgery procedures are classified as restrictive, malabsorptive, or a combination of both. Sleeve gastrectomy (SG) and adjustable gastric banding (AGB) are the most common restrictive procedures. However, these approaches are associated with significant complications, including gastric leak, slippage of gastric band, and erosion [3,4]. Gastric plication is a new restrictive procedure relatively similar to SG; in both procedures a narrow gastric tube is generated. Nonetheless,

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in the laparoscopic gastric plication (LGP) technique, the stomach capacity is restricted by folding the stomach into itself and suturing, which results in minimal risk of leakage, bleeding, and nutritional deficiency. Moreover, LGP is considered a reversible procedure; therefore, it can be considered as an appropriate alternative to other existing restrictive bariatric procedures without using foreign bodies and without gastric resection. Roux-en-Y gastric bypass (RYGB), a combined restrictive and malabsorptive procedure, has been considered the gold standard of weight loss surgery by many authors [5,6]. On the other hand, some studies have documented that mini-gastric bypass surgery (MGB) is a simpler and safer technique than RYGB with comparable results. [7,8] LGP is proposed as a safe and effective treatment for morbid obesity. However, no study has compared the safety and efficacy of this procedure with laparoscopic mini-gastric bypass (LMGB). A prospective randomized clinical trial was designed to compare operative morbidity and results of LGP and LMGB in morbidly obese patients at 1-year follow-up.

Methods

Study designs and patients

This prospective randomized controlled trial study was performed by one surgeon from April 2010 to May 2011. The study was registered with the Iranian Registry of Clinical Trials (www.irct.ir; registration number: IRCT2013012712294 N1). Approval was obtained from the ethical committee of the university before conducting the study. All patients received adequate information regarding current knowledge about morbid obesity management, possible operative complications, and the success rate of each procedure. Informed consent was obtained from all patients who agreed to participate in the study. The inclusion criteria were morbid obesity (BMI >40 kg/m^2 or BMI >35 kg/m^2 with co-existing morbidities), age between 18–65 years, and previous unsuccessful weight loss attempts. The exclusion criteria were previous restrictive or malabsorptive procedure for obesity treatment, previous gastric surgery or history of antireflux surgery, noncompliance to diet, and pregnancy. All cases underwent multidisciplinary evaluation (with the aid of an endocrinologist, a nutritionist, and a psychiatrist) for the surgical treatment of morbid obesity. In all cases, electrolyte, metabolic, and hormonal laboratory tests were performed routinely, and a psychological assessment was performed during at least 2 visits. Forty morbidly obese patients were randomly assigned to either the LGP group (n = 20) or the LMGB group (n = 20) by a block randomization method. Patients were evaluated regarding the presence of medical co-morbidities before surgery and during the follow-up period. Furthermore, all patients underwent ultrasonography for the diagnosis of cholelithiasis preoperatively and postoperatively. The criteria for diagnosis and improvement of co-morbidities were as follows.

With respect to blood pressure (BP), hypertension was diagnosed as systolic BP ≥ 140 mm Hg or diastolic BP ≥ 90 mm Hg or patients who were under medical treatment; remission was described as BP below the cut-off points under no medication, and improvement was regarded as any reduction in the hypertension medication. Diabetes was diagnosed as fasting blood glucose (FBG) ≥ 126 mg/dL or patients who were under medical treatment. Remission was defined as FBG <100 mg/dL and HbA_{1c} $<6\%$ under no medication, and improvement was regarded as more normal FBG (100–125 mg/dL) or any reduction in diabetes medication.

Hyperlipidemia was diagnosed for cholesterol level >200 mg/dL, triglyceride levels (TG) >150 mg/dL, or both, or patients who were under medical treatment. Remission was defined as both cholesterol and TG levels below the cut-off point under no medication, and any reduction in the lipid-lowering medications was considered as improvement.

Gastroesophageal reflux disease was diagnosed if patients experienced symptoms of acid reflux and heartburn or patients who were under medical treatment. Complete remission of symptoms was defined as remission, and any reduction in the symptoms or medications was classified as improvement.

With respect to menstruation, any menstrual cycle <21 days or >35 days in length was considered irregular. Remission was defined as a normal menstrual cycle length (21–35 days) without medical treatment or oral contraceptive use, and improvement in regulation without being in normal range was classified as improvement.

Degenerative joint disease was diagnosed by history and physical exams; improvement was defined as any reduction in symptoms (such as pain, tenderness, swelling, warmth, and crepitus).

Depression was diagnosed as a Beck Depression Inventory score ≥ 14, remission was defined as a score less than the cut-off point, and a reduction $\geq 50\%$ in the score was considered an improvement.

With respect to back pain, pain assessment was performed in patients with chronic back pain for at least 3 months using visual analog scale. Remission was defined as no pain on the assessment, and improvement was regarded as any reduction in the pain score.

Interventions

Laparoscopic gastric plication

The surgery was performed using the same technique previously described by our group of investigators. Details of the technique are completely the same as the two-row plication method [9].

In summary, dissection was started at the greater curvature of the stomach in contact with the gastric wall from the

prepyloric area to 2 cm from the His angle. The anatomy of the His angle was preserved during the dissection. All greater curvature vessels were separated by LigaSure (Covidien, Mansfield, MA, USA). The two-row plication was performed by invagination of 3 sections of the gastric wall (from the perimeter) at greater curvature. Continuous suturing from the fundus of the stomach to the antrum, making 2 layers of plication from the anterior wall of the stomach to its posterior wall, was performed in this stage. A 00 prolene or nylon string was used, and the bulk of each stitch was 1 cm, with a 1-cm interval and a 1-cm distance from the lesser curvature. To prevent absorption by gastric acid over a long-term period, all sutures were extramucosal. In this method, 2 layers of plication were performed continuously in all patients by one surgical string. Finally, a tube shaped stomach was obtained in which the greater curvature had been inverted into the stomach and its space had been filled by layers of the greater curvature.

Laparoscopic mini-gastric bypass

LMGB procedure was performed as outlined by Rutledge et al. [8]. Briefly, a long gastric tube (with an approximate diameter of the esophagus) was created using an Endo-GIA stapler (EndoGIA, Covidien, New Haven, CT) alongside the lesser curvature from the antrum to the His angle. Thereafter, an anastomosis between the distal end of the gastric tube and jejunum to about 200 cm distal to the ligament of Trietz was performed using continuous suturing by a 00 prolene.

Postoperative care and follow-up

During the first 6 postoperative weeks, soft liquids were advised until patients adapted to their new condition. Patients in the LGP group were discharged once liquid food was tolerated. Because the stomach is cut and then anastomosed in LMGB, patients in the LMGB group underwent gastrografin contrast study to detect any leakage at 4 days postoperatively. Patients were discharged after normal gastrografin study and desirable liquid food toleration. In both groups, supplementation with a vitamin B12 tablet, a multivitamin, and Zink-Plus capsule was prescribed. Iron and calcium plus vitamin D supplements were given only in bypass patients. All patients were carefully monitored every 2 weeks during the first month and at 2, 3, 6, and 12 months postoperatively, to investigate the outcome of the surgery (%EWL, BMI) and possible late complications. Any condition necessitating rehospitalization and medical or surgical intervention was regarded as a major complication.

Statistical analysis

Statistical Package of Social Science software (SPSS version 16; IBM Company, New York, NY, USA) was used for statistical analysis. Before the study, the sample size was calculated to provide a statistical power of at least 80% to detect a mean operative difference of .75 standard deviation (SD) (2 sides, $\alpha < .05$). Nineteen patients were needed in each arm to achieve this power. Means of continuous variables were compared with the Student's t tests. Categorical variables were compared with χ^2 and Fisher exact test. Frequencies of categorical variables are reported. Data is presented as mean ± SD, and $P < .05$ was considered statistically significant.

Results

The 2 groups of patients were matched in terms of age, gender, mean weight, BMI, and amount of excess weight. Demographic characteristics of patients in both groups are summarized in Table 1. The 2 groups had comparable rates of medical co-morbidities, which are shown in Table 2. All patients were evaluated 1 year postoperatively, and follow-up visits at 1, 2, 6, and 12 months were completed for all (100%) patients in both groups.

Operation

Both LGP and LMGB procedures were successfully completed in all patients, and there were no deaths. The mean duration of the procedures was significantly shorter for the LGP group than the LMGB group (71.0 ± 11.5 minutes versus 125.0 ± 9.8 minutes; $P < .001$), the mean hospital length of stay was significantly shorter in the LGP group (1.6 ± .5 days versus 5.2 ± 1.0 days; $P < .001$).

Early and late operative complications

There were no infections. The most common early complication was nausea and vomiting in both groups. Nausea and vomiting was observed in 13 (65%) patients who had undergone LMGB, and it was observed in 11 (55%) patients in the LGP group, the condition (nausea and vomiting) persisted for 10 days in 2 patients. Patients in the LMGB group experienced a significantly higher rate of iron deficiency than patients of the LGP group ($P = .035$). Patients in the LMGP group experienced more episodes of

Table 1
Patient characteristics by surgery group

Treatment group	LMGB	LGP	*P* value
Number of patients, n	20	20	NS
Age, yr (mean ±SD)	36.6 ± 13.7	34.6 ± 10.9	NS
Gender ratio, (F:M)	17:3	12:8	NS
Mean weight, kg	139.3 ± 28.2	130.9 ± 20.3	NS
BMI, kg/m^2	49.5 ± 8.0	47.6 ± 5.3	NS
Weight excess, kg	71.6 ± 23.2	65.4 ± 15.0	NS

BMI = body mass index; F= female; LGP = laparoscopic gastric plication; LMGB = laparoscopic mini-gastric bypass; M = male; NS = not significant.

Table 2
Co-morbidity outcomes by patient group

Patient co-morbidities	Treatment group					
	LMGB (n = 20)			LGP (n = 20)		
	Preoperative numbers	Remission	Improvement	Preoperative numbers	Remission	Improvement
Hypertension, n	3	2	1	3	1	2
Diabetes, n	2	1	1	1	0	1
Hyperlipidemia, n	9	4	3	7	3	2
Gastroesophageal reflux, n	5	4	1	4	3	1
Irregular menses, n	4	3	1	4	3	1
Degenerative joint disease, n	5	Not defined	5	5	Not defined	5
Depression, n	4	1	3	3	1	2
Back pain, n	8	4	4	6	4	2

LGP = laparoscopic gastric plication; LMGB = laparoscopic mini-gastric bypass.

marginal ulcer, diarrhea, calcium deficiency, vitamin D deficiency, vitamin B_{12} deficiency, and iron deficiency anemia compared with the LGP group, but there was no significant difference between the 2 groups. New onset cholelithiasis occurred more in the LGP group, but the difference was not statistically significant. Rehospitalization and reoperation were not required in any of the patients. Late complications are listed in Table 3.

Weight loss

Patients were followed up for12 months. Both procedures resulted in significant reduction in the mean %EWL and BMI. Improvement was observed in all co-morbidities in both groups, with the exception of hyperlipidemia, which remained unresolved in 4 patients. Co-morbidity outcomes are listed in Table 2. The mean %EWL and the mean BMI of patients were not significantly different between both groups at 1, 2, 6, and 12 month intervals postoperatively. The mean (SD) % EWL at the 1-year follow-up visit was 60.8% ± 16.6% in the LGP group versus 66.9% ± 23.7% the LMGB group (P = 0.347). The clinical outcome of procedures, the mean %EWL, and the mean percent of weight loss (%WL) at 1-, 2-, 6-, and 12-month intervals postoperatively are listed in Table 4.

Discussion

Bariatric surgery is recognized as an effective and popular procedure as a means for weight reduction in morbidly obese patients. When choosing the suitable technique, a variety of factors must be considered, including effectiveness, simplicity, conservativeness, complication rate, reversibility, cost, and the potential for options (restrictive and malabsorptive; performing by laparoscopic access). The ideal procedure should rarely cause hernia and leave little adhesion.

Table 3
Patient complications by surgery group

Patient complications	Treatment group		
	LMGB n = 20	LGP n = 20	P value NS
Nausea and vomiting, (1 month postoperatively), n (%)	4 (20%)	3 (15%)	NS
Nausea and vomiting, (1 year postoperatively)	1 (5%)	1 (5%)	NS
Hair loss, n (%)	8 (40%)	7 (35%)	NS
Iron deficiency, n (%)	4 (20%)	0 (0%)	.035*
Iron &Vitamin B_{12} deficiency anemia, n (%)	1 (5%)	0 (0%)	NS
Iron deficiency anemia, n (%)	2 (10%)	0 (0%)	NS
Vitamin B12 deficiency, n (%)	2 (10%)	0 (0%)	NS
Vitamin D deficiency, n (%)	2 (10%)	0 (0%)	NS
Hypocalcemia, n (%)	2 (10%)	0 (0%)	NS
Marginal ulcer, n (%)	2 (10%)	0 (0%)	NS
Diarrhea, n (%)	2 (10%)	0 (0%)	NS
Cholelithiasis, n (%)	0 (0%)	2 (10%)	NS
Re-hospitalization,n (%)	0 (0%)	0 (0%)	NS
Major complication, n (%)	0 (0%)	0 (0%)	NS
Reverse operation, n (%)	0 (0%)	0 (0%)	NS

LGP = laparoscopic gastric plication; LMGB = laparoscopic mini-gastric bypass; NS = not significant.
*Statistically significant (P value <0.05).

Table 4
Weight loss and clinical outcomes of the procedures

Number of patients	Treatment group		*P* value
	LMGB	LGP	
	n = 20	n = 20	NS
%EWL at 1 month follow-up	19.7 ± 7.7	22.6 ± 5.3	NS
%EWL at 2 months follow-up	28.0 ± 11.3	31.4 ± 4.5	NS
%EWL at 6 months follow-up	50.4 ± 17.9	47.4 ± 9.5	NS
%EWL at 12 month follow-up	66.9 ± 23.7	60.8 ± 16.6	NS
%WL at 1 month follow-up	9.5 ± 2.8	11.1 ± 2.4	NS
%WL at 2 months follow-up	14.4 ± 3.2	15.5 ± 2.6	NS
%WL at 6 months follow-up	24.2 ± 5.2	23.4 ± 5.1	NS
%WL at 12 months follow-up	32.4 ± 9.0	30.0 ± 8.2	NS
Mean BMI 12 months postoperatively	33.4 ± 7.6	32.7 ± 4.5	NS
Mean weight 12 months postoperatively	93.6 ± 22.0	89.9 ± 15.2	NS
Failure (%EWL <30% at 12 months postoperatively)	0	0	NS

%EWL = percentage excess weight loss; LGP = laparoscopic gastric plication; LMGB = laparoscopic mini-gastric bypass; NS = not significant; %WL = percentage weight lost.

AGB and SG are 2 common restrictive procedures. AGB has been used for many years. This technique is easy to perform, adjustable, reversible, and has a low immediate rate of mortality [10]. However, this technique results in long-term unsatisfactory weight loss in up to 51% of patients [11]. Himpens et al. reported 12-year follow up data of patients who underwent laparoscopic adjustable gastric banding (LAGB) and reported that band erosion occurred in 28% of patients and that approximately 50% of patients required band removal. The reoperation rate was 59.8%, and the authors argued against continuing use of LAGB as a restrictive bariatric procedure [11]. SG is another popular restrictive procedure with promising results in weight loss management. Despite the advantages, some major complications have been reported, including internal bleeding, leakage, fistula, and stenosis. Hemorrhage occurred in about 3.5% of patients [12], and gastric leaks occurred in almost 2.2% of patients [13], which is very difficult to manage and is an irreversible procedure. Although RYGB is considered the gold standard bariatric procedure in The United States, the incidence of complication in this technique remains high. It is reported that leakage occurs in 0% to 2.6% of patients [14,15]; major complications occur in 5% of patients [7], and the need for reoperation is reported in between 0% to 12.6% of patients [7,14,16]. As a result, some studies suggested MGB as an alternative to RYGB. These studies showed that MGB is a better tolerated and simpler procedure than RYGB with the same efficacy as RYGB [7,8] However, MGB is not considered a standard procedure in the United States, and it is still considered an investigational procedure because of its potential long-term complications such as bile reflux. Rutledge et al, in a series of 2,410 cases who underwent MGB procedure, reported leakage and iron deficiency anemia in 1.08% and 4.9% of patients, respectively, and an addition 5.6% of cases experienced dyspepsia and ulcer. In their series, the 30-day mortality rate was .08% [8].

A bariatric procedure that provides desired, sustainable weight loss without possible complications of permanent implant and gastric resection, with lower risk of anastomotic leakage, without nutritional deficiency and marginal ulcers, offering a reversible technique is highly desirable. This study showed that LGP fulfills most of the mentioned criteria.

Brethauer et al. published a nonrandomized trial investigating anterior plication and greater curvature plication (GCP); they reported results from 15 patients (9 cases underwent anterior plication and 6 cases underwent GCP). They stated %EWL was higher in the GCP group compared with the anterior plication group (53% versus 23%) [17], which was consistent with the finding of Fusco et al. in rat models of anterior gastric wall and greater curvature invagination [18]. Anterior plication without release of greater curvature is less invasive, but it does not provide sufficient weight loss and is associated with higher risk of weight gain.

In a previous study, we reported results of LGP in 100 obese patients, the mean %EWL at 1-, 6-, 12-, 24-, and 36–month intervals was 21.4% (100 patients, 100%), 54% (72 patients), 61% (56 patients), 60% (50 patients), and 57% (11 patients), respectively, and 4 cases (4 in 100) needed reoperation with no late complication (4 in 100: leak, 1; perforation, 1; liver abscess, 1; and permanent vomiting, 1) [19].

Our previous study and the study conducted by Skerekas et al. found that gastric plication could not completely eliminate the risk of gastric leakage [19,20]; therefore, the probability of leakage must be carefully considered if the patient experiences any sign of infection; however, in this study no patient experienced leakage.

In this study, all procedures were performed by a single surgeon who had done over 500 LGPs and over 100 LMGBs before this study, eliminating concern for surgeon inexperience. It was shown that LGP provides equally effective weight loss and improvement in obesity-related

co-morbidities as LMGB during a 1-year follow up study. Iron deficiency observed in the LGP group was significantly lower than the LMGB group. Also, the mean duration of procedures and the mean hospital length of stay were significantly shorter for the LGP group compared with LMGB. However, it bears mention that the longer length of hospitalization is not considered a disadvantage for the LMGB group; which is explained by the fact that an equivalent criteria for hospital discharge was lacking. Patients in the LMGB group underwent gastrografin study on day 4 postoperatively, and patients were discharged providing that no leakage was observed, and the patient was convenient. Shorter mean length of hospitalization is reported in previous studies (1.4 days in the Rutledge et al. report and approximately 2 days in the Noun et al. report [21]).

Remarkably, gastric plication is more cost-effective than current available bariatric procedures both initially and in the long term. Gastric plication yields a shorter operative time. Furtheremore, no bands and staplers are required in LGP. Before hospital discharge, gastric plication saves approximately $2,500 compared with LMGB [9], and in the long term, patients who underwent LGP required fewer supplements compared with the LMGB procedure.

LGP is also associated with the advantage of easily-performed follow-up visits, as there is no application of foreign bodies or need for obligatory postoperative procedures, such as the regulation of balloon-size in gastric banding) and no application of foreign bodies. Additionally, because there are no anastomosis or resections, complications such as erosion, infection, and leakage are minimal. LGP is a conservative and reversible procedure, and LGP results in a lower cost. The short-term follow-up period is regarded as the main limitation of the present study. Hence, studies with long-term follow-up are needed to establish clinical benefits of LGP.

Conclusion

Both LGP and LMGB are effective treatments for morbid obesity. Both procedures were able to significantly improve obesity related co-morbidities. It was shown that LGP is a simpler and cheaper procedure with shorter operative time compared with LMGB, with similar weight loss efficacy at 1 year follow-up. It is believed that LGP can be an acceptable alternative to LMGB and other bariatric surgical procedures.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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