Laparoscopic Gastric Plication: An Emerging Bariatric Procedure with High Surgical Revision Rate

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Introduction: Laparoscopic gastric plication (LGCP) reduces gastric volume without resecting or implanting a foreign body. Although still considered investigational, it could be appropriate for young patients with a low body mass index (BMI) and for those unwilling to undergo sleeve gastrectomy, gastric banding, or bypass.

Objectives: The aim of this study was to assess the mid-term results (2 years) of LGCP in terms of safety and efficacy.

Methods: A total of 56 obese patients (47 female; mean age = 30.5 ± 11.7 years; mean BMI = 40.31 ± 4.7 kg/m²) were candidates for LGCP from January 2011 to October 2013. Early and late complications, BMI, and excess BMI loss (EBL) were prospectively recorded at 3, 6, 9, 12, 18, and 24 months follow-up.

Results: Mean operative time was 72.4 ± 15.6 minutes. No conversion was required. Mean hospital stay was 3 days. Mean %EBL was $34.3 \pm 18.40\%$, $40.1 \pm 24.5\%$, $47.4 \pm 30.2\%$, $46.5 \pm 34.6\%$, $47.8 \pm 43.2\%$, and $55.3 \pm 53.6\%$ at 3, 6, 9, 12, 18, and 24 months, respectively. The overall complication rate was 32.14%. Perioperative mortality was zero. Surgical revision was needed in 30 patients: 12 for unsatisfactory weight loss and 18 for gastric prolapse (one acute within 30 days), respectively.

Conclusion: LGCP showed high complication rates requiring surgical revision.

Introduction

OBESITY IS A GROWING EPIDEMIC, nearly doubling since 1980 and affecting 500 million individuals worldwide.¹ The increasing prevalence of obesity and related comorbidities has raised awareness of and demand for bariatric surgery.

In 2011, the most common procedures were Roux-en-Y gastric bypass (RYGB; 46.6%), laparoscopic sleeve gastrectomy (LSG; 27.8%), and adjustable gastric banding (AGB; 17.8%).² However, some novel procedures are emerging, as it is well known that no single bariatric operation can fit all patients. Laparoscopic gastric plication (LGCP) was recently proposed as a restrictive technique to reduce stomach capacity by infolding the greater curvature with sutures. It does not cut away any stomach or implant any device around the stomach. For these reasons, it could be a reasonable option for young patients and for those unwilling to have either a gastric resection or a foreign body implanted, in terms of reversibility. Moreover, the absence of staple lines should avoid the risk of leakage when compared with LSG. LGCP seems to offer a true vertical gastric restriction without the obstruction seen for AGB, where the band creates a true horizontal gastric partition.

The aim of this prospective study was to report, assess, and discuss the mid-term (2 years) results of LGCP in terms of safety and efficacy at a single academic institution, accredited by the IFSO-EAC Centre of Excellence Program.

Patients and Methods

From January 2011 to October 2013, 56 obese patients (47 female) gave informed consent and underwent LGCP for morbid obesity at the authors' institution, after Institutional Review Board (IRB) approval. According to the investigational protocol, LGCP was proposed to patients with a body mass index (BMI) of <50 kg/m² without previous bariatric operations and relevant metabolic comorbidities in their history.

Preoperative evaluation

Patients were selected for LGCP if they met the National Institutes of Health criteria for bariatric surgery after evaluation by a multidisciplinary team (internist, bariatric surgeon, psychiatrist, nutritionist).^{3,4}

Routine preoperative assessment consisted of upper gastrointestinal (GI) endoscopy, barium swallow, and ultrasound (US) scan of the liver.

Surgical technique

All the procedures were carried out under laparoscopy, the patient lying supine, surgeon in between the legs, and assistants on both sides. Pneumoperitoneum (15–16 mmHg) was achieved by inserting a Verres needle under the left subcostal margin. A four-trocar approach was used in all patients.

The dissection and the division of the vascular supply of the greater curve of the stomach was done with the Harmonic® scalpel starting at the antrum, 4–6 cm proximal to the pylorus up to the angle of His, with complete exposure of the left crus as for LSG.

LGCP was modelled on a 34-Fr gastric bougie with a double row of sutures (one interrupted with braided 2.0 thread and one running with polypropylene 2.0) starting 2 cm below the esophageal-gastric junction to the antrum. Plication was achieved with full-thickness stitches, each bite 1 cm apart, in order to reduce unintentional tears or early prolapses. To begin with, a polypropylene 2.0, single-row running suture was used (four patients), but later it was found that it was much easier to use a double row: the first interrupted (template), the second running (final shape). The first 42 patients underwent intraoperative endoscopy to confirm the gastric patency. Dexamethasone 4 mg was administered during surgical procedure and on the first postoperative day (POD-1) to reduce vomiting because of gastric wall edema. No drain or naso-gastric tube was left in place at the end of procedure in any of the patients.

All patients underwent a fast-track protocol with early mobilization and upper-GI series with water-soluble contrast medium on POD-1 (Fig. 1). If good gastric emptying through the duodenum was shown, patients were allowed to sip liquids and start a soft diet.

FIG. 1. Upper gastrointestinal (GI) series after laparoscopic greater curvature plication.

Follow-up

Follow-up controls were scheduled at 1, 3, 6, 9, 12, and 18 months after surgery and then once a year. At each visit, weight, BMI, and compliance to diet were assessed and registered. All patients underwent upper-GI series 6 months after surgery to assess the persistence of plication and rule out gastric prolapse or tube dilation.

Data and statistical analysis

Clinical data were prospectively collected and included age, sex, BMI at surgery, indications to conversion/revision surgery, operative time, early morbidity and mortality (within 30 days), and late complications. Data were then analyzed retrospectively. BMI and %excess BMI loss (EBL) were used to assess weight loss, according to international recommendations.^{5,6} Frequencies and mean values with standard deviations were used to describe the series population.

Results

Anthropometric data

From January 2011 to October 2013, 56 obese patients (47 females) underwent LGCP for morbid obesity. Mean age was 30.50 ± 11.74 years (range 16–72 years). Mean preoperative BMI was 40.31 ± 4.68 kg/m² (range 32.35–58.03 kg/m²). One patient with a BMI of 58.03 kg/m² underwent LGCP because he refused any other bariatric procedure.

Operative data

The mean operative time was 72.4 ± 15.59 minutes (range 45–115 minutes). Intraoperative endoscopy was performed to confirm gastric patency in the first 42 patients and then was abandoned to reduce the risk of endangering plication with overinflation. No conversion to laparotomy was necessary. One patient underwent concurrent cholecystectomy, and operative time in that case was 90 minutes. Mean hospital stay was 3 ± 1 days.

Complications

Perioperative mortality was zero. The overall complication rate accounted for 32.14% (Table 1). Gastric prolapse (Fig. 2) was the unique complication reported in the series, early in one and late in 17 patients. Surgical revision was always needed. Only 6 out of 18 patients had symptoms of gastric prolapse with acute onset that required hospital re-admission. This happened early (5 days after LGCP), requiring urgent LSG due to gastric wall ischemia in only one case. Five subjects suffered from late gastric prolapse >6 months after surgery. The clinical pictures were different, from epigastric pain through gastric occlusion with incoercible vomiting, and the treatment varied accordingly (Tables 1 and 2).

One patient complaining of no symptoms had unsatisfactory weight loss (%EBL < 50%) after 12 months. The patient underwent upper-GI series that revealed upper gastric prolapse that had not been evident at the 6-month follow-up.

In 11 patients, gastric prolapse was documented during the routine upper-GI series taken at 6-month follow-up. Two of these subjects referred with gastro-oesophageal reflux disease (GERD) symptoms.

TABLE 1. COMPLICATIONS

Type of complication	Gastric prolapse	Acute (< POD 10)	N
		Late (> 6 months after surgery)	17
		Failure, gastric prolapse at upper-GI	1
		Gastric prolapse at 6th month upper-GI	9
		GERD symptoms, gastric prolapse at 6th month upper-GI	2
		Symptomatic gastric prolapse in an emergency setting	6

Overall complication rate: 32.14%.

POD, postoperative day; GI, gastrointestinal; GERD, gastro-oesophageal reflux disease.

Redo surgery

Thirty patients (55.57%) underwent surgical revision after a mean time of 18 ± 8 months (range 0–33 months) from LGCP (Table 2).

Twelve patients had redo surgery for unsatisfactory weight loss (%EBL < 50%). All these subjects had some intraoperative evidence of either dilation or prolapse of the gastric plication. Ten underwent LSG, complicated in one case with a gastric leak. It was successfully managed with conservative treatment.

The mean BMI before conversion to LSG was 38 ± 6.5 kg/m² (range 38.45–46.37 kg/m²). After LSG, the mean BMI and %EBL after the 1st month were 34 ± 5.6 kg/m² (range

34.76–42.09 kg/m²) and $20 \pm 35.6\%$ (range 13.06–27.74%), respectively.

Two patients underwent re-plication. At redo, BMI was 41.80 kg/m² and 45.70 kg/m², respectively. BMI and %EBL 1 month after replication were 38.97 kg/m² and 16.86 kg/m² and 41.01% and 22.64%, respectively. Both manifested GERD symptoms and gastric prolapse at upper-GI series 6 months after redo surgery. One underwent LSG 10 months after re-plication.

Eighteen patients needed revision for surgical complications (gastric prolapse; Table 2). These are detailed below.

One underwent fundectomy 15 months after LGCP for weight loss failure (%EBL < 50%) and upper gastric prolapse at upper-GI series at the 6th month. BMI at fundectomy was 36.13 kg/m², BMI and %EBL at the 1st month were 33.59 kg/m² and 22.81%, respectively.

Nine patients needed surgical revision for gastric prolapse at upper-GI series at the 6th month. Redo surgery was performed after a mean time of 17 ± 8.1 months (range 7–33 months). Five underwent LSG (one with concurrent cholecystectomy), two fundectomy (one with concurrent cholecystectomy), two re-plication. One patient presented GERD symptoms and gastric prolapse at upper-GI series after replication and underwent LSG after 5 months.

Two patients presented GERD symptoms and gastric prolapse at upper-GI series at the 6th month. One underwent LSG and one fundectomy 25 and 29 months after LGCP, respectively.

Six patients required urgent redo surgery, varying from adhesiolysis through LSG/fundectomy.

Two patients are still on the waiting list for surgical revision due to insufficient weight loss (%EBL < 50%) or gastric prolapse.

BMI and %EBL

All patients completed the 1st month follow-up (100%), 53 the 3rd month (94.6%), 50 the 6th month (89.3%), 39 the 9th month (69.6%), 38 the 12th month (67.8%), 21 the 18th month (37.5%), and eight the 24th month (14.3%), respectively. Baseline BMI (at time of LGCP) was 40.31 ± 4.68 kg/m² (range 32.35–58.03 kg/m²). Mean BMI values were 35.5 ± 4.8 kg/m² (range 27.3–51.7 kg/m²) at 3 months, 34.5 ± 5.3 kg/m² (range 23.6–50.5 kg/m²) at 6 months, 34.2 ± 6.9 kg/m² (range 19.8–49.8 kg/m²) at 12 months, and 34.8 ± 10.3 kg/m² (range 20.4–47.5 kg/m²) at 24 months, respectively (Fig. 3).

%EBL was $34.3 \pm 18\%$ (range –10.4% to 86%) at 3 months, $40.1 \pm 24.5\%$ (range –25.2% to 109.5%) at 6 months, $46.5 \pm 34.6\%$ (range –12.4% to 157.2%) at 12 months,

FIG. 2. Gastric prolapse at upper-GI series after laparoscopic greater curvature plication.

TABLE 2. REDO SURGERY

N	Cause of redo	N	Type of redo	N	Complications after redo	N	II redo
12	Failure, insufficient weight loss	2	Replication	2	Gastric prolapse	1	LSG
		10	LSG	1	Gastri leak		
1	Failure, gastric prolapse at upper-GI	1	Fundectomy				
9	Gastric prolapse at 6th month upper-GI	5	LSG				
		2	Fundectomy				
		2	Replication	1	Gastric prolapse	1	LSG
2	GERD symptoms and gastric prolapse at 6th month upper-GI	1	LSG				
		1	Fundectomy				
6	Symptomatic gastric prolapse in an emergency setting	2	LSG				
		1	Adhesyolysis				
		1	Fundectomy				
		2	Take down				

Redo surgery rate: 55.57%.

LSG, laparoscopic sleeve gastrectomy.

and $55.3 \pm 53.6\%$ (range 2.4–151.3%) at 24 months, respectively (Fig. 4).

Discussion

Gastric plication was first described in 1976 by Tretbar *et al.* as a bariatric procedure,⁷ and was recently reintroduced and performed laparoscopically by Talebpour and Amoli.⁸

According to American Society for Metabolic and Bariatric Surgery (ASMBS) position statement on gastric plication, this procedure should be considered investigational at present because the quantity and quality of the data available are insufficient to draw any definitive conclusions regarding safety and efficacy.⁹

LGCP has gained popularity among surgeons and patients for different reasons. Neither foreign body implant (i.e., gastric banding) nor intestinal bypass nor gastric resection is required, thus dramatically decreasing the risk of leakage but retaining a high degree of reversibility. In addition, LGCP resembles and reasonably produces a gastric restriction similar to LSG without a staple line.

As LGCP is considered “investigational,” in this study, it was proposed it to a very select sample of patients, according to the investigational protocol mentioned above. In the patient series, LGCP-induced weight loss was encouraging, and results are comparable to those reported by others, with a mean %EBL ranging from $20.5 \pm 9.6\%$ at 3 months to $47.8 \pm 43.2\%$ at 18 months. In a recent review on LGCP (nine studies, 1,407 patients), the mean percentage of excess weight loss (%EWL) ranged from 31.8% to 74.4%, with follow-up ranging from 6 to 24 months.¹⁰ Only Talebpour *et al.* reported a series with a follow-up of > 10 years and a mean %EWL at 3, 4, 5, and 10 years of 66%, 62%, 55%, and 42%, respectively, although in the long term, the number of patients is not consistent enough to draw any definitive conclusion.¹¹ Among the present patients, only eight reached the 24-month follow-up, with a mean %EBL of $55.3 \pm 53.6\%$. The small sample size was mainly due to the high number of conversions to other procedures and very few dropouts. At present, data comparing LGCP to LSG showed that LGCP is less effective in terms of weight loss already at midterm results.^{12,13}

FIG. 3. Mean body mass index (kg/m²). BMI, body mass index.

FIG. 4. Mean percent excess body mass index loss.

In the present series, weight loss was considered unsatisfactory in patients with %EBL < 50%. This was always associated with evidence of gastric prolapse. It is noteworthy that this was found at routine upper-GI series scheduled during follow-up, according to the investigation protocol, and it occurred in more than half of the cases without any symptoms. From this evidence, the increase of BMI was mainly related to an impaired or missing restriction of the gastric fundus and not to a selection bias.

In the present series, perioperative mortality was zero, comparable with that reported in the literature. Minor complications such as nausea, vomiting, and epigastric pain were well-tolerated and easily managed with steroids in the early postoperative period. Symptoms had resolved completely within 1 month.

The durability of LGCP was the key issue. Surgical revision was needed in 30 patients after a mean time of 18 ± 8 months, essentially for dilation of the plication or gastric prolapse, although the clinical presentation was different in each patient. Gastric prolapse was the unique complication reported in the present patient series (Fig. 2). "Prolapsed" was defined as a portion of the plicated stomach popping out the folded greater curvature, similar to a true diverticulum or a gastro-gastric herniation. This occurred mainly in the fundic region, and may be due to the fact that the gastric wall is usually thinner in that area,¹⁴ and incremental strain forces can contribute to further dilation of the pouch according to Laplace's law. The basic mechanism that can be advocated is the late (>6 months) atrophy of the "infolded" stomach, ultimately leading to a loose suture of the plication, prone to herniation between the stitches, whatever technique has been used. Twelve patients had insufficient weight loss and evidence of gastric prolapse at reoperation. One had insufficient weight loss and prolapse at upper-GI series. Nine showed prolapse at upper-GI series at the 6th month follow-up with no symptoms. Two presented with GERD symptoms and prolapse at upper-GI series (Table 1). Moreover, six patients underwent surgical revision for gastric prolapse in an emergency setting. This occurred in the early postoperative period (5 days after LGCP) in just one case, with

abdominal discomfort, fever, and altered white blood cell counts. During urgent laparoscopy, the prolapsed fundus had signs of ischemia.

Most patients had symptoms >6 months after plication. This along with the results of upper-GI series taken routinely after 6 months reaffirms that LGCP durability is a major concern if properly investigated.

Another issue that remains controversial is redo or conversion surgery after LGCP. In the authors' experience, LGCP could be easily dismantled and converted to another procedure. LSG was performed in patients with evidence of dilation along the full length of plication while fundectomy or resection of the gastric prolapse was proposed to those patients still bearing plication in the distal portion of the stomach. As the main rationale behind LGCP was avoiding gastric resection, limited stomach resection (fundectomy) was chosen for those patients with an intact distal portion of the plication at redo surgery, in order to reduce the extent of the resected stomach and related risks. Moreover, resection of the gastric fundus is considered one of the main determinants of weight loss. Conversely, LSG was offered to those patients who showed a complete derangement of the plication, as it was easy to take down sutures and plication. RYGB was not considered because following thorough reassessment, none of the patients displayed severe GERD symptoms with severe oesophagitis before redo surgery. Plication was simply taken down and the stomach restored in patients refusing other bariatric procedures, while re-plication was offered to those unwilling to undergo gastric resection. This approach was not successful, as gastric prolapse recurred in three patients at upper-GI series after 6 months and two of them finally had LSG. There was only one leak after redo LSG in the present patient series.

Data from the literature report a reoperation rate for major surgical complication of 0–15.4%, and the two main causes were obstruction and gastric perforation. Among the 14 selected studies analyzed by Yun *et al.*, gastro-gastric hernia was reported in at least three patients.¹⁰ In the present series gastro-gastric hernia occurred in patients who had undergone both one-row and two-row LGCP.

Although the same surgical technique was used in all patients, LGCP has some intrinsic flaws, given the high rates of redo surgery. This was not related to a “learning curve effect,” as all the procedures were performed by a single senior surgeon, skilled and familiar with intracorporeal stitching, performing all bariatric operations, including duodenal switch and RYGB, and trained for LGCP in an experimental setting. The shrinkage of the gastric fold due to atrophy of the excluded wall make the suture loose with time. However, the main criticism about LGCP and its complications is the lack of standardization of surgical technique. Many surgeons have introduced different techniques. Ahmed El Geidie *et al.* reported their initial results in 63 LGCP patients with a “4 bite-technique” (inner row constructed with two bites in the posterior and two in the anterior gastric wall). They did not report any major complications, reoperations, or readmissions.¹⁵ This technique seems to avoid the creation of a large intraluminal septum and decreases the pockets created between the gastric folds that may collect seroma and lead to gastric obstruction but could increase the risk of intramural hematomas. This technique appears to be superior to the two-bite one described by Talebpour and Amoli.⁸ Conversely, Brethauer *et al.* reported no efficacy with anterior gastric plication.¹⁶

Initially, a single row of stitches (four patients) was used in the present study. Then it was found that applying a first row of interrupted stitches made it easier to make a better plication, as the second row of running suture could be placed more precisely. However, Fried *et al.* reported no difference between single-row and double-row LGCP in terms of weight loss and complication rate.¹⁷

Potential reversibility is still considered one of the most important features of LGCP. This was confirmed in the present experience, as the stomach could be fully restored, even 14 months after LGCP. Talebpour *et al.* reported that LGCP was reversible by simply cutting the sutures in the first 6 weeks, but later reversal was far more difficult due to fibrotic adhesions.⁸ The same difficulty was not experienced in the present study.

Conclusions

LGCP must still be considered investigational due to the high surgical revision and overall complication rate. Although early results in terms of weight loss are encouraging, durability remains an intrinsic point of weakness that must be discussed openly with patients.

Author Disclosure Statement

No competing financial interests exist.

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