Impact of laparoscopic greater curvature plication on weight loss and some metabolic comorbidities, plus important recommendations

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Background
Laparoscopic greater curvature plication (LGCP) is a new bariatric procedure that until now has not found universal acceptance and is practiced by a limited number of surgeons with both promising and disappointing results.

Objectives
The aim of the study was to investigate the impact of LGCP on weight loss and associated metabolic diseases and evaluate its safety.

Patients and methods
A total of 120 morbidly obese patients, 50 hypertensive patients, 48 dyslipidemic patients, and 32 type II diabetic patients underwent LGCP and were followed up for 1 year.

Results
This study comprised 64 women and 56 men. Their mean age was 35.4 ± 11.8 years. Their mean preoperative BMI was 43.7 ± 7.6 kg/m^2, the mean procedural duration was 73 ± 19.7 min, the mean length of hospital stay was 42.3 ± 4.5 h, and the average BMI at 12 months was 27.7 ± 3.6 kg/m^2 ($P < 0.001$). Of 32 type II diabetes mellitus patients, 23 (71.8%) became normoglycemic, 37 (77%) of 48 patients experienced disappearance of dyslipidemia, and 36 (72%) of 50 hypertensive patients became normotensive at the sixth and 12th month. Three patients (2.5%) had gastric stenosis, and three patients (2.5%) had gastric leak. One patient (0.8%) had partial disruption during the first week at the upper end. One patient had prolapse of the intragastric fold causing gastroduodenal intussusception and obstructive jaundice after 8 months.

Conclusion
LGCP has a positive impact on weight loss and associated metabolic comorbidities but has potential specific complications.

Keywords:
bariatric surgery, laparoscopic greater curvature plication, metabolic comorbidities

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Background

Many types of restrictive procedures have been performed to achieve weight loss [1]. Most of them have been abandoned because of poor long-term weight loss, food intolerance, and severe gastroesophageal reflux. Vertical banded gastroplasty in particular has resulted in poor long-term outcomes, and a high percentage of vertical banded gastroplasty patients have required revision to Roux-en-Y gastric bypass (RYGB) to alleviate intolerable reflux symptoms and dysphagia [2].

Some authors believed that irreversible resection of gastric tissue in gastric sleeve surgery and the reported complications such as leak and hemorrhage along the staple line have affected patient and physician acceptance of this procedure [3]. Adjustable banding has some drawbacks such as erosion and migration, proved by endoscopic surveillance after lap band ligation [4–6]. Despite malabsorptive methods having a longer effect on weight loss, the risk of late complications due to vitamin deficiency and anemia is noticeable [7]. Laparoscopic greater curvature plication (LGCP) was initially proposed by Wilkinson and Peloso [8] in 1981 and was introduced in 2006 by Talebpour and Amoli [3] in Iran. LGCP was thought to offer an alternative surgical option to patients willing to undergo a more invasive bariatric procedure, such as RYGB or sleeve gastrectomy [3,9]. Some authors reported that the mean excess weight loss (EWL) in different restrictive methods is almost the same [10,11]. Others reported that the EWL% after LGCP is comparable to the EWL% after sleeve gastrectomy [3,9]. Kourkoulos *et al.* [9] and Talebpour *et al.* [12] in 2012 believed that

laparoscopic gastric plication (LGP) is less invasive and more conservative, with reversible potency and lower risk for complications such as leakage compared with stapler resection procedures.

The aim of the present study was to evaluate the impact of LGCP on weight loss and metabolic comorbidities including type II diabetes, hypertension, and dyslipidemia, and evaluate its safety.

Patients and methods

This prospective study was performed in Minoufiya University Hospitals in Egypt and in other private hospitals in Kuwait (Al Seef Hospital, Hadi Hospital and Tibia Hospital) from September 2009 to March 2014).

Patients were screened and recruited for enrollment from the outpatient population. Their consent was obtained and the procedure was offered in addition to other standard bariatric procedures. Patients who expressed interest in the gastric plication procedure participated in an initial screening process. Those who met the criteria for the present study were evaluated, the details of the procedure were discussed, and it was clearly stated to the patient that this procedure was still under trial. Early findings and complications were discussed with the patients in detail, along with previous successful management options. Patients who agreed to participate in the present study signed an informed consent document and underwent a second level of screening, including laboratory tests, a routine preoperative evaluation, upper gastrointestinal endoscopy when indicated, respiratory function tests, and evaluations by psychologists and nutritionists.

Inclusion criteria

The participants were considered appropriate candidates for the present study if they were willing to give consent and comply with the evaluation and treatment schedule, including the International Fedration of the Surgery of Obesity and metabolic disorders (IFSO), and had a BMI greater than 40 kg/m^2; a BMI of 35–40 kg/m^2 was allowed, with at patients should have no psychopathological illness to be able to understand and tolerate the operation.

Exclusion criteria

The exclusion criteria included pregnancy or lactation at the time of screening for surgery, history of drug and/or alcohol abuse within 2 years of the screening visit, psychological disturbances, previous malabsorptive or restrictive procedures performed for the treatment of obesity, hypothyroidism or Cushing's disease, inflammatory diseases of the gastrointestinal tract within the previous 10 years, or other serious organic disease making the participant a high-risk surgical candidate. Additional exclusion criteria included chronic or acute upper gastrointestinal bleeding, hiatal hernia, previous surgery of the foregut (i.e. hiatal hernia repair or previous gastric surgery), pancreatitis, an immunocompromised status or autoimmune connective tissue disease, and the use of prescriptions or over-the-counter weight reduction medications or supplements within 30 days of the screening visit.

Study endpoint

Weight loss

The main primary study objective was to assess the weight loss. Assessments included absolute change in weight, change in BMI, and EWL%.

Weight was measured at the initial visit, on the day of surgery, and 1, 3, 6, and 12 months after surgery.

Other secondary study endpoints

Adverse events

Surgical safety and the occurrence of adverse events were carefully monitored throughout the entire study period and recorded on the day of surgery, during the first week after surgery, and at 1, 3, 6, and 12 months postoperatively.

Effect on metabolic disease

The effect on type II diabetes, hypertension, and dyslipidemia, and effects on serum albumin, gamma glutamyl transferase (GGT), and blood hemoglobin at 3, 6, and 12 months after surgery were evaluated.

Durability of the plication

We performed postoperative endoscopy in the outpatient setting at 6 and 12 months postoperatively to assess plication durability. Preoperative and postoperative upper gastrointestinal contrast studies were sometimes performed.

Patients underwent upper gastrointestinal endoscopy, blood tests, and abdominal ultrasound preoperatively. Anticoagulants were given, and prophylaxis with antibiotics was given on induction of anesthesia.

Surgical procedures

According to experience gained through the study, the first 40 patients were classified as phase 1 and the remaining patients (80 patients) were classified as phase 2.

The short gastric vessels were divided starting 5 cm from the pylorus and continuing up to the left crus of the diaphragm (Fig. 1).

The fundus and body were completely mobilized (Fig. 2), and a calibration tube of 36 Fr was introduced into the stomach. The stomach was deflated to facilitate the plication, and then the greater curvature was folded inward with two rows of continuous 2-0 polypropylene sutures over a round needle to create a linear intraluminal fold, reducing the stomach capacity (Figs. 3–5). The fold was started 1 cm from the gastroesophageal junction and continued distally to 5 cm above the pylorus. The second row of sutures was applied parallel to the first one (Fig. 4). Initially, the distance of the needle bite of the second row of sutures was 2 cm away from the lesser curve, but in subsequent cases we noticed that the stomach dimensions were not the same along its whole length. Thus we tended to be more flexible when performing the second row of sutures to avoid tension, stenosis, or intragastric fold plug. The bite sites were later adjusted in phase 2 to 2.5–3 cm from the lesser curve on either side because of reported stenosis in phase 1. In phase 1 we stopped plication 3 cm above the pylorus and then at 5 cm in subsequent cases in phase 2 to keep the pylorus empty (Fig. 6).

This modification was made because of the occurrence of gastroduodenal intussusception in one case in our study. In all cases, sutures were approximately not more than 1 cm spaced to avoid gastrogastric hernia. Routine intraoperative methylene blue test was used in phase 2 because of the occurrence of leak in phase 1.

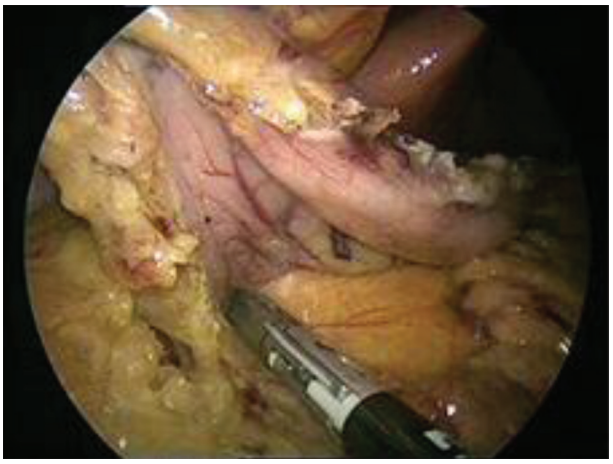
Postoperative care

Pain was assessed by the visual analogue scale and controlled by both pethidine and paracetamol infusion. Low-molecular-weight heparin was administrated

Figure 1

Sealing of the short gastric vessels.

Figure 2

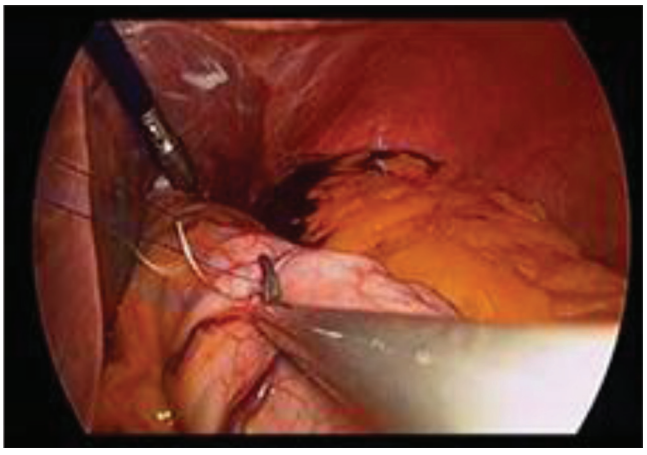


Mobilization of the body and fundus.

Figure 3

First row plication.

Figure 4



Second row plication.

for 15 days postoperatively. The postoperative diet was prescribed in consultation with a dietitian and was based on clear liquids for the first week and semiliquids as tolerated for 3 weeks. Solid food was allowed 4 weeks postoperatively. Follow-up visits for the assessment were scheduled postoperatively at 1 week, 2 weeks, 1 month, 3 months, 6 months, and 12 months. Statistics were recorded at 1, 6, and 12 months.

Results

A total of 120 patients (56 men and 64 women) were enrolled in the present study. Their mean age was 35.4 ± 11.8 years (range 18–63 years), and the average preoperative BMI was 43.7 ± 7.6 kg/m^2 (range 36.5–69.3 kg/m^2).

The procedure duration ranged from 57 to 155 min, with a mean of 73 ± 19.7 min. The mean hospital length of stay was 42.3 ± 4.5 h and ranged from 24 h to 26 days.

The visual analogue scale assessments were performed before discharge, and the average pain score was 2.5, ranging from 2 to 4 (Table 1).

Weight loss

The mean preoperative BMI was 43.7 ± 4.6 kg/m^2.

The mean BMI at 12 months was 27.7 ± 3.6 kg/m^2.

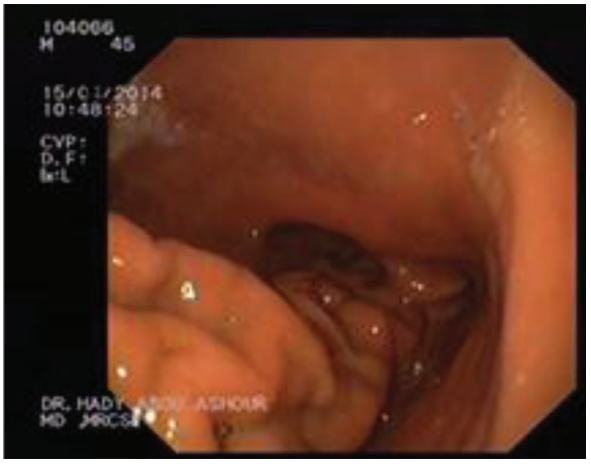
The EWL% for the patients at 3, 6, and 12 months was 29.3 ± 9.3, 42 ± 6.3, and 61.3 ± 3.7%, respectively. The difference in weight loss for patients enrolled in this study was statistically significant ($P < 0.001$) at the 12-month visit (Table 2).

The mean BMI decreased from 43.7 ± 4.6 to 27.7 ± 3.6 kg/m^2, a mean of 36.6% change in BMI at 1 year with an average decrease in BMI of 16 points. The EWL% showed better results during the follow-up periods for patients with BMI less than 45. In our study we had 21 patients with BMI over 45 kg/m^2 and their mean EWL% was 52.4 ± 9.6% over 12 months.

Effects on metabolic comorbidities

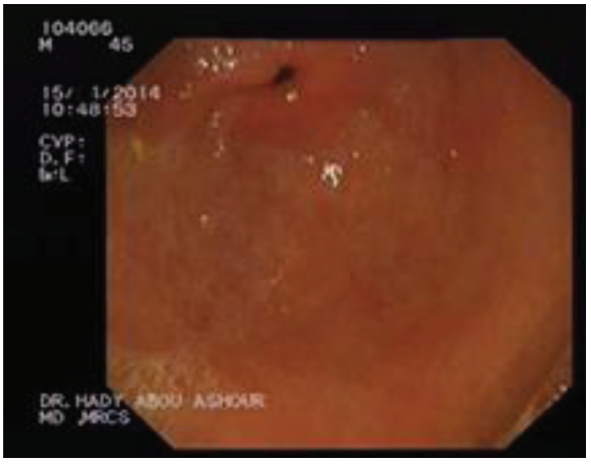
Thirty-two diabetic patients were encountered in our study; 15 of them were receiving insulin only, 12 were controlled with oral hypoglycemic medications only, and five diabetic patients were uncontrolled and did not receive any treatment for diabetes. Of the 15 patients receiving insulin, 10 showed a return to normal glucose level without any medication at 6 and 12 months after surgery. Of the 12 patients receiving oral medications, 10 became normoglycemic without medications. Of the five patients who were on no treatment, four returned to normoglycemic levels. Oral glucose tolerance test was performed for the normoglycemic patients after 12 months postoperatively and was negative except in the case of two patients. Thus, 23 out of 32 type II diabetes mellitus patients (71.8%) had normal blood glucose

Figure 5



Durable intragastric fold (endoscopy).

Figure 6



Empty pyloric region.

Table 1 Pre-op. BMI ,pain score and hospital stay

	Age	Pre op. BMI	Procedure Duration	Hospital stay	Pain score
Mean	35.4 ± 11.8 ys	(43.7 ± 7.6) kg/m^2	73± 19.7 min	42.3 ± 4.5 hrs	2.5
Range	18-63ys	36.5-65.3	57-155 min	24hrs-26 days	2-4

level without any medications, and the rest of the diabetic patients showed better glycemic control at the 6- and 12-month visits ($P < 0.001$).

Of the 50 hypertensive patients, 36 (72%) returned to normal blood pressure levels and the rest of them showed better control; 40 out of 50 patients (80%) showed improvement in the ejection fraction and reduction in the left ventricular size ($P < 0.001$).

Of 48 dyslipidemic patients, 37 (77%) showed improvement in dyslipidemia and returned to normal level by the end of the sixth and 12th month visits ($P < 0.001$) (Table 3).

None of the patients had abnormality in serum albumin or GGT, or appearance of anemia at the third, sixth, and 12th month of follow-up.

Follow-up endoscopy

Thirty-four patients did not complete the 12-month follow-up endoscopic evaluation after the sixth month. The other 86 patients (71.6%) who had completed the 6- and 12-month endoscopic evaluations had durable intragastric fold (Fig. 5) except one patient who had a partially disrupted fold that occurred during the first week at the upper end. This was confirmed by gastrografin contrast imaging without weight regain.

The disruption area was less than one inch and appeared as a small proximal pouch with a wide base and the patient refused intervention and had no further complications throughout the follow-up period.

Complications (Table 4).

Table 2 EWL % in follow up:

Months (%)	3rd (%)	6th (%)	12th (%)	*P* value
Over all mean EWL	29.3 ± 9.3	42 ± 6.3	64.6 ± 7.3	<0.001
Mean EWL for BMI >(45)	—	—	52.4 ± 9.6	< 0.05

Intraoperative complications

Two patients had small subcapsular hematoma in the left lobe of the liver.

Mild intraoperative bleeding from the short gastric vessels to the splenic side was seen in three cases and was dealt with by proper sealing.

The following complications also arose:

(1) Nausea in 44 patients (36.6%) and sialorrhea in 25 patients (20.8%) occurred during the first 30 h; seven patients (5.8%) had persistent vomiting and four of them resolved within a few days.
(2) Three patients (2.5%) showed manifestations of gastric stenosis; one responded to conservative treatment. The other two patients underwent laparoscopic plication undo after failure of conservative treatment and laparoscopic sleeve gastrectomy was performed. The barium study and the endoscopic view proved that the stenosed areas in each case were single and were:
    (a) Subesophageal.
    (b) Midgastric (because of the presence of voluminous intragastric fold, as this is the largest folded area of the stomach) (Fig. 7).
    (c) Prepyloric.
(3) Three patients (2.5%) had manifestations of gastric leak, where perforations were multiple in two of them and were located in both the anterior and posterior wall of the stomach (Figs. 8 and 9). These perforations occurred at the site of the second suture row (highest tension). As the application of endoscopic stents was not suitable

Table 3 Impact on metabolic comorbidities

Metabolic parameter	No. of patients	Impact of LGCP after 12th month	*P* value
Hypertension	50	36 patients (72%) became normotensives	<0.001
Type II diabetes	32	23 patients (71.8 %) returned to normal blood sugar and Glycated Hg returned to normal	<0.001
Dyslipidemia	48	37 patients (77%) returned to normal lipid profile	<0.001

Table 4 Complications

Intraoperative complications	Early intraoperative complications	Late intraoperative complications	Reoperation rate
Small sub capsular haematoma 2 patients (1.6%) Intraoperative (bleeding 2 patients (2.5%), not with ligasure.	Nausea 44 patients patients (36%) Sialorrhea 25 patients (20.8%) Gas bloating 45 (37.5%) Proximal disruption of gastric fold (0.83%) Gastric Leak (2.5%) (phase I) Gastric stenosis ,3 patients (2.5%) (phase I) Wound infection 2 patients (1.6%) Chest infection 3 pateints (2.5%)	Gastrodudenal one patient intussusception (0.83%)	6 patients (5%) all in phase 1 cases

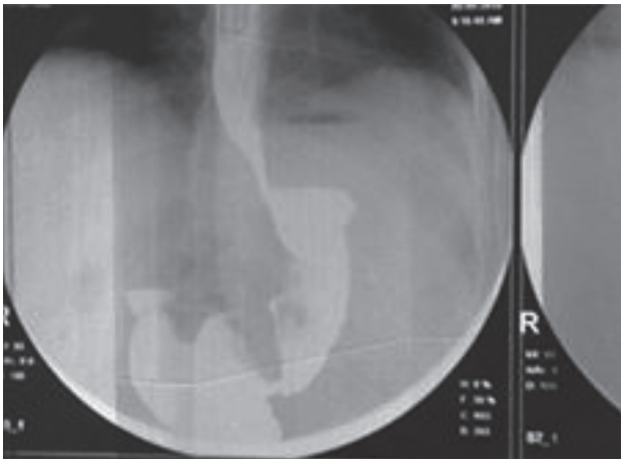
because of large intragastric fold, the tears were managed early by laparoscopic exploration, peritoneal wash, plication undo, identification of tears, trimming of their edges, suture repair, and liberal drainage. Omental flap was used to plug the defects in the stomach with tie over sutures in two cases of leak (Fig. 10). The fistula closed in 26, 24, and 23 days, respectively, with an average of 24.3 days, and the hospital stay was 26, 20, and 17 days, respectively, with an average of 21 days. Omental flap plug was used in two cases where defects were large and the margins were not firm enough to hold secure sutures; moreover, there was not enough distance from the lesser curve to the holes to ensure immediate safe sleeve gastrectomy. Patients received jejunostomy feeding, first at the hospital and then at home, before complete closure of the fistulae, whenever the condition was stable and the leak was minimal, controlled, together with normal passage of stool and no abdominal signs of peritonitis.

(4) One patient showed limited proximal fold disruption in the first week with no weight gain.
(5) Gas bloating appeared during the first postoperative week in 45 patients (37.5%) and disappeared after a few days.
(6) Two patients (1.6%) showed port site wound infection and were managed in a few days.
(7) Three patients (2.5%) had chest infection and responded to conservative treatment.

Late complications

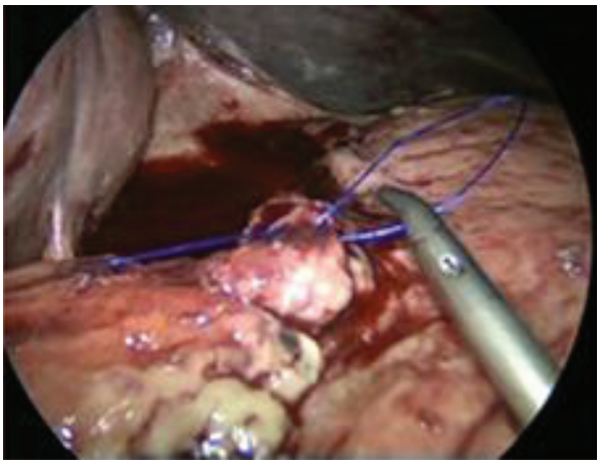
After 8 months one patient showed prolapse of the distal fold through the pylorus and duodenum and presented with vomiting and obstructive jaundice. Laparoscopic exploration was performed in the form of laparoscopic plication undo and withdrawal of the gastroduodenal intussusceptum; then laparoscopic reux-en y gastric bypass (LRYGP) was performed

Figure 7



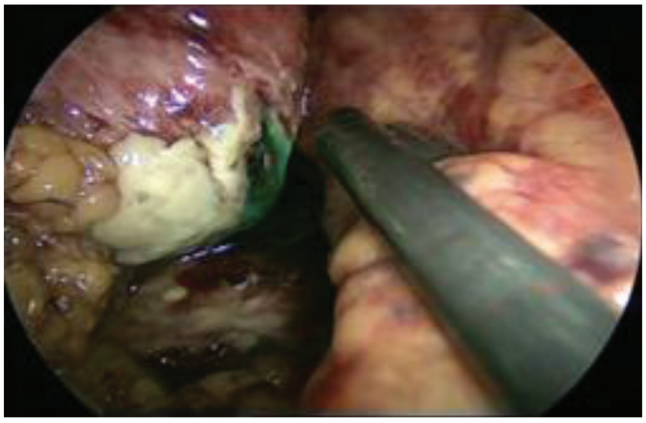
Midgastric stenosis (contrast image).

Figure 8



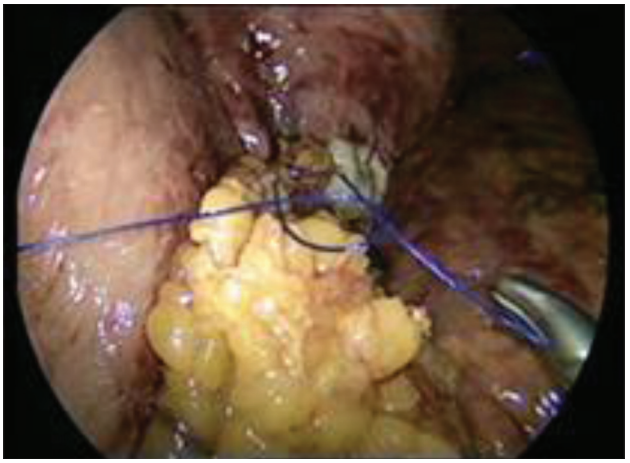
Suturing of perforation in the anterior wall.

Figure 9



Perforation in the posterior wall.

Figure 10



Omental flap plug with tie over suturing.

after 3 months. The overall reoperation rate was 5%, three cases for leak, two for gastric stenosis, and one for fold prolapse with gastroduodenal intussusceptions (Table 4).

Discussion

As the number of bariatric procedures is growing every year, the demand for a cost-effective procedure is gaining prominence. Talebpour and Amoli (2007) [3], Ramos *et al.* (2010) [9], and Brethauer *et al.* (2010) [13] reported that LGCP provided effective surgical weight loss at 12 months that, on average, was greater than 50% EWL. In our study, weight loss was significant over 1-year follow-up as EWL% was 29.3 ± 9.3, 42 ± 6.3, and 61.3 ± 3.7% at the third, sixth, and 12th month, respectively. These results were comparable to those of other standard bariatric procedures such as sleeve gastrectomy and gastric bypass. Our results showed that the EWL% was only 52.4 ± 5.63% for patients with BMI greater than 45 at the 12th month. Thus, LGCP was not the proper surgery for those with BMI greater than 45 kg/m^2.

LGCP can be reversed to other bariatric procedures, as in our study two patients underwent sleeve gastrectomy and one patient underwent RYGB after plication undo. After the occurrence of complications, we changed LGCP to other procedures, similarly to Kourkoulos *et al.* (2012) [10], Brethauer *et al.* (2011) [13,14], Pujol Gebelli *et al.* (2011) [15], Coskun *et al.* (2013) [16], and Ahnfeldt *et al.* (2013) [17], who occasionally changed LGCP to other bariatric procedures in certain instances with no recorded complication. Gastric leak was higher than we expected in this series (2.5%). This is because of the lack of accurate seromuscular needle bite, which could not be addressed especially in thin stomachs, and can cause concealed gastric perforations, which can widen and cause acid exposure and leak.

Talebpour and Amoli (2007) [3], Skrekas *et al.* (2011) [18], Menchaca *et al.* (2011) [19], Andraos *et al.* (2011) [20], and Kourkoulos *et al.* (2012) [10] reported an incidence of leak in their studies, although they reported that plication must be submucosal. This confirms that the leak sometimes could not be avoided even with strong attempts. This indicates that LGCP carries a comparable rate of leakage to sleeve gastrectomy and has not shown superiority with respect to leak. In subsequent cases (phase 2), considerable attempts were made for frequent aspiration of air and fluid using the gastric tube from the lower two-thirds of the stomach, avoiding tight plication or pulling of the continuous suture under tension in partially distended stomach. Because of these precautionary measures we had no recorded leak as in phase 1.

Vomiting due to fold edema and early gastric spasm responded to conservative treatment in a few days. Gastric fold prolapse to the duodenum was reported in one case after 8 months, which was complicated with gastroduodenal intussusception and obstructive jaundice. After this complication we modified the technique described by Talebpour and Amoli (2007) [3] to 5 cm instead of 3 cm above the pylorus to avoid prolapse. Our study was in agreement with that of Shen *et al.* (2013) [21], who reported that the total cost of LSG was $7826 ± 537 compared with LGCP ($3358 ± 264). The overall hospital cost was less when compared with laparoscopic sleeve gastrectomy or RYGB. In the present study the mean cost of LGCP was $3500 ± 312 in our country and was lower than sleeve and gastric bypass cost ($P < 0.05$).

Highly superficial plication disrupted early in this study because of increased intragastric pressure during vomiting in one case. Very deep plication carried the risk of acute gastric perforation and higher risk of leak; moreover, seromuscular suture could not be ensured in thin-walled stomach. Because of the experience gained in phase 1, we encountered neither gastric stenosis nor gastric leak in phase 2; however, this needs to be researched further. In this study, LGCP showed significant impact on metabolic comorbidities as 71.8% of type II diabetes mellitus patients experienced a return to normal blood glucose levels and negative oral glucose tolerance test; the remaining diabetic patients had better glycemic control; 72% of hypertensive patients demonstrated a return to normal blood pressure and the rest of them showed better control; 77% of dyslipidemic patients experienced an improvement of dyslipidemia, which returned to its normal level. This indicated beneficial effects on metabolic syndrome and supports the theory that type II diabetes is a curable surgical disease in obese patients.

No nutritional deficiencies or anemia was reported in this study. LGCP provided effective surgical weight loss at 12 months, especially in those with BMI less than 45 with an overall average greater than 61% EWL. From this study, it can be concluded that LGCP is an alternative restrictive weight loss surgical technique with specific potential serious complications that needs further validation for universal applicability and acceptance.

Important technical pitfalls and recommendations gained from this study

(1) Plication should be done on a completely empty stomach, gas free and fluid free, to avoid thinning of its wall and to reduce its volume to avoid acute gastric perforation during suturing.
(2) Gastric stenosis occurred in three cases in this study. Stenosis was also seen in some studies [16,17]. Therefore, the second row of sutures should not be less than 3 cm from the lesser curve.
(3) Plication should stop 5 cm above the pylorus to avoid fold prolapse.
(4) The second row of sutures should not be more than 1 cm spaced or loose to avoid gastrogastric hernia, which was a reported complication in some studies [15].
(5) Very superficial needle bites cause fold disruption, and very deep bites cause gastric perforation.
(6) The stomach size and thickness in patients were not similar. Some were thick walled, contracted, and easily plicated; others were thin walled, redundant, and difficult to be plicated.
(7) Intraoperative methylene blue test should be used in all cases (gastric plication can cause leakage).

Conclusion

LGCP has a positive impact on weight loss and associated metabolic comorbidities but has potential specific complications.

Acknowledgements

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Informed consent: Informed consent was obtained from all participants included in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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