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ORIGINAL ARTICLE

Gastric Plication as a New Stand-Alone Procedure for the Treatment of Morbid Obesity

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ABSTRACT

Purpose: Gastric plication of the greater curvature is spreading over all the bariatric centers as a new investigational procedure for the treatment of morbid obesity. Conventional bariatric surgeries 'gastric band','sleeve gastrectomy','vertical banding gastroplasty' and 'gastric bypass' are associated with severe complications and a high rate of failure or weight regain.

Materials and methods: Authors present their experience on 482 laparoscopic greater curvature plication (LGCP) performed over a period of 26 months. A total of 449 patients responded to inclusion criteria:147 men and 302 women. Their mean age was 35.99 ± 10.85 years. Their mean body mass index (BMI) was equal to 39.93 ± 6.15 kg/m^2.

Results: The average percentage of excess weight loss (%EWL) at 1, 3, 6, 12, 18 and 24 months was 30.19, 47.07, 63.05, 68.15, 68.62 and 69.29% respectively. Moreover, this study was divided into two subgroups and results were studied based on the type of suturing and patient's BMI over a period of 1 year. The first subgroup included 183 patients, where gastric plication was performed with continuous suturing at the first and second row. The second subgroup included 186 patients, where gastric plication was performed with separated stitches at the first row and continuous suturing at the second row. In the second subgroup, a higher degree of %EWL was found. The complication rate was greater in the first subgroup.The overall rate of immediate surgical complications was 1.33%. Mean hospital stay was 36 hours.

Conclusion: Gastric plication is safe and efficient on EWL based on short-term results. Separated suturing is associated with a higher %EWL and a lower rate of complications, with a short hospital stay. Long-term data are needed to consolidate these results.

Keywords: Obesity, Overweight, BMI, %EWL, Gastric plication, Bariatric surgery, LGCP.

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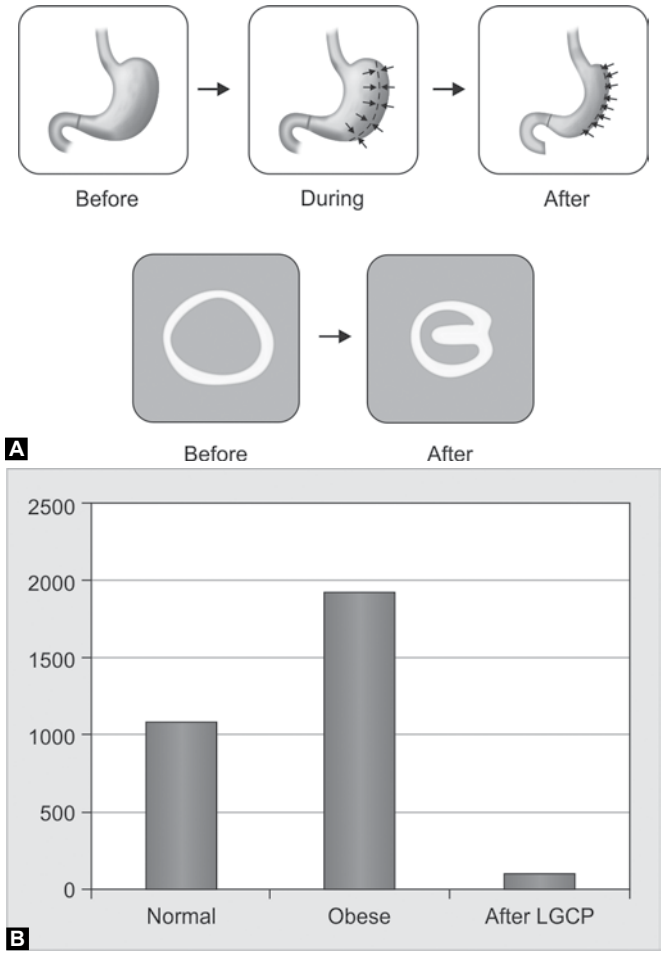
INTRODUCTION

Gastric plication of the greater curvature achieves weight loss by reducing gastric volume by 80 to 90%[1,2] (Figs 1A and B).

Gastric restriction is performed laparoscopically[3-7] by suturing the infolded greater curvature of the gastric wall (Figs 2A and B). Conventional bariatric surgeries, such as 'gastric band', 'sleeve gastrectomy', 'vertical banding gastroplasty' and 'gastric bypass' are associated with severe complications and a high rate of failure or weight regain.[8-18] Published short-term and midterm data on gastric plication



Figs 1A and B: (A) Gastric capacity reduction by folding the gastric greater curvature inward and (B) gastric capacity evaluation in a normal and obese person[1] before and after LGCP as measured by peroperative gastric filling

show that it is effective on excess weight loss (EWL) and is associated with a low rate of complications.[4,5,19-22]

This case series highlights technical steps, results and complication management of this procedure.

MATERIALS AND METHODS

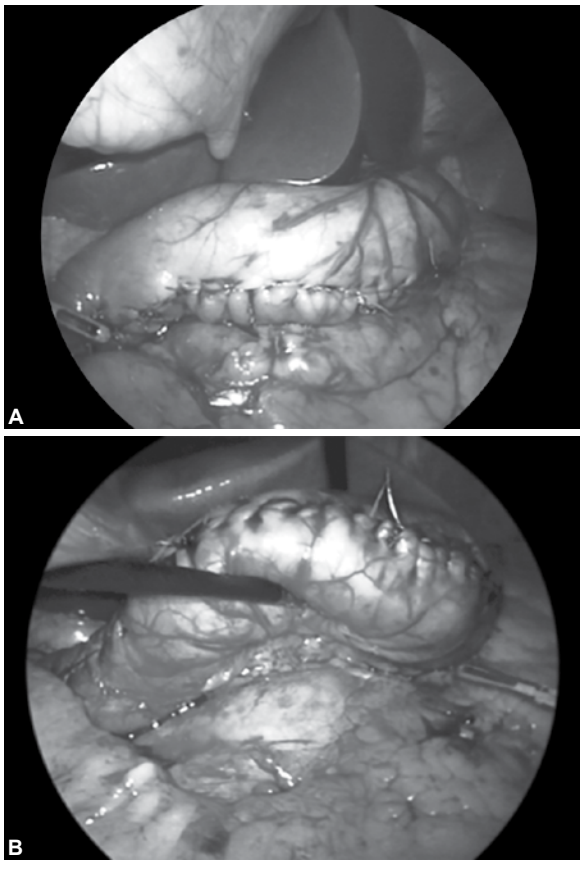
Study patients and endpoints: The present case-series study received the approval of the local ethics committee and was conducted using the National Institute of Health (NIH) inclusion criteria for bariatric surgery,[15,23,24] the United States Food and Drug Administration (FDA) approval of Adjustable Gastric Band (AGB) and the ASMBS position regarding bariatric surgery in class 1 obesity (BMI 30-35 kg/m^2).[24]

A total of 482 patients underwent laparoscopic greater curvature plication (LGCP) from December 13, 2010 to February 4, 2013. Thirty-three cases were excluded for previous bariatric surgery. A total of 449 patients responded to inclusion criteria and are included in the study. Results and complications were recorded till the end of the second year.

Surgical Techniques

Patient Installation

Patients were placed under general anesthesia in an anti-Trendelenburg position at a 30 to 45º French position.



Figs 2A and B: (A) Anterior and (B) posterior laparoscopic views of gastric plication

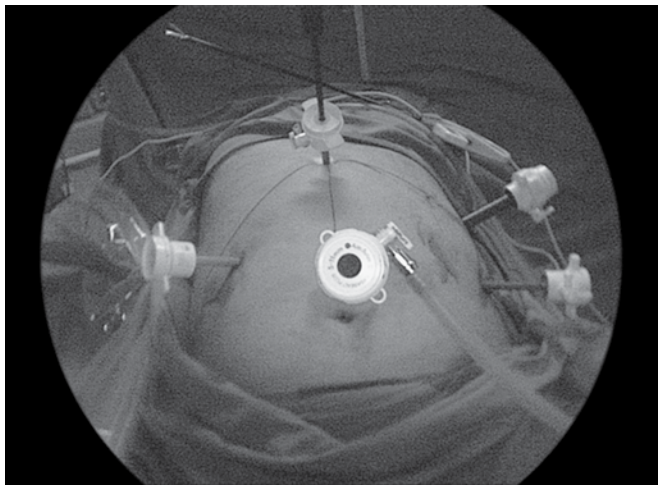


Fig. 3: Trocars placement

Trocar Placement (Fig. 3)

A five-trocar port technique was used for all patients except those with a small left liver for whom a three-trocar technique was adopted.

Dissections (Figs 4A to G)

The greater curvature is completely liberated from gastroepiploic and splenic attachments from the gastroesophageal (GE) junction to 3 cm before the pylorus. The posterior gastric wall was held up and the body of the stomach was freed completely from the gastropancreatic attachment. The posterior fundus was completely liberated from the left crus and the hiatus was inspected to rule out a hiatal hernia. Reparation of the hiatal hernia was performed at the same time when found in order to decrease the restricted gastric volume.

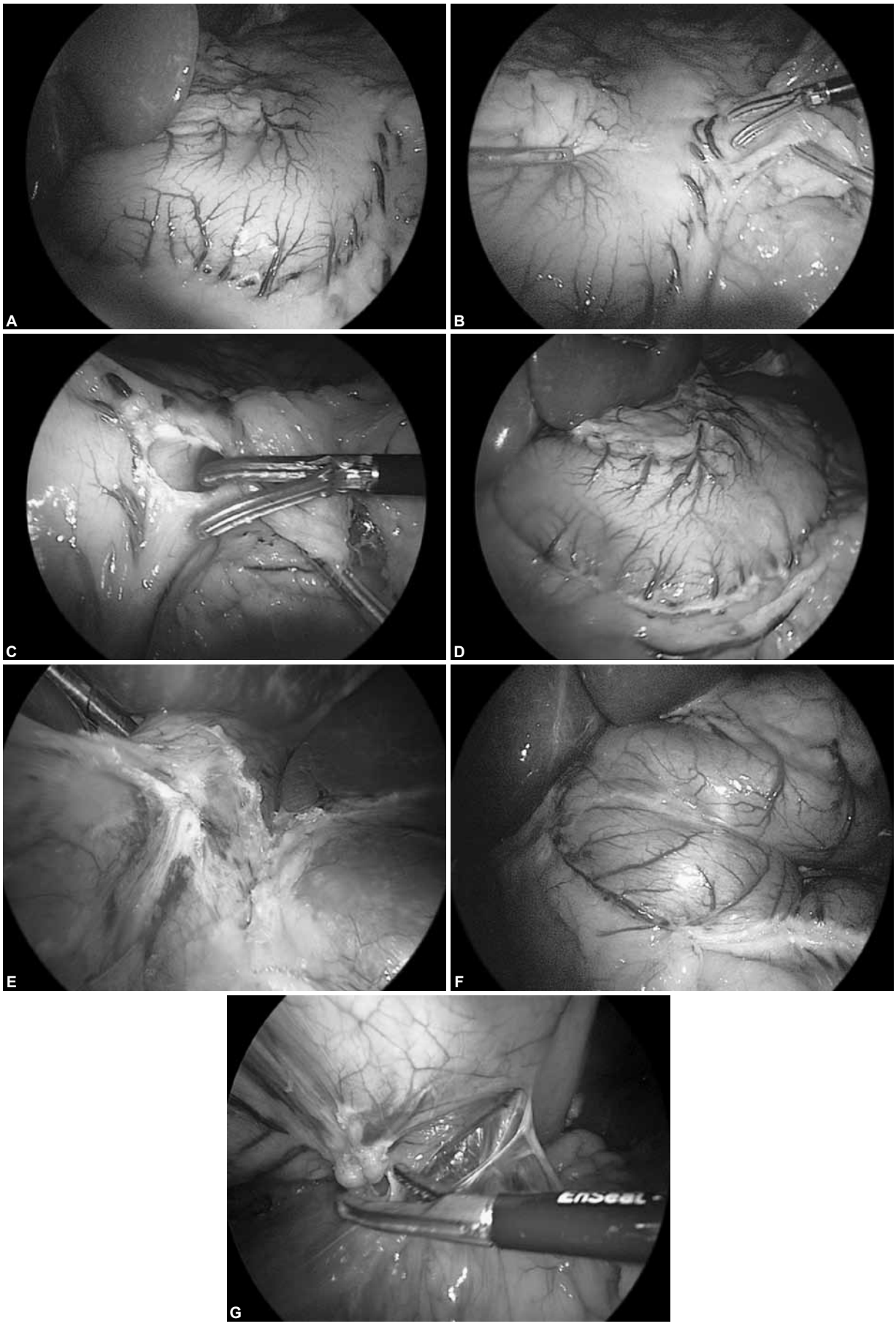
Calibration and Plication (Figs 5A to D)

A complete visualization of the whole stomach, anteriorly and posteriorly, is the key of a good gastric calibration.

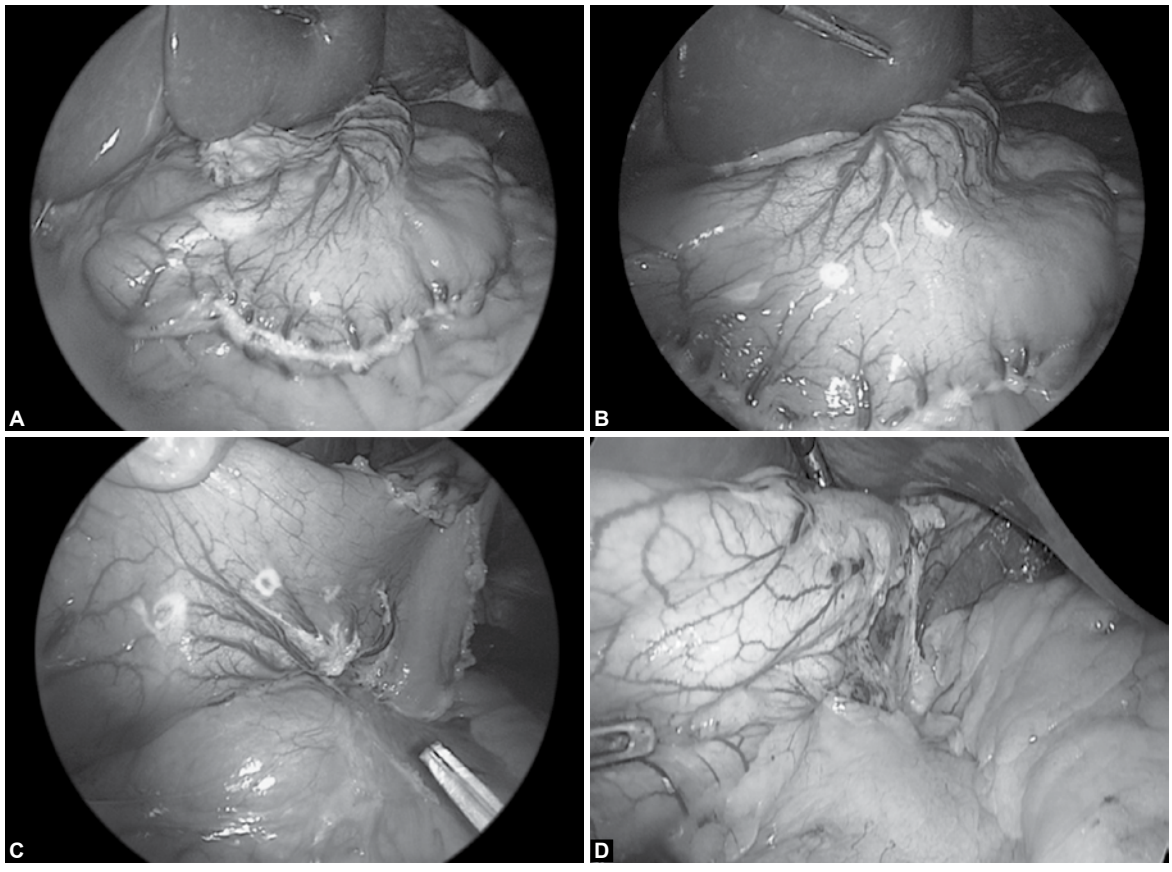
Gastric plication was created by the invagination of the greater curvature over a 36 French calibrating tube. Anterior and posterior marks on the gastric wall were made by methylene blue or bipolar coagulation. These marks help in avoiding the narrowing of the plicated stomach or the widening of the residual gastric space.

Critical Points

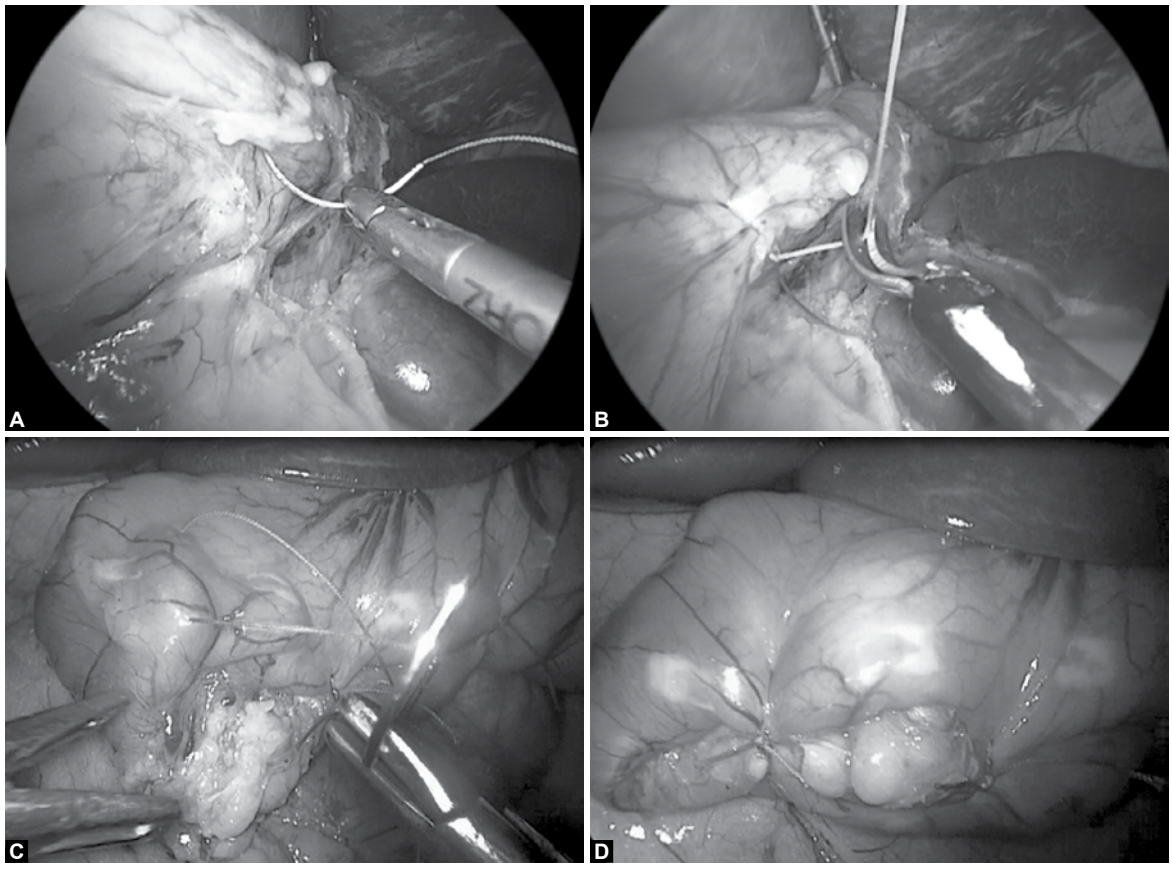
1. The first point of the plication (Figs 6A and B) is started by a cardio plication in case of cardial enlargement with GE reflux. If there is no preexisting GE reflux, the plication is started 1 cm from the GE junction to avoid dysphagia. In case of hiatal hernia with or without GE reflux, the gastric hernia is treated by left and right crus closure after intra-abdominal reintegration. Then, the gastric plication starts 1 cm from the GE junction.



Figs 4A to G: (A) Branches of the crow feet, (B) the beginning of the gastric dissection, (C) entry to the greater sac at the level of the horizontal branch of the crow feet, (D) complete greater curvature dissection (freed from gastroepiploic/gastrosplenic vessels), (E) left crus dissection, (F) dissection stopped 3 cm before the pylorus and (G) posterior gastric attach liberation



Figs 5A to D: (A) French tube calibration, (B) bipolar anterior gastric wall marks, (C) bipolar posterior gastric marks and (D) invagination of the greater curvature

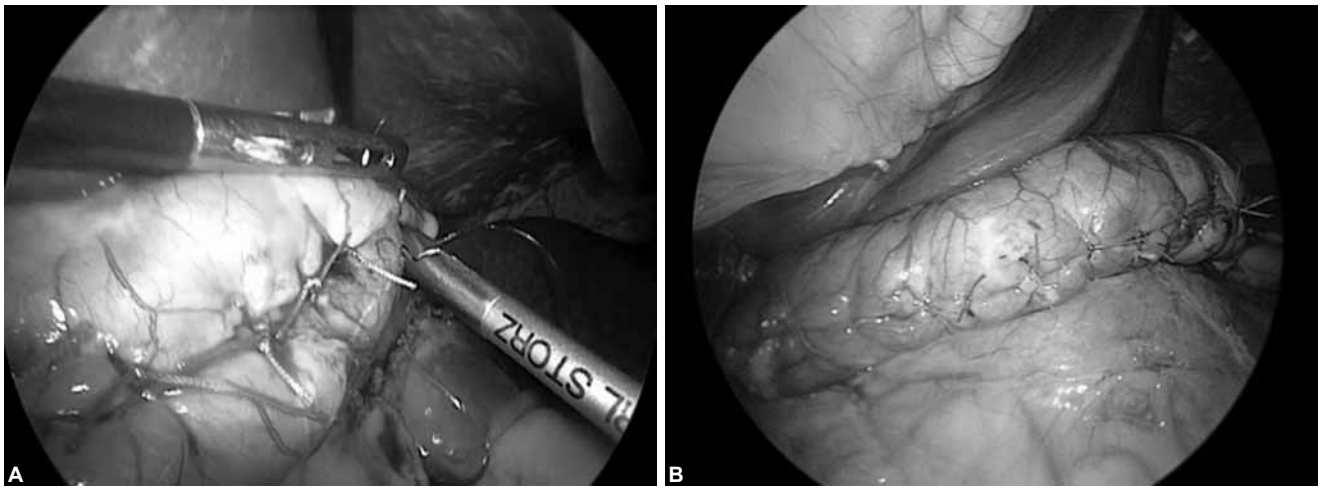


Figs 6A to D: (A) First point: starts 1 cm from the gastroesophageal junction, (B) final view of the first point, (C) the last point: starts 3 cm before the pylorus and (D) final view of the last point

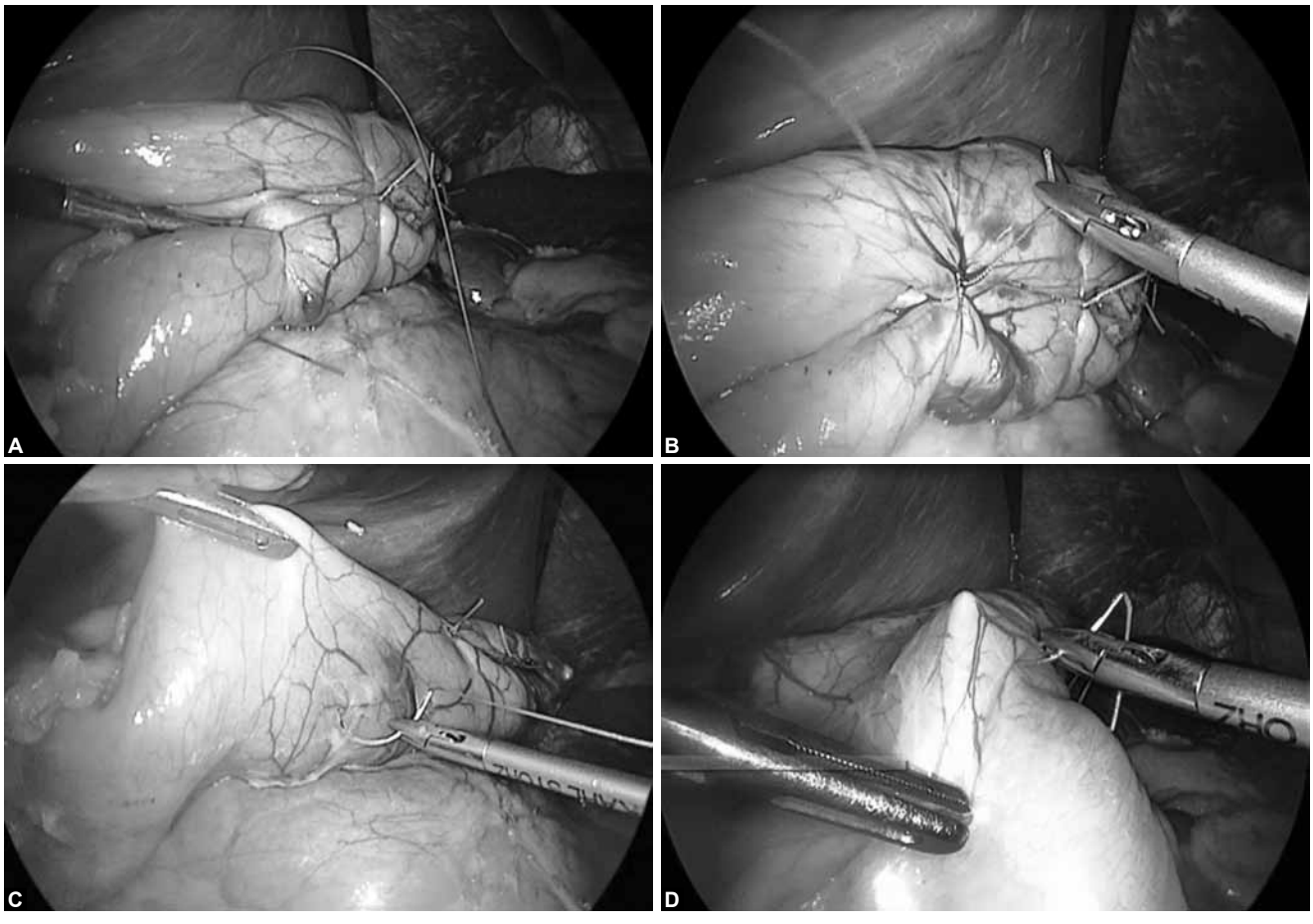
2. The last point of the plication (Figs 6C and D) is stopped 3 cm before the pylorus. This distance prevents gastric obstruction by fold invagination into the pylorus. The angulus points are ath risk of obstruction to because of gastric wall thickness at this level.
3. The first row of stitches (Figs 7A and B) is made with separated nonabsorbable stitches which are 1 cm apart. This way leads to less edema, less venous stasis, and less hematoma compared to continuous suturing; thus, the stomach is better calibrated. The final restricted volume is reached by the end of the first row of separated stitches before edema and venous stasis installation.

Moreover, symmetry of the plicated stomach is better obtained by making separated stitches. Asymmetry will lead to redistribution of intragastric pressure which can lead to partial anterior, posterior, or total gastric expansion.

The way of performing the stitches was also modified (Figs 8A to D). Stitching starts on the posterior gastric



Figs 7A and B: (A) Upper part of the first row, (B) lower part of the first row



Figs 8A to D: (A) The stitching starts at the posterior gastric marks, (B) the stitching ends at the anterior gastric marks, (C) anterior and posterior wall are taken several times symmetrically and (D) final view

marks. Then, the mid-distance from the greater curvature on the posterior gastric wall is taken. The greater curvature is also charged. Subsequently, the anterior gastric wall is symmetrically loaded and sutured to the posterior bites. Finally, the knot is made. This method of stitching will not leave a dead gastrogastric space in which fluid and seroma can accumulate leading to complete gastric compression and obstruction (so-called compartment syndrome).

4. The second row of stitches (Figs 9A to C) consists of continuous nonabsorbable stitches 3 to 5 mm apart. It starts from the HIS angle and stops 3 cm from the pylorus.

Leak and patent lumen tests were performed in all cases with 50 to 60 ml of diluted methylene blue. No drain is placed at the end of the operation.

Postoperative Treatment and Follow-up

At postoperative day 1, patients were given gastrografin meal (Fig. 10). If no obstruction or leak was noticed, the patients were discharged from the hospital at day 2. The patient was discharged from hospital with a prescription of proton pump inhibitor (PPI) twice a day for 6 months to decrease gastric acidity, esogastric reflux and to prevent suture rupture by acid erosion which can lead to early gastric expansion.

STATISTICAL ANALYSIS

All statistical analysis was performed with the use of SPSS software, version 17.0. A descriptive approach is used for all variables. The main variable is the percentage of EWL at different periods after surgery (1, 3, 6, 12, 18 and 24 months). Statistical analysis is done by using different statistical tests for categorical and continuous variables (chi-square test, student test…) in the overall group and in different subgroups by BMI, and types of sutures. The p-values were two-sided, with an α value of 0.05 considered as statistically significant.

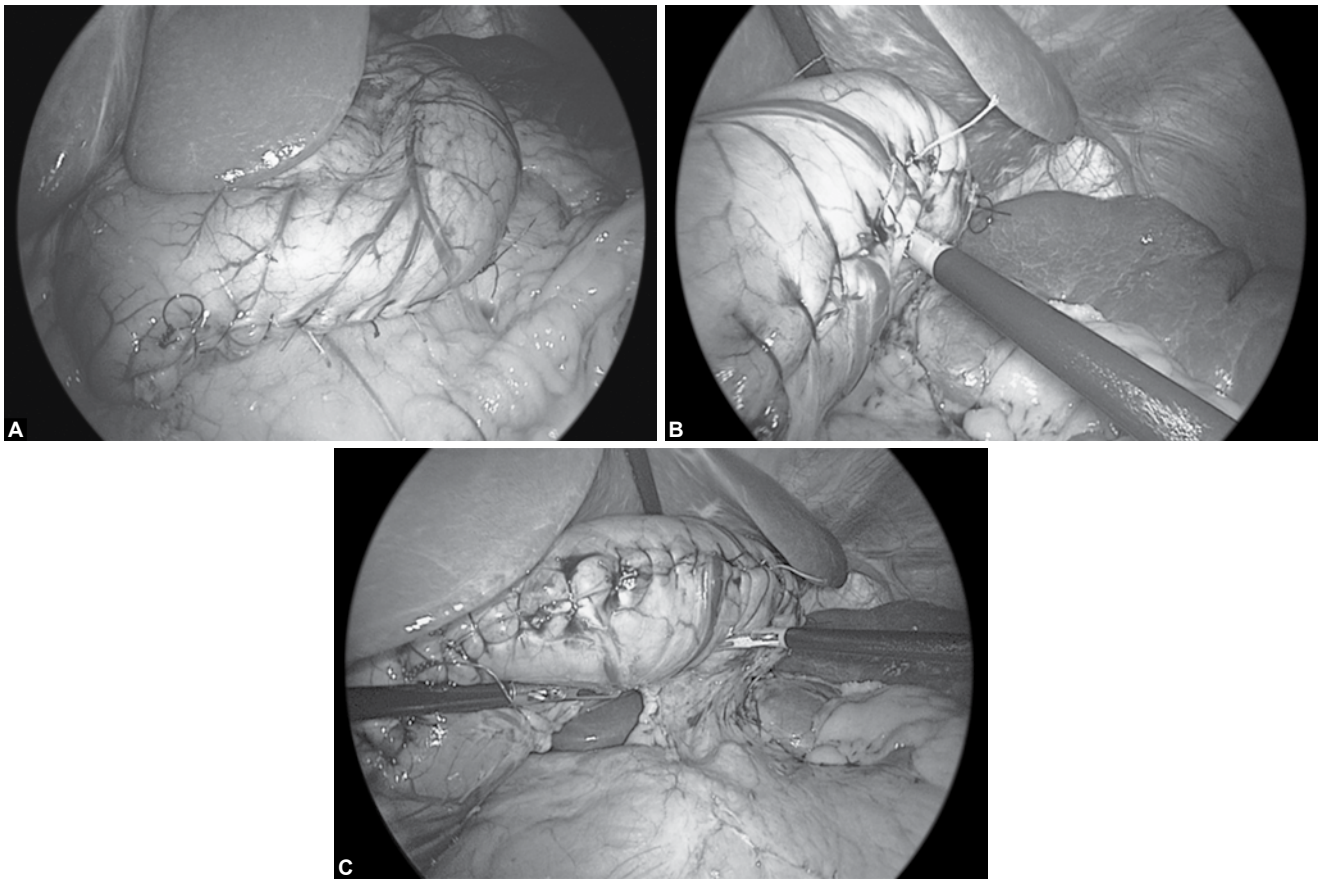
RESULTS

General Characteristics

Surgery Characteristics

Out of the 449 patients undergoing LGCP and over a period of 26 months, 395 (88.0%) were followed over a period of 1 month, 357 (79.5%) over a period of 3 months, 318 (70.8%) over a period of 6 months, 243 (54.1%) over a period of 12 months, 116 (25.8%) over a period of 18 months, and 21 (4.7%) over a period of 24 months.

- Surgery was done in 448 patients by laparoscopy, and in 1 patient by open surgery.
- Mean operative time was 65 minutes.



Figs 9A to C: (A) Anterior lower gastric view, (B) upper gastric view—plicated fundus and (C) posterior gastric view

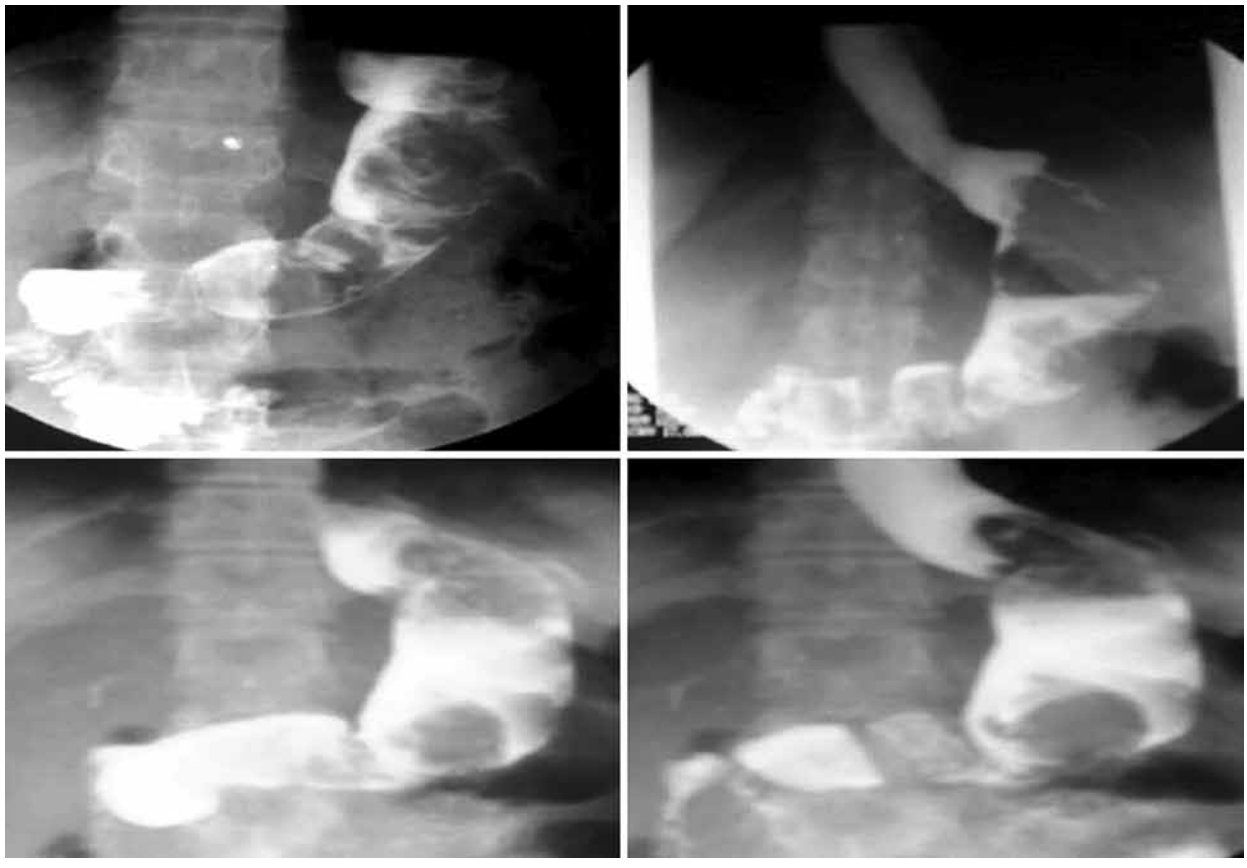


Fig. 10: Postoperative gastrografin meal X-ray (normal gastrografin meal at day 1)

- Mean hospital stay was 36 hours. A total of 428 patients (95.3%) left the hospital after 24 hours stay and 21 patients (4.7%) were kept more than 1 day.

Patients' Characteristics

Over the 449 patients included:

- A total of 147 patients were men (32.7%) and 302 patients were women (67.3%).
- The mean age of all the patients was 35.99 ± 10.85 years.
- The mean BMI was equal to 39.93 ± 6.15 kg/m^2 with a mean body weight of 112.9 ± 23.4 kg.

Excess Weight Loss and BMI

All Patients (n = 449)

A significant EWL is noted until 12 months postsurgery, with a peak of EWL during the first 6 months ($p < 0.001$) (Table 1). However, despite a slight loss of excess weight after the 12 months, this loss seems to be nonsignificant ($p > 0.05$), and a plateau phase seems to be reached at one year postsurgery.

Patients with BMI between 30 and 45 (n = 368)

In a subgroup analysis of patients with a BMI between 30 and 45 (Table 2), similar results are noted as in the overall group. In fact, a significant EWL is also noted until 12 months after the surgery, with a peak of EWL during the first 6 months ($p < 0.001$). However, the slight increase also noted after the 12 months, is nonsignificant ($p > 0.05$), and a plateau phase is reached at 1 year postsurgery, like in the overall group.

Patients with BMI >45 (n = 80)

In another subgroup analysis of patients with a BMI >45 (Table 3), similar results are noted as in the overall group and in the subgroup of BMI between 30 and 45, despite lesser degrees of loss of the excess weight in this subgroup. In fact, a peak of significant EWL is noted until 12 months after the surgery ($p < 0.001$). However, despite a relative gain of weight after the 12 months, this gain seems to be nonsignificant ($p > 0.05$), and the plateau phase seems also to be reached at 1 year postsurgery.

Comparison between Subgroups of BMI

By a comparison between the subgroups of BMI (Graph 1), a significant difference is noted in EWL between the two subgroups (BMI between 30 and 45 and BMI >45) at the different periods. In fact, a more important percentage of EWL is seen in the subgroup of BMI between 30 and 45, and a lower percentage is seen in the subgroup of BMI >45.

Excess Weight Loss and Types of Sutures

To refine the results, the first 80 cases were considered as the learning curve and the study was divided into two

Table 1: Follow-up on % EWL over 1, 3, 6, 12, 18 and 24 months

Time (months)	*Number of patients (N)*	*Minimum %EWL*	*Maximum %EWL*	*Average % EWL ± standard deviation*	*p-value*
1	395	12.05	77.78	30.19 ± 10.6	<0.001*
3	357	19.48	121.43	47.07 ± 15.0	<0.001*
6	318	19.48	140.00	63.05 ± 20.0	0.003*
12	243	20.45	142.86	68.15 ± 19.4	0.84
18	116	20.45	142.86	68.62 ± 22.1	0.90
24	21	39.06	104.65	69.29 ± 20.5	

*Statistically significant

Table 2: Follow-up on % EWL over 1, 3, 6, 12, 18 and 24 months in patients with BMI between 30 and 45

Time (months)	*Number of patients (N)*	*Minimum % EWL*	*Maximum % EWL*	*Average % EWL ± standard deviation*	*p-value*
1	327	14.29	77.78	31.98 ± 10.6	
3	295	22.22	121.43	49.57 ± 14.9	<0.001*
6	261	20.45	140.00	66.17 ± 20.2	<0.001*
12	194	20.45	142.86	70.82 ± 19.9	0.02*
18	93	20.45	142.86	72.12 ± 22.9	0.63
24	17	39.06	104.65	73.90 ± 20.0	0.76

*Statistically significant

Table 3: Follow-up on % EWL over 1, 3, 6, 12, 18 and 24 months in patients with BMI >45

Time (months)	*Number of patients (N)*	*Minimum % EWL*	*Maximum % EWL*	*Average % EWL ± standard deviation*	*p-value*
1	68	12.05	36.29	21.56 ± 5.1	
3	62	19.48	57.14	35.15 ± 8.1	<0.001*
6	57	19.48	75.00	48.79 ± 10.8	<0.001*
12	49	35.82	90.91	57.47 ± 12.7	<0.001*
18	23	38.10	76.32	54.47 ± 10.3	0.33
24	4	44.05	54.05	49.69 ± 4.4	0.37

*Statistically significant

subgroups. The first subgroup includes 183 patients from May 15, 2011 till February 27, 2012, with a follow-up of 18 months. The first and second row of the plication were performed with continuous suturing using nonabsorbable stitches. The second subgroup consists of 186 patients from February 28, 2012 till February 4, 2013, with a follow-up of 12 months. The first row was made with separated suturing stitches over a 36 French calibration tube with anterior and posterior marks. The second row was performed with continuous suturing.

Analysis by Type of Sutures

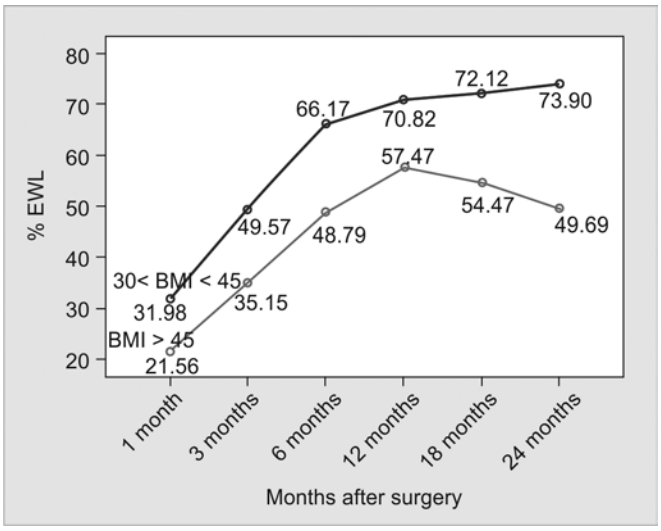
In the continuous suturing subgroup (Table 4), similar results were noted as in the overall group. A significant EWL is noted until 12 months after the surgery, with a peak of EWL during the first 6 months after surgery ($p < 0.001$). However, the nonsignificant changes (66.42%) noted at 18 months ($p = 0.92$) are mostly due to a plateau phase reached by 1 year postsurgery.

Moreover, in the separated suturing subgroup (Table 5), similar results to that in the overall group and the continuous suturing subgroup were noted, with obviously higher degrees of EWL in this subgroup. However, a strong trend to a significant increase to 80.77% is noted at 12 months ($p = 0.07$); a statistical significance is mostly not reached because of the relative small number of patients followed up to this period (only 20 patients).

Comparison between the Two Types of Sutures

By a comparison between the subgroups by the type of sutures, a significant difference is noted in EWL between the two subgroups (continuous and separated suturing) at the different periods, with higher degrees of EWL in the separated suturing subgroup. In fact, a lower percentage of EWL is seen in the subgroup of continuous suturing, and a higher percentage in the subgroup of separated suturing (Graph 2). However, no comparison is done at 18 months because, up to this date, there are no patients in the separated suturing subgroup who reached this period after surgery.

By a comparison between the subgroups of type of sutures, and only including the patients with a BMI >45, a significant difference in EWL is noted between the two subgroups (continuous and separated suturing) at the



Graph 1: Clinical data summary by 30 < BMI < 45 and BMI > 45: EWL% is 31.98% *vs* 21.56% at 1 month ($p < 0.001$); 49.57% *vs* 35.15% at 3 months ($p < 0.001$); 66.17% *vs* 48.79% at 6 months ($p < 0.001$) and 70.82% *vs* 57.47% at 12 months ($p < 0.001$). However, after 12 months, a significant difference is noted between the subgroups, because of a slight trend to an additional increase in %EWL in the subgroup of BMI between 30 and 45, and a slight decrease in %EWL in the subgroup of BMI > 45 ($p < 0.001$)

different periods. This result is similar to that seen in the overall group independent of the BMI, with higher degrees of EWL in the separated sutures subgroup. However, no comparison is done at 18 months because, up to this date, no patient in the separated suturing subgroup has reached this period (Graph 3).

Complications

Major Surgical Complications

a. Peroperative massive bleeding due to mesenteric trocar lesion (0.2%):
   - Treated by laparotomy for hemostasis and open LGCP was achieved.

b. Gastric obstruction (0.4%):
   - Due to gastric fold invagination into the lower esophagus (0.2%)
     – Treated by laparoscopic deplication and a looser gastric plication was performed.
   - Due to gastric fold invagination into the pylorus (0.2%)
     – Treated by deplication.

c. Gastrogastric herniation (0.6%):
   - Leading to esogastric leak and peritonitis (0.2%)
     – Treated by laparoscopic deplication, gastric suture and looser plication.
   - Leading to gastric hernia necrosis and peritonitis (0.2%).
     – Treated by gastric resection of necrotic herniation, and deplication.
   - Leading to late gastric obstruction at 4 months (0.2%).
     – Deplication

d. Gastric leak over a stitch (0.2%)
   - Deplication and gastric suture

e. Subphrenic abscess (0.2%)
   - CT-guided percutaneous drain

f. Gastric bleeding by gastric ulcers at 2 months (0.2%).
   - Blood transfusion, endoscopic sclerosis with PPI

g. Portomesenteric thrombosis (0.4%)
   - One case treated by thrombolysis and heparinotherapy
   - One case treated by intestinal resection and heparinotherapy

h. Gastric line suture rupture and re-expansion (1.78%).
   - Seven cases treated by replication (delayed reintervention).
   - One case treated by sleeve gastrectomy (delayed reintervention).

In total:
- Six cases (1.38%): acute early reintervention.

Table 4: Subgroup 1: Gastric plication with continuous suturing at the first/second rows (n = 183)

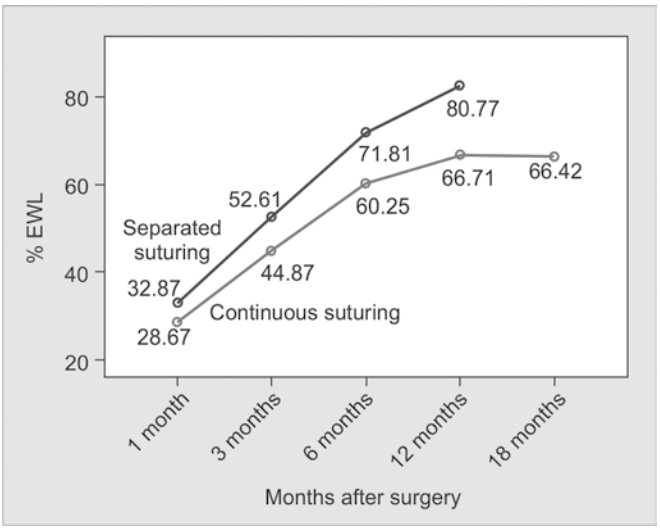
Time (months)	*Number of patients (N)*	*Average % EWL ± standard deviation*	*p-value*
1	173	28.67 ± 9.8	
3	161	44.78 ± 13.5	< 0.001*
6	158	60.25 ± 18.6	< 0.001*
12	146	66.71 ± 17.5	0.002*
18	42	66.42 ± 18.2	0.92

*Statistically significant

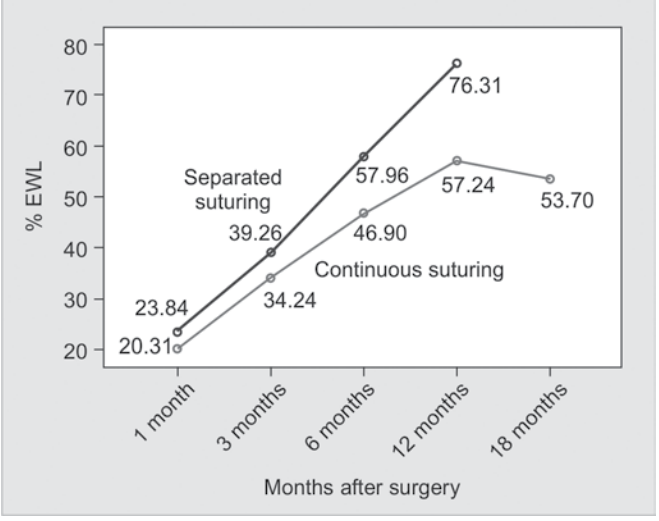
Table 5: Subgroup 2: Gastric plication with separated stitches in the first row with anterior and posterior marks over a 36 Fr tube, and the second row with continuous suturing (n = 186)

Time (months)	*Number of patients (N)*	*Average % EWL ± standard deviation*	*p-value*
1	142	32.87 ± 11.6	
3	121	52.61 ± 14.2	< 0.001*
6	83	71.81 ± 19.7	< 0.001*
12	20	80.77 ± 20.3	0.07

*Statistically significant



Graph 2: Clinical data summary by type of sutures: continuous *vs* separated suturing: %EWL is 28.67% *vs* 32.87% at 1 month (p = 0.001); 44.78% *vs* 52.61% at 3 months (p < 0.001); 60.25% *vs* 71.81% at 6 months (p < 0.001), and 66.71% *vs* 80.77% at 12 months (p = 0.001)



Graph 3: Excess weight loss by type of sutures (continuous *vs* separated sutures) in patients with BMI > 45: %EWL is 20.31% *vs* 23.84% at 1 month (p = 0.03); 34.24% *vs* 39.26% at 3 months (p = 0.04); 46.90% *vs* 57.96% at 6 months (p = 0.002) and 57.24% *vs* 76.31% at 12 months (p = 0.005)

- Two cases (0.46%): percutaneous treatment.
- Ten cases (2.3%): reintervention for gastric re-expansion or late suture line rupture.

Major Medical Complications

- Transitory gastric obstruction by gastric fold edema (3.5%)
  - Treated by IV fluid and PPI.
  - Spontaneous resolution happened in 3 to 5 days
- Right lower lobe pneumonia (0.2%)
  - Antibiotherapy
- Lower limb thrombophlebitis (0.2%)
  - Heparinotherapy

Minor Complications

- Nausea (13.99%)
- Vomiting (12.86%)
- Minor hematemesis (8.53%)
- Hiccup (4.45%)
- Sialorrhea (8.53%)
- Melena (5.25%)
- Diarrhea (3.46%)
- Gastric spasm (3.24%)

DISCUSSION

General overview of the results: In the overall group, a significant increase in the percentage of EWL was noted, and consequently a decrease in body weight, until 12 months after surgery, with a peak of EWL during the first 6 months (p < 0.001). A 'plateau phase' is reached by the first year after the surgery with a loss of around 70% of the excess weight, and a stability in the body weight is noted thereafter in the second year (study follow-up period). These results are similar Talebpour, Brethauer and Ramos's results.[11,13,16]

However, in subgroup-analysis depending on BMI, and type of suturing, the following observations were found:

- The percentage of EWL is more important in patients with BMI between 30 and 45, than those with a BMI > 45.
- Higher percentages of EWL are noted with the separated suturing, relative to the continuous suturing, at different periods of follow-up. A 'plateau phase' is reached at around 1 year after surgery with continuous suturing. However, no data are available in the separated suturing subgroup about whether the plateau phase is also reached after 1 year or higher percentages of EWL are observed thereafter, because no patient in this subgroup has reached a period of follow-up more than 1 year. Moreover, and in a subgroup analysis of patients with BMI > 45, the separated suturing also seems to be superior to the continuous suturing, with higher percentages of EWL observed with the first technique.

Major surgical and medical complications are relatively rare. Globally, the rate of gastric leak is 0.66%. In the continuous suturing subgroup, the rate of leak is 1.09%, whereas in the separated suturing subgroup, the rate of leak is 0.535%. The rate of acute gastrogastric herniation leading to re-intervention is 1.6%, while this complication is inexistent in the subgroup who underwent separated suturing. This can be explained by a better symmetrical folding and adequate gastric calibration that separated suturing can provide. Tightness is the main cause of gastric obstruction, gastrogastric herniation, and gastric leak. Asymmetry is the main cause of total or partial gastric re-expansion, notably at the level of the

gastric fundus. Management of these surgical complications is mainly treated by deplication, and gastric leak suturing. Early reversibility is highly appreciated in case of early complications (leak, obstruction and psychological intolerance) up to 6 months. Late reversibility is rarely needed because gastric re-expansion allows the performance of all kinds of bariatric surgeries. Replication is made in case of suture line rupture, gastrogastric herniation or gastric re-expansion. Minor complications consist mostly of nausea and vomiting related to gastric fold edema and compartment syndrome which can be dramatically decreased by draining the gastrogastric space. This complication disappears spontaneously within 2 to 3 days postoperatively.

CONCLUSION

Laparoscopic greater curvature plication is highly associated with a reduction in body weight, with increasing percentages of EWL during the first year after surgery reaching a plateau phase thereafter. Higher percentages are observed in specific population, particularly patients with BMI between 30 and 45. The new modified technique consisting of separated suturing of the first row is highly superior to the old one with continuous suturing of the first and second row; however, no data exists after 1 year of follow-up with this new technique. Major surgical and medical complications are rare.

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