Scintigraphic evaluation of gastric emptying after greater curvature plication in comparison with sleeve gastrectomy

Original Article

Tarek Osama Hegazy[1], Ahmed Kandeel[2], Mohamed El Shawadfy[1], Khalid Kassem[3], Mohamed Hassan[1]

[1]Department of General Surgery, Faculty of Medicine, Cairo University, Cairo, Egypt
[2]Department of Nuclear Medicine, Faculty of Medicine, Cairo University, Cairo, Egypt
[3]Department of Internal Medicine, Faculty of Medicine, Cairo University, Cairo, Egypt

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ABSTRACT

Introduction: Laparoscopic gastric plication (LGP) is a relatively new restrictive bariatric procedure that emerged to avoid the problems and to reduce the cost of laparoscopic sleeve gastrectomy. In this study we present the initial short-term outcome of LGP and its effect on gastric emptying and compare it with the results of laparoscopic sleeve gastrectomy (LSG).

Methods: From May 2016 to April 2017, a total of 50 patients were allocated to undergo either LGP (n = 25) or LSG (n = 25). Data on the operative time, complications, hospital stay, overall cost of LSG and LGCP, body mass index loss (BMIL), post-operative gastric emptying (the first study to asses gastric emptying after LGP), percentage of excess weight loss (%EWL), and improvement of comorbidities were collected during the follow-up examinations.

Results: All procedures were completed laparoscopically. The mean operative time was significantly higher for the LGP group. The mean hospital stay, cost and %EWL were significantly higher in the LSG group. The mean gastric emptying t1/2 was 40 ± 13 minutes for LGP group and 28.3 ± 8.31 minutes for LSG group (P = 0.001).

Conclusion: There is significant acceleration of gastric emptying after LSG more than after LGP with significant effect on weight loss.

Key words: Obesity; Gastric plication; Sleeve gastrectomy; Gastric emptying; Scintigraphy

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Corresponding author: Dr. Tarek Osama Hegazy, Department of General Surgery, Faculty of Medicine, Cairo University, Cairo, Egypt. E-mail: ticegy@yahoo.com

INTRODUCTION

Approximately 1.7 billion people worldwide suffer from obesity related serious health problems. Obesity has a mortality rate of approximately 0.1% in developed countries and leads to major healthcare cost [1].

The laparoscopic gastric plication (LGP) is a safe procedure for obesity treatment, with stable and very good immediate results. It has the fewest postoperative complications in bariatric surgery. Surgery and hospitalization costs are the lowest in bariatric surgery and there is no need of any special devices (endostaplers, gastric banding, surgical mesh and so on). Therefore, this procedure is a feasible technique for every hospital equipped for laparoscopic surgery [2].

The potential advantages of LGP over other restrictive methods are as follows. The patient is independent postoperatively with easy follow up which means the patient is free from any obligatory post-operative procedures e.g. balloon size regulation in gastric banding. No foreign body reaction is the next advantage of LGP as only two or three threads are used with no use of mesh or band and less cost due to no need for stapler or band are very important factors for patients. Also, less complication such as leakage, infection or erosion should be noted since this method is the most conservative procedure among other bariatric surgeries with no resection or anastomosis [3].

If needed, this method is reversible just by cutting the suture lines and releasing the adhesions. It can be followed by adding another method as a second stage operation in cases with insufficient weight loss. This second stage could be sleeve gastrectomy or even re-plication, which saves the bypass procedure for later [4].

Radionuclide studies on gastric emptying and motility are the most common physiological studies available for studying gastric motor function, the study is non-invasive, uses a physiologic meal and is quantitative [5].

METHODS

This was a non-randomized controlled prospective study comparing laparoscopic greater curve plication to laparoscopic sleeve gastrectomy. The allocation of patients to either group depended on the choice of the patient after discussion with the surgeon. The study had been conducted in Cairo University hospitals in the period between May 2016 and April 2017 after approval from the ethics committee of faculty of medicine Cairo University and obtaining informed consent from all patients including approval of protocol of treatment.

Fifty morbidly obese patients were included and divided into 2 groups:

Group (1):25 patients underwent LGP.

Group (2):25 patients underwent LSG.

Informed written consent was obtained with explanation of the possible complications that could occur in the peri-operative period.

Study population

The patients were considered appropriate candidates for the present study if they were well informed, motivated obese patient with BMI 35:45 Kg/m^2. Any patient with BMI >45 Kg/ m2, severe medical diseases making anesthesia risky. Inability or unwilling to change life style after surgery, drug or alcohol addiction. Psychologically unstable and if had a redo surgery, were all excluded. All patients were subjected to full clinical preoperative evaluation as well as investigations. Clinical evaluation aimed at assessment of degree of obesity, preoperative evaluation and detection of different complications of morbid obesity. During the operation, the operative time was noted, any operative events, complications or conversions documented.

Laboratory investigations

Hormonal assay to exclude endocrinal causes of obesity, pulmonary evaluation, cardiac assessment, abdominal ultrasound, and endoscopic evaluation of stomach if there were symptoms of GERD were done.

Surgical technique

Laparoscopic sleeve gastrectomy: Gastric transection started 3 - 5 cm proximal to the pylorus over a 36 fr. bougie.

Laparoscopic greater curvature plication: After release of the greater curvature, plication started 1-2cm from the angle of Hiss and continued to 5-7 cm from the pylorus over a 36 Fr. Bougie using seromuscular 2- 0 non-absorbable stiches in the form two rows of running sutures. The distance between each stitch and lesser curvature was 2cm anteriorly as well as posteriorly. The distance between each stitch and the following stitch was 2cm as well.

Post-operative diet regimen

Patients were encouraged to move out of bed few hours after surgery, Anticoagulation DVT prophylaxis (enoxaparin 40U/day S.C) was given during hospital stay. IV PPI was given to all patients on day zero post-operatively and was continued orally after patients started oral feeding for at least 2 months. Patients started oral fluid intake on the 1:3 post-operative day, after which, a Gastrographin study was done. A post-

surgical diet progression from liquids to solids during 2 to 4 weeks focusing on meeting protein, fluid needs and additional daily micronutrient supplements intake was advised for all patients.

Follow-up and data collection

All patients were followed up for early post-operative complications (<30 days) like bleeding, leakage, superficial and deep infections. The primary study objective was to assess gastric emptying after 1 month. The other main primary outcome is to assess early post-operative complications and weight loss. The weight loss assessments included the percentage of excess Body weight loss (%EBWL). The weight was measured at the initial screening visit, 1, 3 months, and 6 months after surgery. The collected data from the designated patients were analyzed and compared with other variables. Data were recorded prospectively on a dedicated database (Microsoft Excel) and were retrieved for this study.

Scintigraphic assessment of gastric emptying

Patients were fasting for at least 8 hours before the study. At time of the study none of patients had diabetes or under medications known to affect gastric motility (such as metoclopramide, opiates or antispasmodic agents). Imaging was performed in a supine position on a dual-head gamma camera equipped with an all-purpose, low-energy, parallel-hole collimator covering an NaI (Tl) crystal of 3/8-inch thickness, set at 140keV, with a 20% window, zoom 1.0 using a matrix size of 64x64 for dynamic acquisition and 128x128 for static acquisition at different time intervals. Patients could sit between each measurement. Considering the early performance of gastric emptying study at 4-6 weeks after LSG/LGP and with respect to starting the stage of eating solid food, the small size of the pouch after surgery and the nauseating effect of fried or cooked egg, we practiced a modified technique for labeling a boiled egg with 99mTc-sulfur colloid (total activity of 1mCi), to be more tolerable by patients after LSG/LGP, instead of being cooked or fried as described in other studies.

This procedure was done as shown in Figure 1, using a syringe with a small gauge needle to pierce the shell of the raw egg carefully then inject the tracer inside the egg. The site of puncture was sealed by small piece of adhesive tape to prevent the fluid inside the egg to come out the shell during boiling. Labeled egg was then boiled for few minutes to become ready for eating.

One labeled egg was ingested in a bread sandwich (about 100 grams). A sequential static acquisition was started immediately after the patient completed the meal, obtaining 1 min frame at 0, 30, 60, 90 and 120 min.

Data processing

Visual assessment of the activity in the remaining gastric pouch to draw regions of interest (ROIs) including any visualized activity in the proximal and distal regions with care to adjust the ROI to avoid activity from adjacent small bowel in anterior and posterior views of the composite image. Calculation of a geometric mean (the square root of the product of counts in the anterior and posterior ROIs) obtained simultaneously during anterior and posterior views acquisition. Time activity curve obtained from the geometric mean of gastric counts displayed for all time points was constructed and gastric retention at 30, 60, 90 and 120-minute post meal ingestion were calculated as a percentage of the counts obtained at the first image (0 time, 100%). T1/2 emptying time for solid meal was computed by interpolation from the observed data.

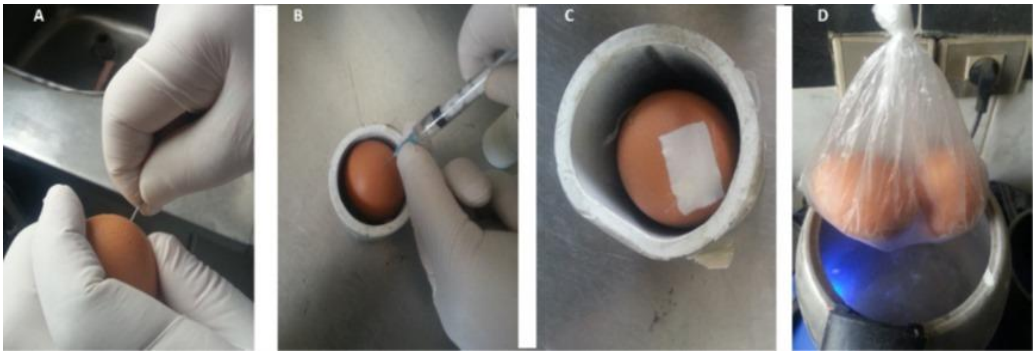

Fig 1. Steps of labelling a raw egg with 1 mCi of Tc-99m sulfur colloid to be ready for boiling. (A) Gentle piercing the shell of the egg with a needle (A). Injecting the radio tracer (B). Sealing the site of puncture with adhesive tape (C). Boiling the labeled eggs in water (D).

Table 1: Comparison between LGP and LSG according EBW loss % after 3 months and 6 months.

	EBW loss % after 3 months		EBW loss % after 6 months	
	LGP	LSG	LGP	LSG
Mean	31.2%	39.63%	46.32%	55.87%
N	25	25	25	25
Std. Deviation	10.9%	7.26%	6.56%	6.94%
Minimum	17 %	25%	37%	43.89%
Maximum	52.8 %	49%	58%	63%
Median	28%	40%	48.7%	56.45%
Mean±SD	31.2±10.9%	39.63±7.26%	46.32 ±6.56 %	55.87 ±6.94 %
P.value	0.003, Significant		< 0.001, Significant	

Statistics

Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 24. Data was summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the non-parametric Mann-Whitney test [6]. For comparing categorical data; Chi square test was performed. Exact test was used instead when the expected frequency is less than 5. Correlations between quantitative variables were done using Spearman correlation coefficient [6]. P-values less than 0.05 were considered as statistically significant.

RESULTS

The operative time was more in LGP group ranged from 120 – 210 minutes with mean 174 ± 23 minutes, while in LSG group ranged from 90 – 180 minutes with mean 126 ± 31 minutes (P value < 0.001).

The LGP patients were discharged after 3 – 17 days with mean hospital stay 5.9 ± 3.79 days which was significantly less than hospital stay in LSG which ranged from 2 – 5 days with mean hospital stay 2.84±.9 days (P value <0.001), except for one case which had fever and tachycardia denoting leak, managed conservative and discharged after 7 days.

All patients were done laparoscopically and completed with no conversion, no blood transfusion needed in all cases.

Regarding complications all cases of Group 1 complained of nausea and mild vomiting for 2:4 days, 3 cases for 1 week and 2 cases complained of continuous vomiting for 2 weeks, while in Group 2 there was 4 cases of wound infection and there was one case complicated with leakage at day 14 and managed by upper esophagogastroscopy and insertion of stent. Patient was discharged after 1 week and stent was removed after 5 weeks.

There was significant vomiting more in LGP cases ranged from 2 – 14 days with mean 3 days, while in LSG cases vomiting was only 1-2 days (P value < 0.001). There were only 2 cases re-admitted in LGP group due to severe vomiting which was improved by antiemetics and proton pump inhibitor.

From the economic point of view, the consumables cost in Group 1 varied from 3030-3063 Egyptian pounds (L. E) with a mean ±SD of 3049.2±12 L.E. while in Group 2 cost varied from 16,000 -19,800 L.E with a mean ±SD: 17,200±510 L.E. with P value <0.0001.

Table 1 shows comparison between LGP and LSG according EBW loss % after 3 months and 6 months. Mean EBW loss in LGP group at 3 months was 31.2 ±10.9 % which was less than mean EBW loss after LSG (39±7 %) with significant P value of 0.003.

And weight loss continued to 6 months to reach in LGP group to 46 ± 6% and more in LSG group (55 ± 6.6 %) with significant P value 0.001.

In Group (1) just 3 patients were associated with co-morbidity two of them were complaining of hypertension and was cured after the operation, the other case was DVT. While in Group (2) there was only one patient with hypertension.

Gastric emptying

The gastric emptying was accelerated in both groups with significant faster in LSG group. The mean T1/2 of gastric emptying after LGP was 42 ± 13 minutes while in LSG group was 28 ± 8 minutes (P value <0.001) (Table 2).

T½ gastric emptying after LGP was accelerated and ranged from 26 – 71 minutes with mean 40.3 minutes,

showing less normal gastric retention with mean gastric retention only 38 % after 60 minutes (Table 3, Figure 2).

Table 2: Half gastric emptying after LGCP and LSG for solid.

	Half gastric emptying	
	mean	SD
LGP	42.0	13.1
LSG	28.3	8.3
P value	< 0.001	< 0.001

Table 3: Gastric retention for solid after LGP and LSG.

	% Gastric retention			
	30 min	60 min	90 min	120 min
LGP	61	38.48	25	12
LSG	42.36	20.8	11	3.84
P value	<0.001	<0.001	<0.001	<0.001

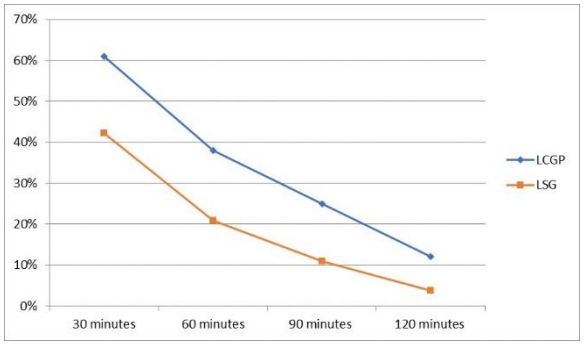

Fig 2. Percentage of gastric retention for solids post LSG and LGP.

These results showing more accelerated gastric emptying than normal obese patients where T½ of gastric emptying has a mean 74.9±7.1 minutes [5].

DISCUSSION

The field of bariatric surgery is continually evolving. Since the introduction of surgical procedures to induce weight loss, many different operations have been tried and abandoned owing to the poor long-term weight loss and/or metabolic or mechanical complications.

Mean post-operative hospital stay was more in LGP group with mean 5.9 ± 3.7 days compared to 2.8 ± .9 days in LSG group P value < 0.001. Comparing with previous studies where hospital stay was less in LGP with mean 3 days in Talepbour et al. series in 2012 [7].

Gastric plication is a procedure, which takes more than 2 hours to perform, which is a potential drawback to the surgeon himself that may cause shoulder and back pain. In the largest published series by Talebpour et al. (800 patients) the mean operative time was 72 minutes, which is about half the time of the operation in the current study. This may be because he has performed large number of cases, which improved his skills. In current study Operative time in LSG (126 ±31 minutes) was more than the operative time in previous studies [7].

Normally the patient can tolerate oral fluids after 2 days. Post-operative vomiting in LGP cases may be the result of tight sutures or fold oedema and usually resolves by conservative management (antiemetics and PPI). Post-operative vomiting was reported after gastric plication in 15 patients (1.4%) out of 1055 published cases in 10 studies, however, these studies didn't give a definition for prolonged vomiting, which casts a shadow on comparability of the study results. Prolonged vomiting in the published studies was explained by over plication or adhesions and most of the cases resolved after conservative management or gastroscopy.

In a study conducted by Talebpour over 800 patients, nausea and vomiting were seen in all cases. Epigastric pain was seen in 21.2% of cases for 48 hours and relieved rapidly by antacids [7].

Also, in a study on 42 patients, nausea, vomiting, and sialorrhea occurred in 20%, 16%, and 35% of patients, respectively. In all cases, these symptoms were resolved spontaneously in no more than 2 weeks. They attributed these events to the restriction induced by the invagination of the greater curvature and/or edema caused by venous stasis and stated that qualitative endoscopic findings suggest that the greater curvature fold gets smaller, that may be related to the resolution of the initial edema, although the radiological findings did not reveal significant dilation of the LGP at six months [8].

Most of these conditions could be managed conservatively allowing fold edema to resolve, however in cases of persistent vomiting which may denote obstruction operative removal of the outer raw of sutures and looser replication is indicated [9].

It is important for the patient to follow the post-operative diet regimen, during first 4 postoperative weeks no solid food should be taken and must be liquid (2 weeks), and semi-solid food (2 weeks) until the patient could be able to eat normal meal.

The current study revealed that serious complications after sleeve gastrectomy were significantly higher than after gastric plication and this could be explained by

the absence of a staple line in the stomach in gastric plication.

In the current study the mean Excess weight loss after LGP was more in the sleeve gastrectomy after 3 and 6 months, the difference was significant (P value 0.003, < 0.001) but acceptable in comparison with sleeve gastrectomy and other gastric plication studies. A recent meta-analysis done in 2013 included 11 studies between 2000 and 2012 showed that the excess weight loss 6 months after sleeve gastrectomy was 50.6% [10].

In sleeve gastrectomy patients the pattern of weight loss was accepted and progressive during the whole year, except for one case who lost weight during the 1st six months then stopped losing weight which we attribute to the patient's eating behavior (sweet eater).

Gastric emptying after 1 Month showed that mean gastric emptying is significantly higher after sleeve gastrectomy (t1/2 28.28 ±8 minutes) than after gastric plication (t1/2 41 ± 13.1 minutes) with P value <0.001) which indicate more physiological changes after sleeve gastrectomy which indicate that gastric plication more physiological operation than sleeve gastrectomy. Also, the initial gastric emptying at 1 month didn't seem to be correlated with excess weight loss at 3 or 6 months in both groups.

Similarly, to our results Melissas and colleagues showed in their study that gastric emptying half time for solids after sleeve gastrectomy was accelerated significantly, from 86.5 to 62.5 min to 60,8min after 6,12 months respectively, while percentage of gastric retention increased from 52% to 72%,74% after 6,12 months, respectively [11]. Although our indices showed faster emptying which is attributed to that gastric emptying is enhanced in the short-term period after surgery as we assessed emptying after only 1 month [5].

According to the authors after reviewing the text, this is the first study ever to assess gastric emptying using radionucleotide after gastric plication so no comparison to other work could be done.

CONCLUSION

There is significant acceleration of gastric emptying after LSG more than after LGP with significant effect on weight loss. The short-term outcomes of our study demonstrate that compared with LSG, LGP is inferior as a restrictive procedure for weight loss, despite its significantly smaller cost. Longer follow-up and prospective comparative trials are needed to confirm the long-term outcomes of this novel procedure and make definitive conclusions.

Yet some study limitations should be addressed, first is the non-randomization as plication is not a familiar process to patients, and plication was done only to those who approved and consented for the procedure**.** Also, the number of cases is another limitation, so more studies are needed to prove our conclusions. After searching the text, according to authors there was no previous study that studied gastric emptying after gastric plication.

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