Comparative Study between Laparoscopic Banded Sleeve Gastrectomy and Conventional Laparoscopic Sleeve Gastrectomy

Helmy M, MD, MRCS; ElAbbassy IH, MD, MRCS; Ebied HF, MD, MRCS
Department of General Surgery, Ain Shams University, Cairo, Egypt

Context: Laparoscopic sleeve gastrectomy (LSG) has become a very popular bariatric surgery because it does not require anastomosis or intestinal bypass. The gastric tube created in LSG may dilate with time and this might be a potential cause of failure. The hypothesis of the possible superiority of laparoscopic banded sleeve gastrectomy (LBSG) over the conventional one was evaluated in this study.

Patients and methods: This is a randomized prospective comparative study including 40 morbid obese patients who were equally divided into two groups. Group 1, were offered LSG, while group 2 were offered LBSG. The primary endpoint was the intra-operative assessment of the procedure, whilst the secondary endpoint was the assessment of post-operative sequelae after 3, 6 and 12 months.

Results: There was no significant statistical difference between performing LSG with and without using a band as regard intra-operative complications, percentage of excess weight loss (%EWL) and the post-operative one year follow-up. However, the mean operative time showed a significant statistical increase in those with LBSG due to application of mesh.

Conclusion: LBSG is a safe procedure, however, it is more time-consuming than the conventional LSG. Therefore, we recommend conducting other multi-centric studies on larger number of patients that would be followed-up for a longer period of time to determine the long-term weight loss after LBSG and to detect the incidence of any additional complications from this procedure.

Key words: Sleeve gastrectomy, band, laparoscopic, complications, vomiting.

Introduction

It has been proved that the gastric tube created in laparoscopic sleeve gastrectomy (LSG) may dilate with time and this might be a potential cause of failure.[1] This was suggested to be avoided by banded sleeve gastrectomy, which is a hybrid operation between sleeve gastrectomy (SG) and vertical banded gastroplasty (VGB) using the GaBP Ring Autolock™ or other banding materials.[2]

The hypothesis of the possible superiority of laparoscopic banded sleeve gastrectomy (LBSG) over the conventional one will be evaluated in this study by comparing both procedures as regard the operative technique and the postoperative outcomes.

Patients and methods

This is a randomized prospective comparative study that was approved by the Ethical and Scientific Committee, General Surgery Department, Ain Shams University in March 2014. The study included 40 morbidly obese patients, who were admitted to Ain Shams University Hospitals, Cairo, Egypt. They were equally divided into two groups. Group 1, were operated on by LSG, while group 2 were offered LBSG. An informed consent was taken from all patients who accepted to participate in our study.

According to the National Institute of Health (NIH) criteria for being operated on by a bariatric procedure, patients included in the study were ranging between 18-60 years old, having body mass index (BMI) between 40 and 55 Kg/m^2 or having BMI over 35 Kg/m^2 with co-morbidities. However, the exclusion criteria for patients were being <18 or > 60 years, having contraindication to laparoscopy, being morbidly obese with BMI >55 Kg/m^2, patients with chronic liver disease and cardiovascular disease or patients refusing participation in the study. Full history was taken preoperatively from all patients and the routine investigations were done.

Operative technique

All procedures were performed under general anesthesia in the supine anti-Trendelenburg position with the legs apart, after fixation of the patient to the table with belt and application of compression bandage around both legs up to mid-thigh. The monitor was placed at the left side of the

patient, the surgeon stood between the patient's legs with one assistant on the left side of the patient. After penetrating into the abdominal cavity with a 12 mm single-use separator trocar through the rectus abdominis two hand breadth under the xiphi-sternum, insufflation of carbon dioxide was commenced with a set point at 14 mmHg. When a pressure of 14 mmHg was reached, trocars were inserted as shown in **(Figure 1).**

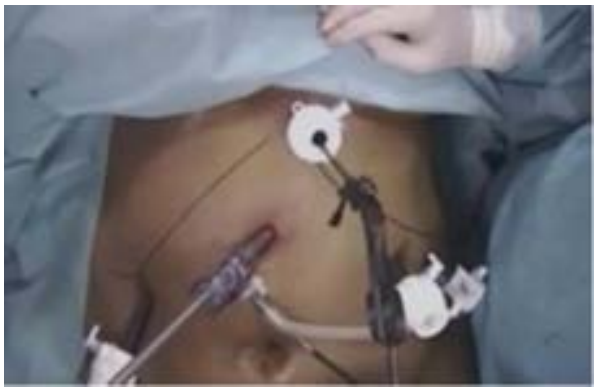

Fig 1: Trocar placement sites.

A liver retractor was introduced through port in the epigastrium and a 30 degree high definition television (HDTV) optic was used. The epigastrium region was exposed by lifting the left lobe of the liver with a liver retractor, pulling down the fundus of the stomach with alligator forceps. Dissection was started on the greater curvature approximately 4 cm proximal to the pylorus. The greater curvature of the stomach was separated from the greater omentum using vessel sealing device. Once the bursa omentalis was entered, the dissection was continued in a cephalic direction until the upper pole of the spleen was reached. At the level of the spleen, the short gastric vessels were carefully coagulated. The dissection progressed until the left crus of the diaphragm was well visualized.

A 40 F gastric tube was introduced by the anesthetist and advanced into the stomach. Two 60 mm green linear staplers were used starting about four cm from the pylorus. The tip of the stapler was oriented towards the left of the visible endings of the lesser curvature vessels, then, four to five 60 mm blue linear staplers were used to resect the stomach up to the angle of His. Suturing of stapled line was done using absorbable suture (vicryl 2/0) in continuous manner **(Figure 2).**

The integrity of the stapled line was tested as the anesthesiologist placed an orogastric tube into the stomach and the pylorus was compressed with a surgical grasper. Methylene blue was injected into the stomach and the stapled line was inspected carefully for leak.

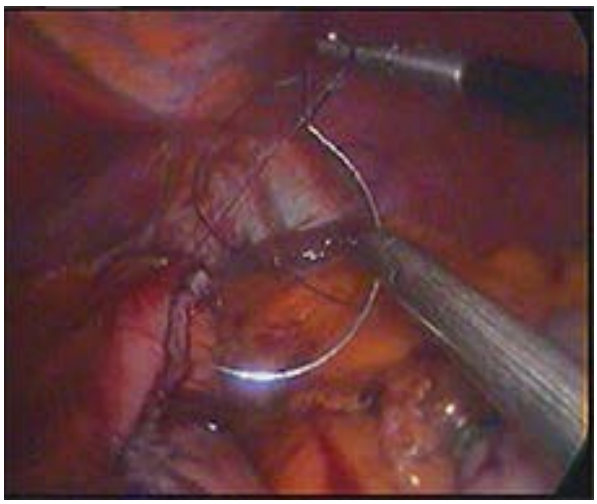

Fig 2: Suturing of stapled line.

The specimen was removed through the patient's left trocar then, the trocar openings were closed. Tube drain was inserted from the left port and was situated under the sleeved stomach and fixed to the skin by silk suture.

This technique was used for both patients in group 1 and group 2, however, for patients in group 2, this was followed by application of a band. After suturing the stapled line with Vicryl 2/0, a canal was then created around the sleeved stomach using a dissector and vessel sealing device (about 6cm distal to the angle of His).

Prolene mesh (6.5cm) was introduced into the peritoneal cavity through the 12 mm trocar. The mesh was placed circumferentially around the gastric tube through the previously created canal **(Figure 3).**

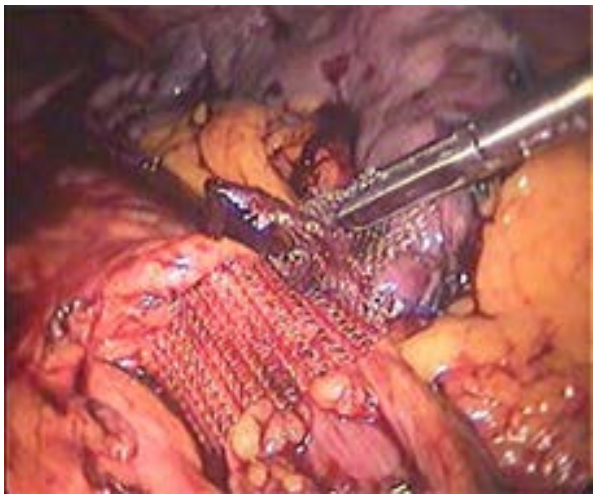

Fig 3: Placing the mesh circumferentially around the gastric tube.

The two tapered tips of the mesh were approximated to each other and were sutured

using a non absorbable suture (Prolene) to fix the mesh around the sleeved stomach pouch **(Figure 4).**

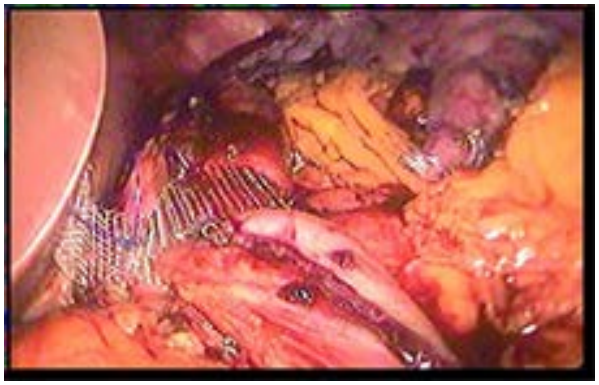

Fig 4: Fixing the mesh around the sleeved stomach pouch.

Postoperatively, a prophylactic dose of IV anticoagulant was given for all patients at the night of operation and patients were monitored for short term complications, such as hemorrhage, leakage, infection, deep venous thrombosis or vomiting.

They were discharged home after demonstrating that they were ambulatory, tolerating a liquid diet, and achieving pain control and were followed-up two weeks later and subsequently at 3, 6 and 12 months.

The primary endpoint was the intra-operative assessment of the procedure regarding technical challenges, operative time, incidence of bleeding, and rate of conversion to open surgery.

The secondary endpoint was the assessment of post-operative sequelae of the performed procedure, such as post-operative pain, length of hospital stay, the incidence of complications and the percentage of excess weight loss (% EWL) after 3, 6 and 12 months.

Data were analyzed using PASW version 18 (IBM© Corp., Armonk, NY, USA), normality of data was tested using D'Agostino-Pearson test. Normally distributed numerical variables were presented as mean±SD. Numerical data were compared using unpaired t test, while qualitative data were compared using Fisher exact test.

Results

The median age for patients in group 1 was 40 years, twelve of them were females (60%) and eight (40%) were males. Two patients (10%) were reported to be hypertensive and two patients (10%) were diabetic in this group. However, the median age for group 2 was 41 years with 13 females (65%) and seven males (35%), two (10%) of them had hypertension and three (15%) had diabetes. There was no significant statistical difference between both groups as regard the preoperative BMI. **(Table 1).**

Table 1: The median age and BMI of the patients

	Group 1	Group 2	P value
Median age (years)	40±7.1	41±7.1	0.637
Median BMI (Kg/m2)	45.45±3.6	46.1±2.2	0.162

There was a significant statistical difference between the two groups in mean operative time which was increased in group 2 due to application of mesh around the sleeved stomach. The initial ten cases showed a mean operative time of 92 minutes (85-100), while the last ten cases had mean operative time of 70 minutes (65-80).

Intra-operative bleeding was reported in two patients in group 1 due to splenic hilar traction, whereas it was reported in four patients in group 2. Two of them were from posterior fundic vessels and the others were from excessive dissection on the lesser curvature. This bleeding was controlled using a vessel sealing device. Otherwise, no more intra-operative complications occurred. **(Table 2).**

Table 2: The mean operative time and intra-operative bleeding in both groups

	Group 1	Group 2	P value
Mean operative time (min)	59±7.7	79.9±7	<0.001
Number of patients with intra-operative bleeding (%)	2 (10%)	4 (20%)	0.66

The mean hospital stay was 2.4 days with a range from two to four days and all patients showed mild postoperative pain which was controlled by IV analgesics. There were five patients suffering from vomiting, two patients (10%) from group 1 and three patients (15%) from group 2. Vomiting started at day one postoperatively and was controlled by medications, such as proton pump inhibitors and antiemetic drugs. All of the patients were improved by the 3rd postoperative day.

There were two patients (one from each group) that had wound infection and were managed by oral antibiotics. Otherwise, there were no other early morbidities like leakage or hemorrhage and the mortality rate was zero %. **(Table 3).**

Table 3: The post operative complications

	Group 1	Group 2	P value
Number of patients who developed vomiting (%)	2 (10%)	3 (15%)	1
Number of patients who developed wound infection (%)	1 (5%)	1 (5%)	1

The percentage of EWL was calculated as the ratio between postoperative weight loss and excess weight over the ideal body weight (IBW) which was calculated according to BMI. The mean percentage of excess weight loss (%EWL) was measured at 3, 6 and 12 months. There was no significant statistical difference in weight loss in both groups after one year follow-up. **(Table 4).**

Table 4: Percentage of EWL in both groups

	Group 1	Group 2	P value
3 months	21.3±1.8	21±1.8	0.56
6 months	42.6±2.5	41.9±2.5	0.41
12 months	59.2±4.2	58.3±4.2	0.49

Discussion

The popularity of LSG has been widely increased all over the world in the last few years and it now took the second place, after RYGB, as the most commonly performed bariatric procedure.[3]

Primarily, LSG was indicated to reduce operative risk in super obese patients. However, nowadays it is widely accepted as a stand-alone operation. LSG was first reported in 2003 as a primary operation in the management of morbid obesity.[4] The results of its early and mid-term weight-loss, and resolution of the associated co-morbidities were found to be equal to those of RYGB.[5]

By time, after this purely restrictive procedure, dilatation of the gastric tube may occur and this might be responsible for insufficient weight loss.[6] Moreover, its five-year results are not satisfactory and there are many doubts regarding long-term weight loss.[7]

LBSG was first introduced using a polyurethane GaBP ring[8] (which is an annular restrictive ring that was placed around the surgically created pouch during a gastric bypass procedure to provide a stabilized pouch outlet). Others used a similar technique wrapping the sleeve stomach with a piece of AlloDerm®.[9] Whenever a new technology rolls in, questions about its feasibility, safety, efficacy and reproducibility are raised. The risk versus benefit ratio of any new procedure must be weighed before it can be promoted as a standard procedure.

In 2014, Karcz and his colleagues encompassed 50 morbid obese patients in their randomized comparative study. Twenty five of them had a mean BMI of 56.1Kg/m^2 and underwent LBSG, whereas the rest 25 patients had a mean BMI of 57.1 Kg/m^2 and underwent conventional LSG. After one year follow-up, weight loss was found to be equal in both groups with percentage of EWL after 12 months of 58 for LBSG versus 58.4 for LSG patient.[10] This is consistent with our study in which we followed-up weight loss in both groups with the same diet control recommendations and % EWL was measured at 3, 6 and 12 months. We noticed that there was no significant statistical difference in both groups in EWL percentage after one year follow-up.

Alexander and his colleagues in 2009 had a randomized comparative study between 27 patients who underwent LBSG and 54 patients who underwent laparoscopic RYGB matched for sex, age, and initial BMI. They reported that after short-term follow-up, the LBSG had results similar to laparoscopic RYGB as regard the weight loss in one year follow-up.[9]

In the study done by Karcz and his colleagues, the band used was placed 4 cm away from the angle of His. Their results showed that two of those patients (8%) that were operated upon using the band, underwent laparoscopic removal of it due to uncontrollable vomiting.[1] However, in our study, all patients that developed vomiting post-operatively were soon controlled by proton pump inhibitors. Thus, persistent vomiting was not considered to be a complication as we placed the mesh six cm away from angle of His in order to avoid stenosis. Moreover, placing the mesh at that position helped us to be away from the incisura and avoiding creating high pressure zone that might predispose to leakage through the gastro-esophageal junction. Migration of the mesh was avoided by limited dissection just close to the lesser curvature of the stomach using vessel sealing device. This limited dissection also helped to avoid ischemic insult of the sleeved pouch as it depends on the lesser curvature blood vessels after dissection of the gastro-epiploic arcade.

In the early post operative follow-up, we reported four patients that developed vomiting after LBSG compared to two patients after conventional LSG. All of them were controlled by medications and were completely relieved on discharge.

We believe that vomiting occurred in those who underwent LBSG due to tissue edema after the procedure and placement of the prolene mesh (synthetic material). However, these factors were all temporary and were managed conservatively.

There was no significant statistical difference with control group who underwent conventional LSG.
We reported four cases who had an intra-operative bleeding, two of them were due to spelenic hilar traction, while the others were from dissection close to lesser curvature and controlled by vessel sealing device. This bleeding occurred in the first two cases in a trial to standardize our technique and it did not occur later due to raising our learning curve. However, Karcz and his colleagues did not report any cases of intra-operative bleeding during dissection and application of the band.[1]

In our study, the mean operative time for LBSG was 79 minutes due to the limited and meticulous dissection on the lesser curvature and manipulation of the prolene mesh. However, Konrad Karcz and his colleagues reported a mean operative time of 59 minutes where they placed a Minimizer ring by specific introducer.[1]

In comparison to other studies who used synthetic band, Arceo-Olaizand and his colleagues in 2008 used a synthetic band in association with laparoscopic RYGB. They found that the band was associated with an increased frequency of vomiting but this was minimal. Otherwise, there were no postoperative complications reported and the mortality rate was zero%.[11]

Limitations of our study were that we had a small number of patients with short-term results. We acknowledge that this was a pilot study, and the intention was to establish the feasibility and safety of this new LBSG technique after determining the weight loss results and complication rates. However, we intend to follow those patients for a longer period of time to document the long-term effect of this procedure.

Conclusion

There was no significant statistical difference between performing LSG with and without using a band as regard intra-operative complications and the early post-operative one year follow-up. Thus, LBSG is a safe procedure, however, it is more time-consuming and technically more difficult than the conventional LBSG. Therefore, we recommend conducting other multi-centric studies on larger number of patients that would be followed-up for a longer period of time to determine the long-term weight loss after LBSG and to detect the incidence of any additional complications from this procedure.

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