

Original Research Article

Outcome of over-sewing reinforcement of gastric staple line during laparoscopic sleeve gastrectomy in morbid obese patients: single center experience

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ABSTRACT

Background: During laparoscopic sleeve gastrectomy (LSG), different staple line reinforcement techniques are adopted by many bariatric surgeons, aiming at reducing the incidence of bleeding and leakage from the staple line.

Methods: Fifty patients suffering from morbid obesity with body mass index above 35kg/m² were prepared for LSG. The patients were enrolled in a prospective, randomized controlled study comparing the effect of staple line reinforcement by suture over-sewing versus non-reinforcement. Patients were classified randomly into two groups. In group I, after gastric stapling, the staple line was reinforced by suture over-sewing using continuous extra-serosal invaginating absorbable polyglycol sutures. In group II (non-reinforcement group), staple line over clipping by 10 mm clips was used when needed.

Results: Three cases (12%) in group II presented with collected hematomas and staple line bleeding necessitated laparoscopic evacuation and staple line bleeding control by suture over-sewing or additional clipping. In group I, one case (4%) of hematoma responded well to per-cutaneous drainage. There were 2 cases of leakage (8%) in group II versus no detectable cases in group I. Stenosis was detected in one case (4%) in group II while no detected cases in group I. The operative duration was 135 minutes in group II versus 110 minutes in group I.

Conclusions: Reinforcement by suture over-sewing of the staple line as a step in LSG is a safe, technically easy, of low cost and can reduce the incidence of postoperative complications as bleeding and leakage although it significantly prolongs the operative time.

Keywords: Laparoscopy, Over-sewing reinforcement, Sleeve gastrectomy, Staple line

INTRODUCTION

This is an exciting time in medicine. The pace of Morbid obesity is increasing all over the world. It predisposes to the development of various co-morbidities, such as cardiovascular diseases and type 2 diabetes mellitus. Bariatric surgery is being considered an evidence-based approach to achieve sustained weight loss in morbidly obese patients, however the results vary depending on the

procedure used.¹ Sleeve gastrectomy for obesity was first described by Marceau in 1993 as a part of bilio-pancreatic diversion procedure.² In 2000, Ren, et al, also performed laparoscopic sleeve gastrectomy as a part of bilio-pancreatic diversion with duodenal switch operation as a two-staged approach for morbidly obese patients.³

LSG became one of the most popular and widely used bariatric procedure nowadays.^{4,5} Review of the literatures

pointed that LSG alone is simple, effective and has certain advantages when compared to other weight losing procedures as adjustable gastric banding and laparoscopic Roux-en-Y gastric bypass.^{6,7}

Despite the wide steps in development of surgical staplers, staple line complications are common, clinically demanding, cost expensive for the patient, and can produce significant morbidity and mortality rates.⁸ These serious complications include bleeding and leakage. Hence, adopting special surgical techniques that can lead to reduction of the incidence of these complications is now of great interest to surgeons.

At present, there are several techniques for reinforcing gastric staple lines. Surgeons can over-sew the staple line with suturing technique or buttressing using either synthetic or biologic tissue-buttressing materials.⁹ However, some surgeons choose not to reinforce staple lines anymore either due to the cost benefit or lack of clear published data about the benefits of these techniques. Therefore, more extensive data are needed to clearly determine if staple line reinforcement is beneficial or not.¹⁰

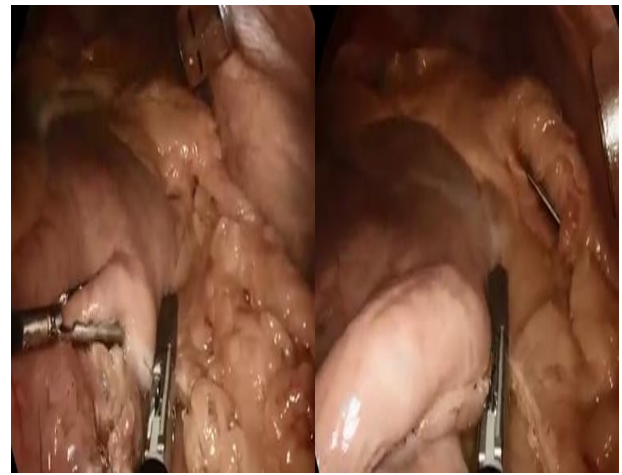
The aim of this study is to detect the outcome of staple line reinforcement in LSG done by suture over-sewing technique in comparison to non-reinforcement in prevention of stable line complications as bleeding and leakage.

METHODS

Fifty patients suffering from morbid obesity scheduled for LSG were enrolled for this study in October 6 University Hospital in the period between 2014 and 2016. The patients were included in a prospective, randomized controlled study comparing the effect of staple line reinforcement by suture over-sewing technique versus non-reinforcement. Inclusion criteria for patients' selection were bulk eaters, body mass index (BMI) more than 35kg/m² with or without associated comorbidities as diabetes or cardiovascular diseases and failed conservative measures for reduction of body weight for 2 years. Exclusion criteria from the study included those who had previous bariatric procedure, severe cases of ischemic heart diseases (IHD), and those who required other intraoperative techniques to control staple line bleeding. All patients scheduled for surgery were subjected to complete lipid profile, routine preoperative laboratory investigations, echocardiography and abdominal ultrasound.

The patients were randomly arranged into 2 groups each included 25 patients. Group I is scheduled for staple line reinforcement by over-sewing using absorbable polyglycol sutures and group II scheduled for only over clipping of the staple line, when necessary, without any reinforcement technique.

All patients were operated upon in October 6 university hospital under general endotracheal anesthesia by the same surgery team. The patients were placed in supine position and then Trendelenberg's position once the ports have been introduced. A 12mm port was placed either at the umbilicus or above and to the right 13-15cm from the xiphoid process, depending on the size and contour of the abdomen and used for the introduction of 30° scope. A 5mm port was placed sub-xiphoid for liver retractor. Two additional 12mm ports were introduced in each flank for the operating surgeon. Another 5mm port was placed in the left anterior axillary line for the assistant to produce traction on the omentum and stomach and to be a site for a drain at the end of the procedure.



Figures 1: Devascularization using harmonic device.



Figures 2: Stapling and gastric resection.

Using the harmonic scalpel, a window was made in the omental bursa approximately 4cm proximal to the pylorus. The antrum was mobilized by dissection and sealing of the gastroepiploic vessels on the greater curvature. The dissection was stopped about 2cm proximal to the pylorus (Figure 1). After mobilization of the antrum, the stomach was retracted inferiorly and toward the patient's right side for better exposure of the cardia, spleen and left crus. Proceeding superiorly,

sealing and dividing the short gastric vessels very close to the serosa of the stomach were done. A 32 French oro-gastric bougie was introduced inside the stomach. Author used during present study 2 types of endo-staplers for gastric resection; the Endo GIA (Covidien) and Ethicon endo-surgery stapler. The stomach was stapled starting 4cm proximal to the pylorus till the angle of His. The last used cartridge was placed about 1 to 2cm from the gastro-esophageal junction (Figures 2). The resected specimen was then removed through the site of one the of 12mm ports. After testing for leaks with air and 100ml methylene blue dye, a drain was placed nearby the staple line.



Figure 3: Suture over-sewing of the staple line.

In Group I the entire staple line was reinforced with a continuous extra-serosal invaginating suture using 2-0 monofilament absorbable polyglycol suture (Figure 3).

In Group II (non-reinforcement), 10mm clips (Covidien Endo Clip) were applied to the bleeding points in the staple line. No additional reinforcement technique was used in this group. Cases in group II that required other maneuvers to control staple line bleeding was excluded from the study.

All patients were statistically evaluated as regards the durations of the operations, lengths of hospital stay, rate for staple-line bleeding within the first 72 hours, postoperative leakage and stenosis occurring up to 4 to 6 weeks postoperatively.

Analysis was performed using SAS software. Continuous variables were compared using the Mann-Whitney U test and Student's t-test as appropriate. Categorical variables were compared using Fisher's exact test. Differences with a p-value <0.05 were considered statistically significant.

RESULTS

Fifty patients (31 females and 19 males) fulfilling the inclusion criteria of the study were randomly subdivided into 2 groups each involved 25 patients. The

demographic data of both groups were listed (Table 1). The mean BMI in group I was $44 \pm 6.5 \text{ kg/m}^2$ while in group II it was $43 \pm 7.5 \text{ kg/m}^2$ (Table 1). In group I, the associated co-morbidities were diabetes mellitus (7 patients), IHD (2 patients), hypertension (4 patients) and hyperlipidemia in 11 patients. In group II, diabetes was present in 6 patients, IHD in 3 patients, hypertension in 6 patients and hyperlipidemia in 13 patients (Table 2). Both groups subjected to the same steps of laparoscopic sleeve gastrectomy. In group I, additional staple line reinforcement by continuous extra-serosal invaginating sutures by 2-0 monofilament absorbable sutures was done for all patients. In group II, only additional clipping of the bleeding points of the staple line was necessitated in 19 cases and the remainders did not require over clipping.

Table 1: Patients' demographic data.

Patients characteristics	Group I (n = 25)	Group II (n = 25)	p-value
Age (years)	Range: 29-50 Median: 35	Range: 32-47 Median: 39	0.24
Sex ratio, Male/ female	17/8	14/11	0.46
BMI (kg/m ²)	44 ± 6.5	43 ± 7.5	0.15

Table 2: Patients' co-morbidities.

Co-morbidity	Group I		Group II		p-value
	n	%	n	%	
Diabetes mellitus	7/25	28	6/25	24	1.0
Hypertension	4/25	16	6/25	24	0.12
IHD	2/25	8	3/25	12	1.0
Hyperlipidemia	11/25	44	13/25	52	0.12

Table 3: Post-operative bleeding.

Bleeding	Group I		Group II		p-value
	n	%	n	%	
Incidence	1/25	4	3/25	12	0.11
Re-operation	0	0	3	12	

Table 4: Post-operative leakage.

Leakage	Group I		Group II		p-value
	n	%	n	%	
Incidence	0/25	0	2/25	8	0.21
Management (CT)			1	4	
Guided drainage (endoscopic stent)			1	4	

All cases in both groups were completed laparoscopically. No major intra-operative complications were encountered in both groups. Postoperative follow up of the cases in group II revealed, 3 cases (12%) of bleeding presented with collected hematomas and staple line bleeding that necessitated laparoscopic evacuation

and staple line bleeding control by suture over-sewing with invagination in 2 cases and additional clipping in the other case. In group I, one case presented with controlled hematoma that responded well to percutaneous drainage under image (ultrasound or computed tomography) (Table 3).

Two cases (8%) in group II presented with fever, abdominal pain and tachycardia in the fifth and eighth postoperative days respectively. Radiological studies revealed presence of staple line leaks which were considerable in first one and minor in the second one. The minor one passed conservatively using antibiotics, parenteral fluids and percutaneous drainage and was controlled within 12 days. The second patient required endoscopic stenting using a self-expandable stent placed at the level of the gastro-esophageal junction with proper control within 4 weeks. No leaks were detected in any patient in group I (Table 4). One case (4%) presented with stenosis of the sleeve was detected in group II within the first 30 days. This patient was presented with repeated vomiting and responded well to repeated endoscopic dilatation. No cases of stenosis were detected in the reinforcement group (Table 5). The operative duration was significantly longer in the reinforcement over-sewn group (range: 120 -170 min., median: 135 min) than the clipping group (range: 100-135 min., median: 110) (P-value <0.01). The length of hospital stay was somewhat longer in the non-complicated cases in the non-reinforcement group than over sewing group and ranged from 2 to 5 days (Table 6). Cases that showed postoperative complications had prolonged hospital stay than the others.

Table 5: Post-operative stenosis.

	Group I		Group II		p-value
	n	%	n	%	
Incidence	0/25	0	1/25	4	0.41
Endoscopic dilatation	0	0	1	4	

Table 6: Operative duration and hospital stay.

	Group I	Group II	p-value
Operative duration	135 min	110 min	<0.01
Length of hospital stay	3±0.5 day	4±1.5 day	0.25

DISCUSSION

Laparoscopic sleeve gastrectomy has been shown to produce an excellent weight loss and control of comorbidities in the short term and midterm in morbid obese patients.^{7,11}

Newly invented stapling devices make LSG a simple procedure, but complications related to the staple line are

serious, costly, and sometimes fatal for patients.^{8,12} Despite the advances in technology of surgical stapling devices, the rates of bleeding and leakage range from 1-5%, and more than 3% of LSG patients require reoperation.^{8,10} A large series has demonstrated that the most serious complications included staple line leaks (0-10%), staple line bleeding (0-10%), and surrounding organ injury (0-5%).¹³ Many factors were responsible for these complications including local tissue ischemia, increased intra-gastric pressure and undue lateral traction during gastric resection.¹⁴ Another meta-analysis study demonstrated that, non-reinforced staple lines during surgery had a leakage rate of 2.75% and a bleeding rate of 3.45%.^{8,15,16} The outcome of these complications can range from relatively minor to life-threatening complications. The high incidence and seriousness of the staple line complications have motivated the surgeons to develop additional techniques towards staple line reinforcement to decrease the incidence and outcome of these complications. A study done by Rosenthal RJ, et al, showed that among the current staple line reinforcement techniques, over-sewing is the most popular among bariatric surgeons.¹⁷ The study stated that over-sewing is used more often than buttressing techniques that used synthetic polymers or biologic materials and found to be more effective in reducing staple line leakage and bleeding rates. However, there is no general agreement between surgeons as regards the best suture material and suture technique to use in the staple line reinforcement.

In present study, LSG with reinforcement of the staple line using a continuous over-sewing extra-serosal invaginating sutures was done using 2-0 Monofilament absorbable suture in group I, while non-reinforcement of the staple line using only clipping over the staple line was done when needed in group II. The incidence of staple line bleeding postoperatively in the non-reinforcement group was 12% that necessitated laparoscopic redo and control by additional clipping and suture over-sewing. While, the incidence of bleeding was 4% in the over-sewing reinforcement group with postoperative controlled hematoma that responded well to conservative management without the need for reoperative intervention. This result was statistically insignificant (p-value = 0.11) although author considered it as clinically significant. The incidence of staple line leak in the non-reinforcement group was 8% that passed conservatively either by CT guided drainage or endoscopic stenting, while no cases were detected in the reinforcement group. This result was also statistically insignificant (p-value = 0.12) although it was of clinical significance. However, the overall collective incidence of staple line bleeding and leakage in the non-reinforcement group was 20% versus 4% in over-sewing reinforcement group which was statistically significant (p-value <0.02).

Himpens and colleagues reported their experience in the management of 29 patients with gastric leak after sleeve gastrectomy with stenting.¹⁸ They left the stents in situ on

average for 7 weeks. Immediate success was observed in 19 patients, whereas 5 patients required placement of a second stent and 2 required surgical intervention.

Tissue thickness may be an important factor in considering staple line complications. A recent study examining the thickness of excised sleeve gastrectomy specimens demonstrated that male gender and BMI $>50\text{kg/m}^2$ were associated with thicker tissue in the antrum.¹⁹ The cases demonstrated leakage and bleeding in present study had BMI over 52kg/m^2 . This explains the relation and impact of BMI on the incidence of staple line complications in LSG. This was consistent with a systemic analysis done by Aurora et al. included 4,888 patients, showed that patients with BMI $>50\text{kg/m}^2$ were associated with higher leak rates although the difference was not statistically significant.²⁰

As regards the type of the stapler that author used (Ethicon versus Covidion) author did not find an impact on the outcome of LSG in present study. Also, the age at the time of surgery did not significantly impact the leak or bleeding rates in the current study. Nevertheless, no correlation could be observed in the present study, especially for type 2 diabetes, or cardiovascular disease with incidence of staple line complications. The correlation between the bougie size and the incidence of staple line leak could not be confirmed in present study possibly due to low sample size of present study. In other literatures, larger size bougies were associated with a significant decrease in incidence of leak with no change in weight loss.²¹

The incidence of stenosis following SLG in present study was 4% in the non-reinforcement group that was managed by endoscopic dilatation with no detected cases in the oversewing reinforcement group and was statistically insignificant. In a study by Lalor PF et al, the rate of post-operative stenosis was reported as less than 1%.²²

The overall reoperation rate in present study was 6% and was totally belonged to the non-reinforcement group with a significant statistical difference between both groups.

The operative duration in the present study showed significant difference between both groups (135 min in oversewing group and 110 min in non-reinforcement group). Author relied this to early growing of the learning curve as regards this type of surgery. Other factors influenced operative time should be taken into consideration as the incidental operative bleeding complications, and the need for additional suturing and clipping. This is of great importance, as that group of patients frequently has additional comorbidities in addition to morbid obesity, putting them at higher surgical risk.

The postoperative hospital stay did not show significant difference in both groups. In a recent prospective

randomized trial, Dapri and colleagues compared the rate of staple line bleeding after LSG using 3 different techniques that were stapling the stomach with no reinforcement, reinforcement with suturing or buttressing with Gore Seamguard.⁹ They observed a significantly lower rate of bleeding with the use of buttressing material, while there was no difference in the leakage rate.

Rosenthal et al reported that 100% of participants agreed that reinforcement reduced bleeding. Seventy-seven percent thought it was acceptable to buttress the staple line and 95% supported oversewing.¹⁸

In their meta-analysis, Shikora et al, found that, compared with do nothing; all options of staple line reinforcement were effective in preventing complications. Other surgical maneuvers that should be adopted to reduce the incidence of bleeding and leakage without staple line reinforcement are; selection of adequate size stapler for the thickness of the gastric wall and use of proper stapling technique.¹⁰

Suture oversewing is obviously having the least cost among the reinforcement techniques but to some extent it prolongs the operative time, which might be also costly. Still, there is no general agreement about the best suture material (absorbable versus. non-absorbable) or type of suturing technique used. In addition, some surgeons prefer to oversew suture the entire staple line, while others only oversew selected parts of the staple line.

CONCLUSION

Postoperative staple line complications especially leakage still represent a challenge for bariatric surgeons and all future efforts directed towards a further reduction of these complications to make the LSG a widely accepted and safer procedure. The present study has concluded that suture oversewing of the staple line as a step in LSG is a safe, technically easy, of low cost and can reduce the incidence of postoperative complications as bleeding and leakage although it significantly prolongs the operative time.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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