



Role of Staple Line Reinforcement by Oversewing in Preventing Leakage and Bleeding after Sleeve Gastrectomy

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Abstract

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BACKGROUND: Staple line (SL) bleeding and leakage after laparoscopic sleeve gastrectomy (LSG) are still commonly challenging complications. Some surgeons use SL reinforcement (SLR) to decrease the rate of bleeding and leakage, by different methods such as oversewing, fibrin glue, and bovine pericardium, but their role in preventing complications is still controversial.

AIM: The aim of this study is to evaluate the incidence of SL bleeding and leakage after LSG by oversewing SL using V-Loc suture material.

METHODS: This is a retrospective study carried out on 200 consecutive patients with (body mass index [BMI] >40 kg/m²) or (>35 kg/m² plus comorbid diseases associated with obesity), divided into two groups according to SLR. Study participants were divided into two equal groups, each one included 100 patients; Group A underwent LSG without SLR, and Group B underwent LSG with SLR.

RESULTS: Post-operative SL bleeding was 4% in Group A and 2% in Group B ($p = 0.315$). Bleeding control by reoperation was 4% in Group A and 0% in Group B ($p = 0.021$). Just two patients had leakage in Group A (2%) and were managed with endoscopic stenting ($p = 0.105$). Operative time was shorter in Group A than in Group B, with a mean of 80 and 91.41 min, respectively ($p < 0.001$).

CONCLUSION: SLR with V-Loc suture was not effective in reducing the incidence of post-operative bleeding or leakage. However, it has a positive effect on reducing the incidence of reoperation, despite the prolongation of operative time. There is a need for more studies including larger samples to investigate the effectiveness in reducing the post-operative complications of sleeve gastrectomy operation; therefore, more prospective studies on a wide population are advised to ensure the effectiveness of reinforcement of staple line in the prevention of sleeve gastrectomy complications.

Introduction

Sleeve gastrectomy is the most popular procedure done by many bariatric surgeons since the early 2000s. Nowadays, laparoscopic sleeve gastrectomy (LSG) has been the most common bariatric procedure [1], [2], [3].

Although surgical staplers are continually improving, the staple-line (SL) leaks and bleeding are still the main post-operative complications after LSG. Post-operative leakage is less common than bleeding but more life-threatening and its incidence ranges from 0.5 to 2.7% [4]. The bleeding incidence ranges from 1.1 to 8.7%, and it may require reoperation [5]. There are different methods used to ensure the safety of suture lines, but the best of them is still debated. These methods include oversewing by absorbable or non-absorbable suture materials, fibrin glue, and bovine pericardial strips or the use of porcine small intestinal submucosa strips [6].

Due to the prevalence of post-operative complications and the possibility of fatality [7], [8], some bariatric surgeons routinely use the reinforcement of SL. However, some authors found that SL reinforcement (SLR) is an unnecessary procedure and has no role in preventing these complications [8].

SL leakage is caused by many factors such as improper instrumentation or mechanical faults and this type of leakage usually appears in the first 48 h, or sometimes is caused by ischemia of stapling line due to massive dissection, which usually appears 7 days after surgery [9]. Higher incidence of bleeding and leakage occurred at the start of the learning curve of most surgeons, so we think that correct surgical technique with soft handling of tissues plays a great role in decreasing the incidence of complications. Several studies have revealed that SLR reduces the risk of bleeding and leakage, but its efficacy is still controversial [10].

The aim of this study was to evaluate the incidence of SL bleeding and leakage during LSG after SLR by oversewing using V-Loc suture material.

Methods

In this cohort study, we collected data retrospectively from the medical records of patients who underwent LSG from July 2017 to March 2020 at the surgery department of Al-Azhar University Hospital in Egypt.

All the operations were done by the same team who followed the same protocol. All of the patients provided informed consent before undergoing LSG, and the Local Ethics Committee approved the study.

Two hundred patients were intended to be included in the study and divided into two equal groups: Group A included 100 patients who underwent LSG without SLR and Group B included 100 patients who underwent LSG with SLR by oversewing using V-Loc prolene sutures (v_loc suture absorbable 2/0).

The inclusion criteria included patients with BMI $>40 \text{ kg/m}^2$ or $>35 \text{ kg/m}^2$ with comorbid diseases (diabetes mellitus and hypertension) associated with obesity. We excluded patients who were older than 60 years or had a bariatric procedure earlier or patients with concomitant cholecystectomy or hiatal hernia repair. After patients' selection, we recorded all the full history taken, clinical examination, laboratory blood tests (complete blood picture, blood grouping, liver function, Renal function, random blood sugar, viral hepatitis markers, thyroid profile, coagulation profile, and results of the histopathologically examined specimens), pelvic-abdominal ultrasonography, chest radiography, pulmonary function tests, and ECG. All patients who have a history of cardiac disease or are older than 50 years, underwent an electrocardiogram (ECG) after a cardiac consultation. Patients with evident gastroesophageal reflux symptoms in their history (frequent heartburn, regurgitation, water brash, and choking during sleep) were subjected to upper gastrointestinal endoscopy.

All patients underwent the procedure under general anesthesia and were given 2g of first-generation cephalosporin (Cefazolin) 2 h before the operation. Procedures were done using five ports five ports placed in the upper abdomen through anterior abdominal wall.

Insufflation was done using a veress needle in the left subcostal space. For full visualization of the stomach, the left lobe of the liver was retracted upward from the 10-mm port. Starting division of the greater curvature of the stomach using bipolar technology (LigaSure; Covidien/Medtronic Inc., Mansfield, Massachusetts, USA) started 4cm from the pylorus. Dissection continued toward the gastric fundus with a division of short gastric vessels until the left crus of the diaphragm. A 39F bougie is used for calibration, then the gastric sleeve is created, and stapling was done by a linear cutting Endo GIA 60mm (60 mm, Endo

GIA™ reinforced reload with Tri-Staple™, Medtronic®, Minneapolis, USA) started 4 cm from the pylorus and ended at the angle of His.

In Group A, there was no oversewing of the SL, and if any bleeding point was detected, it was controlled by the application of a titanium clip over the bleeding point.

In Group B, SLR was done by continuous oversewing using V-Loc suture material taking full through the layer of the gastric sleeve, as shown in (Figure 1a and b).

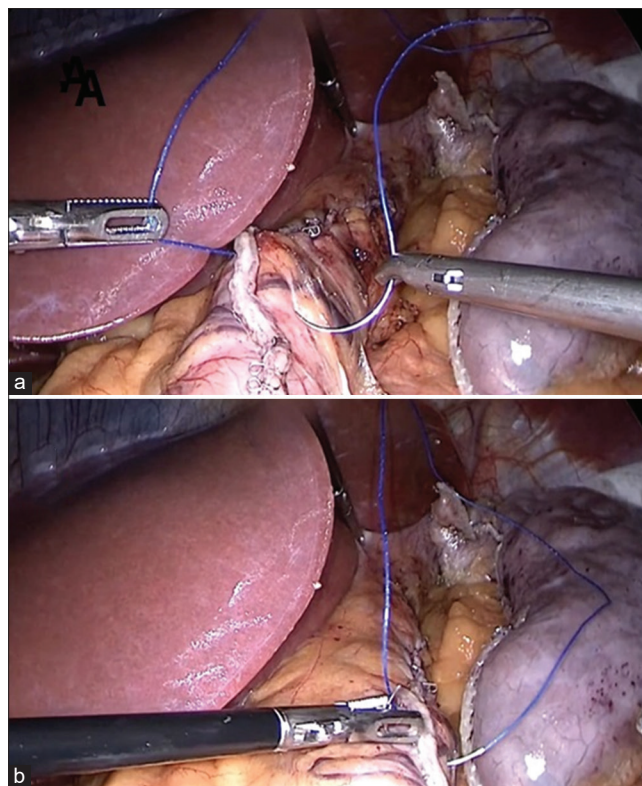


Figure 1: (a and b) Oversewing using V-loc thread continuous full through sutures

At the end of the procedure in both groups, an injection of methylene blue dye was done to ensure that there is no leakage, and an 18 F tube drain was routinely inserted from the left subcostal assistant port and positioned beside the SL. The transected gastric part was retrieved via a 15 mm port on the right flank.

The skin was closed using absorbable 4/0 sutures in a subcuticular manner followed by a sterile dressing.

All patients were advised for the early mobilization and low-molecular-weight heparin (Clexane) was given subcutaneously to all patients in a prophylactic dose. On the 1st post-operative day, all patients were advised to start clear fluids orally, and they received proton pump inhibitors (omeprazole 40 mg twice daily), and for 3 months. If suspected post-operative leakage (post-operative tachycardia, fever, or severe abdominal pain), post-operative assessment (by pelvic and abdominal ultrasound, gastrografin leak test, and

pelvic and abdominal computed tomography scan with oral contrast) was performed. Most of the patients were discharged on the second post-operative day, and the drain was left for observation for any possible leakage or bleeding and then removed on the third post-operative day during the first outpatient clinic (OPC) visit.

Selected histopathology examination was the followed policy for the resected gastric portions according to previous studies performed at our institute [11]. The selected ones were chosen if there were any suspicious naked-eye lesion; a histopathologist grossly examined the sent specimens and microscopically examined random biopsies from gastric mucosa and wall using the ordinary stains Hematoxyline and Eosin.

Follow-up

All patients were evaluated regarding operative time, post-operative hospital stay, and complications such as leakage and bleeding. Patients were instructed to return to the emergency department if they have severe sudden abdominal pain, persistent vomiting, tachycardia, and or fever. Patients were appointed for a follow-up visit on the 3rd day postoperatively, then once weekly until the end of the 1st month. Then, patients were advised for a follow-up in an OPC once a month for the next 3 months, and then every 3 months for 1 year. Patients were examined clinically during their visits for their weight, and they were asked about any complaints. The leakage was developed in two cases in Group A, one case was managed by endoscopic mega stenting and the other was managed by endoscopic clipping (Figure 2a and b) without the need for reoperation. After endoscopy, a gastrografin meal was done to ensure that the leakage site is already controlled as shown in Figure 3.

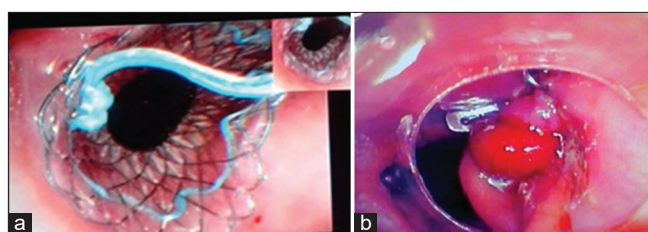


Figure 2: (a) Endoscopic stenting used to close the leakage site and (b) endoscopic clipping

Statistical analysis

All statistical analyses were performed with the Statistical Package for the Social Sciences Version 23.0. Armonk, NY. Categorical variables are expressed as percentages and numbers, and continuous variables are presented as means and standard deviations (SD). Qualitative variables have been expressed using absolute and relative frequency. The χ^2 test and ANOVA have been used to evaluate the significance. A cutoff of 0.05 is used for assigning significance,

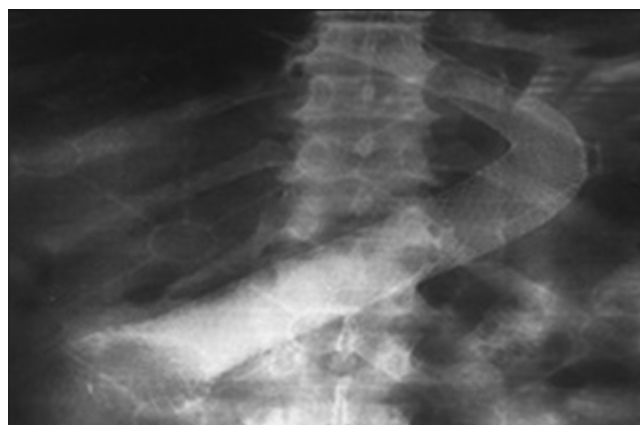


Figure 3: Gastrografin film after endoscopic stenting to ensure the control of leakage after stent application

Results

Table 1 revealed a total number of 200 patients who were subjected to LSG divided into two Groups A and B, including 159 females and 41 males. The age in Group A ranged from 20 to 52 years, and in Group B from 25 to 55 years with a mean (\pm SD) BMI of 44.4 ± 5.2 in Group A and 46.12 ± 6.5 in Group B. Associated morbidities (Diabetes mellitus and or hypertension) were also documented and compared in both Groups. No statistical significance was detected regarding sex, age, BMI, or comorbidities.

Table 1: Distribution of demographic data and comorbidities

Demographics and comorbidities	Group A: Without SLR* (n and %)	Group B: With SLR (n and %)	p-value
Sex			
Males	16 (16)	25 (25)	0.337
Females	84 (84)	75 (75)	
Total	100	100	
Age			
Mean \pm SD	34.12 ± 8.44	38 ± 8.80	0.005
Range	20–52	25–55	
BMI			
Mean \pm SD	44.4 ± 5.2	46.12 ± 6.5	0.192
Range	35–57	36–55	
Comorbidity			
Diabetes mellitus	8 (8)	5 (5)	0.841
Hypertension	16 (16)	12 (12)	

*SLR: Staple line reinforcement

In Table 2, we showed that the mean operating time in Group A was 80 min, which was shorter than in Group B at 91.41 min; the difference was statistically significant ($p < 0.001$). The difference in the duration of hospital stay between the two groups was statistically significant ($p < 0.001$). There was an increase in the hospital stay in Group A due to the presence of six patients with complications, which increased their hospital stay – two cases with leak managed by endoscopic stenting and four cases with bleeding managed by reoperation. On the contrary, the two reported cases of bleeding in Group B did not have a significant increase in the hospital stay as one patient was drained by a pigtail insertion 5 days postoperatively without admission, and the other patient had a drain and stopped spontaneously after 7 days of discharge.

Table 2: Distribution of the patients between the two groups with regard to the operative time and the length of hospital stay

Item	Group A	Group B	p-value
	Without SLR (n = 100)	With SLR (n = 100)	
Operative time (Min)			
Mean \pm SD	80.00 \pm 11.20	91.41 \pm 15.7	<0.001
Range	55–90	60–120	
Days of hospital stay			
Mean \pm SD	1.11 \pm 0.15	1.32 \pm 0.2	<0.001
Range	1–2	1–5	

There were two cases of leakage (2%) in Group A, but no patients (0%) with leakage in Group B. The leakage was located about 4cm below the gastroesophageal junction and was managed by endoscopic mega stenting without a need for reoperation. Four (4%) cases of bleeding occurred in Group A and were managed by reoperation and control of the bleeding points at the suture line. On the contrary, two (2%) patients in Group B had bleeding and were managed conservatively by monitoring the amount of blood collected in a drain, which was gradually decreased and stopped spontaneously without reoperation as shown in Table 3.

Table 3: Incidence of bleeding and leakage and how they were controlled

Item	Group A (n = 100)	Group B (n = 100)
	Without SLR (%)	With SLR (%)
Incidence of leakage	2 (2)	0
Management of leakage by endoscopic stenting	2 (2)	0
Incidence of bleeding	4 (4)	2 (2)
Control of bleeding by reoperation	4 (4)	0
Control of bleeding conservatively	0	2 (2)
Total complications	6	2

Histopathological examination was requested for 15 patients who had suspicious lesions noticed by the naked eye on the resected parts of the stomach. The results were all negative for malignancy or any specific unexpected inflammation (Figure 4).

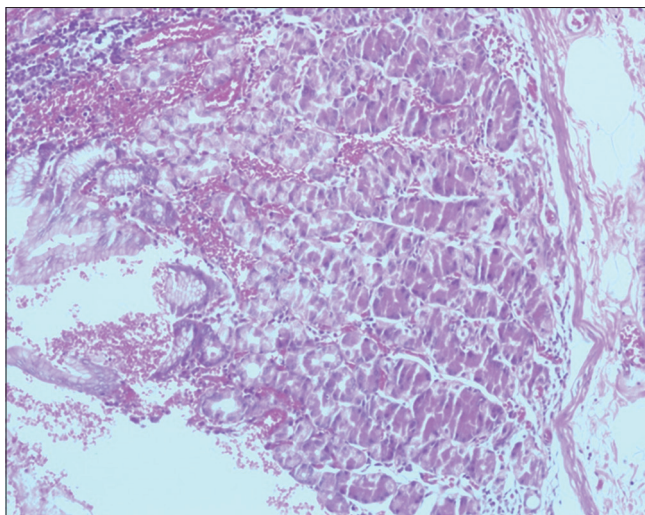


Figure 4: A histopathology picture of normal looking gastric mucosa of a sleeve gastrectomy specimen (H&E, \times 100)

Discussion

Many surgeons prefer to routinely do SLR during gastric sleeve operations, others prefer to leave

the SL without reinforcement. Among many different reinforcement methods, suturing is still the most popular maneuver used by many surgeons. Studies have shown decreased leakage rate when using buttressing materials which were attributed to distributing tension over the whole SL [12], [13].

In this study, we used oversewing method for reinforcement of SL using V-loc continuous suture, whereas other surgeons used different suturing techniques [14].

In this study, two cases of leakage (2%) were reported in Group A, while no leakage was detected in Group B (0%); it was statistically insignificant ($p = 0.213$). In addition, bleeding occurred in four patients in (4%) Group A and two patients (2%) in Group B, with no statistical significance ($p = 0.215$). The results may have clinical relevance, despite the statistical insignificant that could be traced back to the small sample size.

Two patients required reoperation to control bleeding in Group A by oversewing the SL as the bleeding severity was more evident in this group. On the contrary, the bleeding in Group B was less severe and managed conservatively as the bleeding stopped spontaneously without a significant drop in hemoglobin level or any affection of the vitals.

In a study on 100 patients done by Kwiatkowski *et al.* [15], the incidence of bleeding was 4.6% and leakage 2.3% in the non-reinforced group compared with 0% in the reinforcement group, which is almost similar to our results.

Knapp's *et al.* [16], in a review, which is one of the largest systemic reviews on reinforced and non-reinforced groups including 4881 patients, showed that the incidence of leakage was 3.2% and 3.9%, respectively, and the incidence of bleeding was 2.6 and 1.7%, respectively, without statistical difference between the two groups.

The total incidence of complications was statistically insignificant ($p = 0.102$). However, it affected significantly the length of hospital stay ($p < 0.001$), which was prolonged in Group A. This was explained by the reoperation of two patients and the occurrence of leakage in two patients in that group, otherwise two patients with bleeding were managed conservatively in Group B without reoperation.

There was a significant increase in the operative time in Group B compared with that in Group A, with a mean of 91.41 and 80 min, respectively. More studies are recommended to study this significant increase in the operative time of the two procedures.

Histological examination of the excised gastric parts in such operations is controversial; some hospitals routinely perform histopathology examination, while others follow the policy of selection of cases according to the naked eye features or the prior laparoscopic abnormalities [17]. In this study, 7.5% of the patients

were asked for a histopathological examination, which is consistent with a peer study done by Baheeg *et al.* in 2022 [7]. The limitations of this study include the lack of studying patients' satisfaction as well as the inability to study the association or relation with other comorbidities.

Conclusion

Reinforcement of SL using V-Loc suture during LSG had no significant role in the prevention of post-operative bleeding or leakage, but it has an efficient role in reducing the incidence of reoperation to control post-operative bleeding, although it increases the operative time. Therefore, more prospective studies on larger population are advised to ensure the effectiveness of reinforcement of SL in the prevention of sleeve gastrectomy complications.

Ethical Approval

Local ethical approval was obtained.

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