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ORIGINAL ARTICLE

Staple Line Reinforcement During Laparoscopic Sleeve Gastrectomy: Absorbable Monofilament, Barbed Suture, Fibrin Glue, or Nothing? Results of a Prospective Randomized Study

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Abstract

Background Laparoscopic sleeve gastrectomy (LSG) is associated with serious complications, such as staple line (SL) leaks and bleeding. In order to prevent the occurrence of these complications, surgeons have advocated the need to strengthen the staple line. The aim of this randomized controlled study was to compare the efficacy of three different ways of strengthening of the SL in LSG in preventing surgical post-operative complications.

Methods Between April 2012 and December 2014, 600 patients (pts) scheduled for LSG were prospectively randomized into groups without SL reinforcement (group A) or with SL reinforcement including fibrin glue coverage (group B), or oversewn SL with imbricating absorbable (Monocryl™; group C) or barbed (V lock®) running suture (group D). Primary endpoints were post-operative leaks, bleeding, and stenosis, while secondary outcomes consisted of the time to perform the staple line reinforcement (SLR) and total operative time.

Results Mean SLR operative time was lower for group B (3.4±1.3 min) compared with that for groups C (26.8±8.5 min) and D (21.1±8.4 min) ($p<0.0001$). Mean total operative time was 100.7±16.4 min (group A), 104.4±22.1 min (group B), 126.2±18.9 min (group C), and 124.6±22.8 (group D) ($p<0.0001$). Post-operative leaks, bleeding, and stenosis were recorded in 14 pts (2.3 %), 5 pts (0.8 %), and 7 pts (1.1 %), respectively, without statistical difference between the groups.

Conclusion Our study suggests that SLR during LSG, with an imbricating or non-imbricating running suture or with fibrin glue, is an unrewarding surgical act with the sole effect of prolonging the operative time.

Keywords Staple line · Reinforcement · Sleeve · Glue · Leak

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Introduction

Originally described as a first-stage procedure for the treatment of super-obese patients, laparoscopic sleeve gastrectomy (LSG) has rapidly gained momentum as a stand-alone procedure owing to its indisputable advantages such as absence of implantable foreign body, avoidance of malabsorption, relative simplicity of execution, and good results in term of weight loss.[1,2] A pivotal role in performing LSG is played by stapler devices. Despite constant technical improvements of surgical staplers, the rate of post-LSG's complications related to staple line (SL) remains quite relevant. This becomes more prominent in the presence of a long SL combined with pylorus

sparing technique and its consequent increase in intragastric pressure, which are considered the main causes of the two most worrisome post-operative complications after LSG: bleeding and leaks. In order to prevent the occurrence of these complications, surgeons have advocated the need to strengthen the SL. Buttressing with specific bioabsorbable materials, oversewing, or application of sealant agents have been proposed. Current data shows a post-LSG leak incidence that can reach as high as 7 %, while staple line hemorrhage ranges from 0 to 8.7 %, regardless of the methods used to reinforce the staple line.[3,4] The purpose of this randomized controlled clinical trial was to compare the efficacy of three different ways of strengthening of the SL in LSG in preventing surgical post-operative complications.

Material and Methods

This is a prospective randomized, open label, comparative study that included all morbidly obese patients who underwent LSG between April 2012 and December 2014 at our University Hospital. During weekly meetings of the study scientific committee, patients who were scheduled for a sleeve gastrectomy for the following week were randomly allocated to one of the treatment groups at a 1:1 ratio. Randomization was carried out by an independent researcher using a computerized randomization protocol provided by Microsoft© Office Access 2003 software. The surgeons were blinded to the treatment groups until the end of gastric stapling. These steps were taken to limit bias in the way to perform sleeve gastrectomy. The 600 patients were randomly assigned to no staple line reinforcement (group A; $n=150$), Evicel ® fibrin glue (Ethicon, Sommerville, USA) cover (group B; $n=150$), oversewn SL with imbricating absorbable (Monocryl™; Ethicon, Cincinnati, USA) running suture (group C; $n=100$), or oversewn SL with non-imbricating running suture using V-Loc™ V suture (Covidien, New Haven, USA) (group D; $n=100$). All procedures were performed by three experienced surgeons. The study was designed as a pilot study; for this reason, we did not calculate a priori the required sample size for each outcome. According to our bariatric program and to French High Authority of Health criteria for bariatric surgery, all patients were evaluated and followed up by a multidisciplinary team of specialists including an endocrinologist, a dietician, and a psychiatrist before being considered as bariatric surgery candidates. Inclusion criteria were a body mass index (BMI) greater than 40 kg/m^2 or greater than 35 kg/m^2 with associated obesity-related comorbidities. Exclusion criteria were age greater than 65 years and previous bariatric procedures. All data collected were stored in a database created specifically for the follow-up of our bariatric patients. No grants or funds from pharmaceutical industry were obtained for this study.

Main outcome measures were post-operative complications such as post-operative leaks, bleeding, and stenosis, while as secondary outcomes we considered the time to perform the staple line reinforcement (SLR) and total operative time. Bleeding was recorded as a surgical complication when hemoglobin dropped to more than 3 g/dl in post-operative period. Patients with symptoms consistent with stenosis underwent further workup to confirm the diagnosis. Stenosis was defined as focal narrowing of sleeve seen on upper gastrointestinal contrast study and/*or* endoscopy. Time for SLR was calculated as the time between the end of the last fired GIA reload and the end of the roofing of the entire SL in group B, and the time between the end of the last fired GIA reload and the end of the oversewing of the SL in groups C and D. Total operative time was recorded as the time between the first skin incision and the end of skin closure.

Surgical Technique and Post-operative Management

The patient is placed in supine position, with the arms extended, in a modified lithotomy position and in reverse Trendelenburg position with a 10° tilt. Thromboprophylaxis was performed by external pneumatic compression during surgery and by administration of low molecular weight heparin for a period of 21 days along with use of elastic stockings, in post-operative period. A five-trocar technique was used. The greater curvature of the stomach was dissected free by dividing the short gastric vessels with the harmonic scalpel, starting opposite to the Crow's foot (approximately 6 cm proximal to the pylorus) and reaching the angle of His. Posterior gastric adhesions were divided when present. Calibration was obtained by passing a 36-Fr gastric bougie, pushed toward and along the lesser curvature, and the stomach was transected with sequential firings of linear green and blue GIA reloads (60-mm Echelon®, Ethicon Endosurgery Cincinnati, OH). In order to reduce intraoperative bleeding, we waited 30 to 60 s between stapler closure and firing. Blood oozing was treated by diathermy coagulation before to reinforce or not staple line. In group B, SL was reinforced by application of 2 ml of human, aprotinin-free, fibrin sealant (Evicel®, Ethicon 360). A nitrogen sprayer device associated to a laparoscopic application cannula permitted to vaporize a thin layer of Evicel® over the staple line. In group C, staple line was strengthened by a continuous imbricating running suture using Monocryl ™. Finally, in group D, the whole SL was reinforced by a transfixing non-sero-serosal running suture using V-Loc ™ 90 (Covidien, Mansfield, Ma). V-Loc™ suture consists of a barbed absorbable thread with unidirectional barbs that make the device self-anchoring.[5–7]

The resected stomach was extracted from the abdomen in a plastic bag. The SL was tested with methylene blue pushed in the nasogastric tube; this latter was left in place for the first 24 post-operative hours. No intraoperative leak has been shown.

A silicon drain was placed along the SL. In order to rule out post-operative leaks, all the patients were double-checked with a methylene blue test and upper gastrointestinal series on post-operative day (POD) 2 and, if no leakage was detected, oral fluid diet was started. The patients were discharged on POD 5 after eating mashed foods. The post-operative assessments were conducted by a bariatric surgeon from our team at 1, 3, 6, 9, 12, 18, 24, and 36 months post-operatively and yearly thereafter

Statistical Analysis

Continuous demographic variables were expressed as mean± standard deviation, and range; categorical variables as well as complications were reported as number and percentage. Continuous outcome variables were generally reported as mean± standard deviation, and range. Fisher's exact test and chi-square test were used to investigate relationships between categorical variables. Comparison of continuous outcomes between the four groups was carried out by means of parametric and non-parametric test, as appropriate (i.e., analysis of variance [ANOVA] and Wilcoxon/Kruskal–Wallis tests). A p value <0.05 was considered to be significant. Statistical analysis was performed using Statistical Package for Social Sciences, version 17 (SPSS, Chicago, IL).

Results

Patient characteristics are shown in Table 1. Mean age was 37.6±11.5 years (range, 18–65) and mean preoperative body mass index (BMI) was 43.4±8.5 kg/m^2 (range, 35–74.2), without statistically significant differences between groups (p=0.7).

All the procedures were performed laparoscopically without conversion to open surgery. Mean operative time to perform SLR was statistically different between the three reinforcement groups (p<0.0001), being lower for group B (3.4± 1.3 min) compared with that for groups C (26.8±8.5 min) and D (21.1±8.4 min). Mean total operative time was statistically significantly different too (p<0.0001), being lower for the group B, 104.4±22.1 min, versus 126.2±18.9 min (for group C) and 124.6±22.8 (for group D). Besides, SLR significantly increased total operative time, as shown by comparison with the group without SLR (group A, 100.7 min±16.4) (Table 2).

No intraoperative complications and no post-operative mortality were recorded during the study period. Post-operative complications are summarized in Table 3. A leak was recorded in 14 patients (2.3 %): three leaks in group A, four leaks in group B, three leaks in group C, and four leaks in group D with no statistically significant difference between the groups (p=0.9). The leaks were, in all cases, located at the gastroesophageal junction area. The average time interval between LSG and leak diagnosis was 7.7 days (range 5–15). Eight out of 14 patients were reoperated for gastric leak closure and drainage; and in 4 cases, jejunostomy feeding tube was placed for enteral nutrition. In two of the eight patients, the reoperation was followed by endoscopic stenting. In the remaining patients, leak was managed by CT scan drainage of perigastric collection (two cases), internal–external fistula drainage (three cases), and endoscopic stent placement (one case). The average time for resolution of the leak was 67.2 days (range 21–181).

One patient in each group experienced an important bleeding during the first 72 post-operative hours. Patients underwent to laparoscopic evacuation of a large hematoma and hemostasis of an active bleeding at level of SL. One patient in group B was readmitted to the hospital on post-operative day 10 for fever and abdominal pain. A large perigastric hematoma was detected by a CT scan and radiologically drained. The overall rate of post-operative bleeding was 1 %, with no significant difference between the groups (p=0.89).

Post-operative stenosis was noted in seven patients (0.8 %): two stenoses in groups A, B, and D and one in group C, with no statistically significant difference between the groups (p=.0.93). In all patients, stenosis was located at the level of incisura angularis. The average time between LSG and diagnosis of stenosis was 42.3 days (range 18–75). One patient in group B underwent five sessions of endoscopic dilation without success and subsequently underwent conversion to gastric bypass, 5 months after the LSG. The remaining patients were

Table 1 Patient characteristics

	Group A No SLR	Group B Evicel®	Group C Monocryl™	Group C V-Loc™	p value
Number	150	150	150	150	–
Sex ratio (F/M)	123/27	123/27	118/32	120/30	0.85
Age (years)[a]	39.3±11.3 [20–61]	37.2±11.1 [19–65]	35.5±11.2 [19–61]	37.1±11.7[19–59]	0.09
BMI (kg/m^2)[a]	43.3±5.1[37–74.2]	43±5.7 [35–62]	44±13 [35–62]	43.8±10.7 [35–62]	0.74

[a] Mean±SD [min–max]

SLR staple line reinforcement, *BMI* body mass index, *F* female, *M* male

Table 2 Patients' operation data and hospital stay

	Group A No SLR	Group B Evicel®	Group C Monocryl™	Group D V-Loc™	*p* value
Time for SLR (min)[a]	–	3.4±1.3[2–6]	26.8±8.5 [14–50]	21.1±8.4[10–41]	<0.0001
Total operative time (min)[a]	100.7±16.4 [60–158]	104.5±22.1 [65–168]	126.2±18.9 [85–165]	124.6±22.8 [80–172]	<0.0001
Hospital stay (days)	5.7±1.1[3–18]	6.1±6.1 [4–60]	6±4.6 [5–37]	6.1±4[5–22,24]	0.35

[a] Mean±SD [min–max]

SLR staple line reinforcement

successfully treated by a median of 2.2 sessions of endoscopic dilatation. Table 4 shows patient's distribution, type of SLR, and number of complications among the three different surgeons. No statistical difference was recorded.

Discussion

In the present study, we analyzed the efficacy of SLR in reducing post-operative complications. To achieve this, we compared the outcomes of SLR when using monofilament running suture, V-Loc™ running suture, and fibrin glue (Evicel®) to a group of LSG without reinforcement. Our results suggest that post-operative leaks, bleedings, and stenoses are not influenced by the three SLR methods evaluated.

Surgeons have used V-Loc™ in multiple laparoscopic and robot-assisted procedures including urologic, gynecologic, and general surgery, as well as in bariatric surgery showing a significantly shorter operative time without increase in post-operative complications.[8–12] However, few reports exist regarding its use in SLR. Fibrin glue (Evicel®) is a hemostatic fibrin sealant agent derived from human plasma, conceived to mimic the final steps of blood coagulation cascade. Besides the approved hemostatic and sealant capacities, fibrin glue has shown to stimulate fibroblast migration and wound healing both in in vitro experiments and in clinical trials on high-risk colorectal anastomosis.[13,14] The evidence for using fibrin sealant in SLR in LSG is currently limited but in some cases very encouraging.[15] Gentileschi et al. compared, in a prospective randomized trial, fibrin glue to oversewing and buttressing of the SL in LSG. The authors concluded that fibrin glue application was as safe as the other two techniques and appeared to be time and cost saving.[16]

Our study showed a statistically significant difference when comparing the time spent by each technique to perform SLR. In fact, SLR was faster with the application of fibrin glue than when V-Loc™ buttressing or conventional suturing was performed. Similarly, a significant decrease in total operative time was recorded in the glue group reflecting the shorter time required for SLR. In the presence of an operating room personnel familiar with fibrin glue preparation, this method of SLR has demonstrated to be a time-saving technique. On the other hand, suturing the entire SL appeared to be time-consuming in this study especially in the conventional monofilament group. As already demonstrated in LRYGB, also in LSG, V-Loc™ suture showed a significant reduction in time for SLR when compared to conventional suture material.[11,12]

In terms of post-operative complications, our results did not demonstrate any clinical advantages of any SLR methods when compared to non-SLR group. No differences were recorded between the different SLR methods regarding the post-operative SL hemorrhages. These are unexpected results especially regarding the use of fibrin glue, which was shown to be more effective in achieving hemostasis and controlling post-operative re-bleeding than conventional methods in several randomized trials.[17,18] The respect of the waiting time before firing the stapler reloads was possibly responsible for proper SL hemostasis achieved in the other groups.

In the current study, SL leaks occurred independently from the SLR mode and no statistically significant

Table 3 Post-operative complications

	Overall %, (*n* pts)	Group A No SLR	Group B Evicel®	Group C Monocryl™	Group D V-Loc™	*p* value
Bleeding	0.8 % (5)	0.6 % (1)	1.3 % (2)	0.6 % (1)	0.6 % (1)	0.89
Leak	2.3 % (14)	2 % (3)	2.6 % (4)	2 % (3)	2.6 % (4)	0.96
Stenosis	1.1 % (7)	1.3 % (2)	1.3 % (2)	0.6 % (1)	1.3 % (2)	0.93
Overall morbidity	4.3 % (26)	4 % (6)	5.3 % (8)	3.3 % (5)	4.7 % (7)	0.87

SLR staple line reinforcement, *pts* patients

Table 4 Patient's distribution among the three different surgeons

	N (%) pts	Group A *n*/%	Group B *n*/%	Group C *n*/%	Group D *n*/%	Leak[a] *n*/%	Bleeding[a] *n*/%	Stenosis[a] *n*/%	*p*
Surgeon 1	223 (37.2)	36/24	33/22	75/50	79/52.7	4/27.6	2/40	2/28.5	0.7/0.9
Surgeon 2	167 (27.8)	50/33.3	50/33.3	40/26.7	27/18	5/35.7	2/40	2/28.5	0.7/0.8
Surgeon 3	210 (35)	64/42.7	67/44.7	35/23.3	44/29.3	5/35.7	1/20	3/43	0.9/0.8
Total	600	150	150	150	150	14	5	7	

[a] Measure was calculated exclusively on patients with this kind of complication (per-protocol analysis); *p* was calculated on the totality of complications for each surgeon

pts patients

difference was recorded between the different groups. Post-operative leak after LSG usually appears just below the gastroesophageal junction, and it seems to be related to two different factors: increased intragastric pressure and SL strength.[19] Resection of more than two thirds of the stomach and gastric fundus causes a tenfold reduction in the compliance of the sleeve.[20] This issue associated to pylorus sparing can result in a high intraluminal pressure which may exceed the strength of the tissue and SL, especially where the gastric thickness is lower, such as at the gastroesophageal junction level.[21] The usefulness of oversewing SL in order to straighten SL and to prevent leaks is highly debated. Ser et al. cut down to zero the rate of fistulas after starting to suture the SL.[22] On the other hand, Choi et al., in a meta-analysis of 1335 patients, did not show any advantage of SLR using the oversewing method.[23] In this present study, oversewing SL did not protect the occurrence of leak. Furthermore, while different types of suture material changed the operative time, they did not affect the rate of leaks. As already demonstrated by the experimental study of Nemecek et al., fears related to the structure of the V-Loc™ seem hypothetical.[5] This was also demonstrated in our series where similar rates of leaks were seen in groups C and D. Moreover, leaks occurred in patients where SL was not reinforced as well as in whom SL was oversewn. These results negate the theory of an increased risk of tearing at the point of suture penetration.[24] The analysis of patients in group B showed that even fibrin glue was not able to fully protect from leaks. This leaves us to assume that the sealing ability and the capacity to stimulate the migration of fibroblasts in these patients have not been able to counteract the increase of intragastric pressure, associated with tissue ischemia as evidenced by leak onset many days after the LSG.

Regarding post-operative stenosis, we noted an average rate of 1.1 % without difference between the groups. This complication is currently reported to occur in 0.6 to 2.4 % of LSG operations.[2,25] Many surgeons agree that there is a direct correlation between bougie size and stenosis. Smaller bougie size and thus tighter sleeve appear to be related to a greater incidence of stenosis.[26] Another possible cause frequently invoked to explain the origin of stenosis is oversewing staple line.[26] Running suture may further narrow the gastric tube and create an asymmetry of the sleeve and thus generate a symptomatic stenosis.[27,28] Our results seem to contrast with these theories. For all LSG, we used a 36-Fr bougie and we recorded almost the same rate of stenosis both in not oversewn groups (A and B) and in oversewn groups (C and D).

A limitation of the present study is the lack of comparison with another widely used reinforcement technique, such as the staple line reinforcement with absorbable polymer membrane (Gore Seamguards®). In three randomized trials of respectively 75, 90, and 120 patients comparing several reinforcement techniques, authors found that staple line reinforcement with Seamguards® significantly increases hemostasis, but no conclusive evidence supported the leak reduction.[16,29,30] On the other hand, Gagner and Buchwald in a systematic review found that patients reinforced with Seamguards® had a leak rate significantly lower than the other reinforcement options.[31] The aforementioned results along with ours suggest that larger randomized controlled trials are needed before to state the superiority of a technique over the others.

Conclusion

The present study suggests that SLR during LSG, with an imbricating or non-imbricating running suture or with fibrin glue, is an unrewarding surgical act with the sole effect of prolonging the operative time. Nevertheless, SLR continues to be used by surgeons as a personal preference and as a security shield rather than for its advantages. Large multicenter RCTs are needed to assess the real benefit of SLR, extending the analysis also to SL buttressing.

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