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Staple-line reinforcement during laparoscopic sleeve gastrectomy using three different techniques: a randomized trial

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Abstract
Background The main drawback of laparoscopic sleeve gastrectomy (LSG) is the severity of postoperative complications. Staple line reinforcement (SLR) is strongly advocated. The purpose of this study was to compare prospectively and randomly three different techniques of SLR during LSG.
Methods From April 2010 to April 2011, patients submitted to LSG were randomly selected for the following three different techniques of SLR: oversewing (group A); buttressed transection with a polyglycolide acid and trimethylene carbonate (group B); and staple-line roofing with a gelatin fibrin matrix (group C). Primary endpoints were reinforcement operative time, incidence of postoperative staple-line bleeding, and leaks. Operative time was calculated as follows: oversewing time in group A; positioning of polyglycolide acid and trimethylene carbonate over the stapler in group B; and roofing of the entire staple line in group C.
Results A total of 120 patients were enrolled in the study (82 women and 38 men). Mean age was 44.6 ± 9.2 (range, 28–64) years. Mean preoperative body mass index was 47.2 ± 6.6 (range, 40–66) kg/m^2. Mean time for SLR was longer in group A (14.2 ± 4.2 (range, 8–18) minutes) compared with group B (2.4 ± 1.8 (range, 1–4) minutes) and group C (4.4 ± 1.6 (range, 3–6) minutes; $P < 0.01$). Four major complications were observed (3.3 %): one leak and one bleeding in group A; one bleeding in group B; and one leak in group C, with no significant differences between the groups. No mortality was observed.
Conclusions SLR with either polyglycolide acid with trimethylene carbonate or gelatin fibrin matrix is faster compared with oversewing. No significant differences were observed regarding postoperative staple-line complications.

Keywords Laparoscopic sleeve gastrectomy · Morbid obesity · Staple line reinforcement

Laparoscopic sleeve gastrectomy (LSG) has gained more and more interest among surgeons and patients since its first application in 2000 [1] because of its encouraging results in terms of weight loss and resolution of comorbidities. The most important advantages of this relatively new bariatric technique are the absence of implantable nonabsorbable material, the maintenance of gastrointestinal continuity, the avoidance of malabsorption, and the convertibility to other operations [2, 3]. The main drawback of LSG is the severity of postoperative complications: bleeding [4] and gastric leak [5]; less severe complications are development of gastroesophageal reflux disease (GERD) [6], stricture [7] or dilation of the gastric tube [8], and insufficient weight loss [9]. The incidence of significant hemorrhage from staple lines is reported to be in the range of 1.6–10 % [10–12].

Staple-line leaks represent the most dangerous and life-threatening complication after LSG, with a mean incidence of 2.7 % from 24 studies with 1,749 patients [13]. Leaks after sleeve gastrectomy commonly occur at the proximal aspect of the staple line immediately below the gastroesophageal junction because of the creation of a high internal pressure.

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Staple-line reinforcement (SLR) is actually strongly advocated but not well standardized. There are different options of SLR: oversewing the staple line, or buttressing it with specific bioabsorbable material, such as glycolide trimethylene carbonate copolymer (Gore Seamguard®; W. L. Gore and Associates, Inc., Flagstaff, AZ) [14, 15], or bovine pericardium strips (Peristrips Dry and PSD Veritas; Synovis Surgical Innovations, St Paul, MN) [16, 17], or porcine small intestinal submucosa (Surgisis Biodesign, Cook Medical, Inc., Bloomington, IN) [18, 19]. No literature study reports the application of hemostatic agents or sealants over the staple line after sleeve gastrectomy.

The purpose of our prospective and randomized study was to compare three techniques of SLR during LSG: oversewing (group A), buttressing transection with Seamguard® (group B), and staple-line roofing with Floseal® (group C). Floseal® is a bovine-derived gelatin matrix of human derived thrombin mixed with other components. It has never been applied during sleeve gastrectomy as a staple reinforcement or hemostatic agent in humans.

Materials and methods

Between April 2010 and April 2011, 120 patients were enrolled in our prospective and randomized study in order to compare three different techniques of SLR during LSG [27, 28, 30]. Forty patients were allocated to the arm of oversewing (group A), 40 patients to the buttressing of the staple line with Gore Seamguard® (group B) and 40 patients to the staple line roofing with Floseal® (group C). Randomization was performed by using a shuffling method with Excel®. Patient characteristics are reported in Table 1. Mean age was 44.6 ± 9.2 (range, 28–64) years. Mean preoperative body mass index (BMI) was 47.2 ± 6.6 (range, 40–66) kg/m^2. All patients gave informed consent before entering the study. Institutional review board approval was obtained before starting the trial.

Our primary endpoints were defined as the operative time to perform the SLR and the incidence of postoperative staple-line bleedings and leaks. Operative time was calculated as follows: oversewing time in group A; positioning of Seamguard® in group B; roofing of the entire staple line in group C. Total operative time also was calculated. Moreover, mean additional costs were calculated using hospital current fees for each material but not for operating room occupancy. Results are expressed as mean ± standard deviation. Statistical analysis was performed by *t* test. Statistical significance was set at a $P < 0.05$.

Surgical technique

The patient lies in a supine position on the operating table with his arms extended in abduction and legs opened, in reverse trendelenburg position with a 10° tilt. The surgeon stands between the legs with the assistant on the left side of the patient and the cameraperson to the patient's right. Abdominal insufflation is set at 15 mmHg. Trocars are placed as follows: a 10-mm trocar (T1) 20 cm below the xyphoid process for the 30° optical system, a 5-mm trocar (T2) on the left anterior axillary line, a 12-mm trocar (T3) on the left midclavicular line just between the first and the second trocars, a 15-mm trocar (T4) on the right midclavicular line, and a 5-mm trocar (T5) below the xyphoid process. Using a 5-mm dissecting coagulator (Ultracision, Ethicon Endo-Surgery), the greater curvature of the stomach is mobilized at a point 3 cm proximal to the pylorus. The lesser sac is entered, and staying close to the wall of the stomach, the greater curvature ligaments (gastrosplenic and gastrocolic) are divided all the way up to the angle of His. It is important to identify and mobilize the angle of His with exposure of the left crus of the diaphragm to

Table 1 Patient characteristics

Characteristics	Group A oversewing	Group B Seamguard®	Group C Floseal®	*P* value
Gender (*n*)				
Female	35	34	33	0.18
Male	5	6	7	
Age (years)				
Mean ± SD (range)	44.6 ± 9.6 (28–59)	44.1 ± 8.3 (28–51)	44.1 ± 10.3 (33–64)	0.45
Weight (kg)				
Mean ± SD (range)	125.8 ± 12.5 (95–184)	145.2 ± 16.3 (99–194)	140.4 ± 15.2 (96–199)	0.1
BMI (kg/m^2)				
Mean ± SD (range)	47.2 ± 6.3 (40–62)	47 ± 6.7 (42–60)	47.4 ± 6.5 (42–66)	0.07

SD standard deviation; *BMI* body mass index

delineate the gastroesophageal junction and to facilitate complete resection of the gastric fundus. Retrogastric adhesions are taken down with the Ultracision device to allow for complete mobilization of the stomach, to eliminate any redundant posterior wall of the sleeve, and to exclude the fundus from the gastric sleeve.

After a complete mobilization of the stomach has been reached, a 40-Fr orogastric tube is inserted transorally into the pylorus and placed against the lesser curvature. This will help to calibrate the size of the gastric sleeve, prevent any constriction at the gastroesophageal junction, and provide a uniform shape to the entire stomach.

Gastric transection by Echelon Flex (Ethicon Endo-Surgery) stapler begins at a point 3 cm proximal to the pylorus, leaving the antrum and preserving gastric emptying. We use the green cartridge for the first firing and blue cartridges for the remaining ones in all cases. In group B, the stapler is supported by the application of the Gore Seamguard® (W. L. Gore and Associates) before the introduction of the device in abdomen. When using the Seamguard®, no modification of the type of cartridge is made. The stapler is fired consecutively along the length of the orogastric tube until the angle of His is reached. Care must be taken not to narrow the stomach at the angularis. It is important to inspect the stomach anteriorly and posteriorly to ensure no redundant posterior stomach.

The entire staple line is inspected for bleeding and tested for leak. The patient is placed flat, and an atraumatic clamp is placed near the pylorus. The integrity of the staple line is tested by insufflating air under saline and infusing 30–60 cm^3 of methylene blue into the remaining stomach. In group A, the staple line is reinforced by seroserosal running sutures by using absorbable material from the last firing of the stapler towards the first one. We believe that when the oversewing is performed, it must be done over the entire staple line, because even though leaks occur mostly in the proximal 3–5 cm, bleedings occur along the entire staple line. In group C, the entire staple line is covered by Floseal® (Figs. 1, 2). The matrix is gently squeezed over the entire staple line. Once the matrix has been applied, a little gauze is introduced into the abdomen and, using a dissector, is used to plug the staple line in case of bleeding. At the end, the entire staple line is washed and the residual material is aspirated. The resected stomach is extracted through the periumbilical incision at the end of the procedure. No drains or nasogastric tubes are left in place. The fascial defects are closed with a figure-of-eight 2/0 non-absorbable suture to prevent port-site hernia.

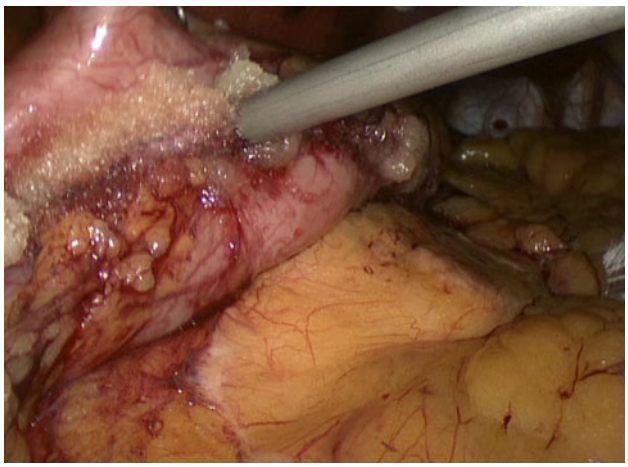

Fig. 1 Floseal® application over the staple-line

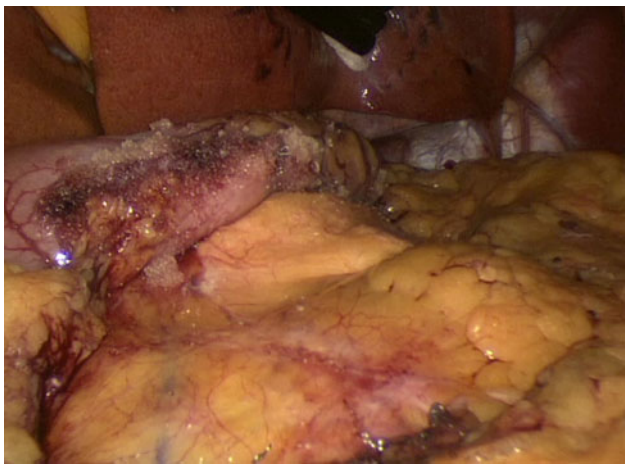

Fig. 2 Floseal® application at the end of the procedure

Results

All patients enrolled in our study were submitted to LSG without conversion to open surgery. The mean operative time was 58.5 ± 12.7 min (range, 32–75); mean hospital stay was 3.2 ± 1.2 (range, 2–12) days. Mean time for SLR was longer in group A (14.2 ± 4.2 (range, 8–18) minutes) compared with group B (2.4 ± 1.8 (range, 1–4) minutes) and group C (4.4 ± 1.6 (range, 3–6) minutes; $P < 0.01$; Table 2). Mean total operative time was significantly longer in group A (84 ± 4.6 (range, 68–116) minutes) compared with groups B and C (64 ± 3.4 (range, 52–94) minutes in group B; 66 ± 3.2 (range, 55–90) minutes in group C). Four major complications were observed (3.3 %): one leak and one bleeding in group A, one bleeding in group B, and one leak in group C, with no significant differences between the groups. The two leaks were diagnosed in the first 2 weeks postoperatively by swallow studies and CT scans. No mortality was observed.

All postoperative complications were successfully treated. The patient with the leak in group A, located in the proximal 2–3 cm of the staple line, had a percutaneous

Table 2 Difference in performing SLR

	Group A oversewing	Group B Seamguard®	Group C Floseal®	*p* value
Time for SLR (min), mean (range)	14.2 ± 4.2 (8–18)	2.4 ± 1.8 (1–4)	4.4 ± 1.6 (3–6)	<0.01

SLR staple-line reinforcement

CT-guided drainage and total parenteral nutrition for 2 weeks. Two patients with bleeding (one in group A and the other in group B) were treated with blood transfusions and intensive-care unit observation for 48 hours. The patient with the leak in group C, located at a point 7–8 cm from the gastroesophageal junction, underwent relaparoscopy and a minimal leak was observed, which was treated with a single stitch and drainage.

Additional costs were required in all the groups. Group A was the least expensive with a mean additional cost for each patient of 8 Euros; group B required a mean additional cost for each patient of 580 Euros and group C a mean additional cost of 120 Euros.

Discussion

To date, there is no high-grade evidence in the literature about the need for SLR during LSG, although it is extensively debated and highly recommended by most of the authors [20–23]. The main potential advantages of SLR are the improvement of staple-line strength, with reduction of the incidence of staple-line bleeding, a major complication of this effective bariatric procedure. Whatever technique is used, the operation time is obviously prolonged with consequences on overall operating time. As for staple line leaks, the evidence about a reduction of the incidence of this complication with SLR is even lower and weaker [43]. In other words, SLR is strongly advocated for staple-line hemostasis with potential advantages on staple-line strength and a supposed reduction of staple-line leaks.

A lot of different materials and techniques for SLR are available for each surgeon armamentarium, although standardization is still lacking. This is due to the variability of techniques without a clear advantage of one technique over the others. Many authors in the past have discussed and analyzed each single technique, but no consensus has been reached.

Shikora et al. [24] reviewed the use of buttressing materials to reduce hemorrhage and leakage during laparoscopic gastric bypass. The author concluded suggesting that SLR with bovine pericardial strips may decrease the risk of acute staple-line failures in the procedure. Consten et al. [22] reviewed the use of stapled buttressed absorbable polymer membrane for LSG, successfully decreasing hemorrhage and leakage from the staple-line in laparoscopic gastrointestinal surgery.

Lee et al. [25, 37] reviewed the evidence for use of fibrin sealants during laparoscopic gastric bypass and reported a decreased anastomotic leakage rate and staple-line failures. Gagner et al. [26] described an experimental study in pigs using bovine pericardium to reinforce the staple line, without any evidence of reduction of complications.

Recently, Chen et al. [20] published an interesting review of the literature and described their experience with Peri-Strips and SeamGuard® in a series of 35 patients, with no difference in the incidence of leaks between patients who received SLR and those without any reinforcement. To detect a statistically significant difference almost 10,000 procedures would be required, because the risk of leak in sleeve gastrectomy is low. So, they concluded that the routine reinforcement is questionable, although a decrease in hemorrhage has been reported.

In a recent article, Dapri et al. [38] randomly compared three different groups with a total of 75 patients: no SLR (group 1), buttressing of the staple line with Gore Seamguard® (group 2), and staple line suturing (group 3). In their experience, Seamguard® reduced blood loss during stomach sectioning, but there were no significant differences in terms of postoperative leaks between the three techniques.

In a new and interesting systematic review and meta-analysis [43], seven studies, comprising 3,299 patients, were examined for evaluation of population odds of leak (7.69), which was considered clinically significant. Meta-analysis of three studies comprising 1,899 patients revealed no clear benefit of reinforcement group, although with marginal significance. The authors underline two important aspects: current staplers may not be uniformly reliable, and SLR does not seem to have any clear benefit, at least concerning leak rate.

The use of hemostatic agents and sealants has been largely reported in bariatric surgery [25, 29, 39–41] in various procedures. In two different papers [39, 40], we reported the results of a large multicenter, randomized study concerning the use of a fibrin glue during laparoscopic gastric bypass showing a reduction of the incidence of complications in the fibrin glue group. Following the trial, we continued to investigate the potential benefit of sealants in bariatric surgery and, with the growing experience with LSG, we decided to study the application of hemostatic agents during this procedure.

We did not find any specific report about the use of hemostatic agents (such as Floseal®) during LSG for

hemostasis of the surgical field or SLR. The idea of using Floseal® came from the experience with this matrix in general surgery and from the incidence of 3 % of cases of bleeding after LSG in our previous experience with this procedure.

Our study compared three different techniques of SLR, hoping to find the best technique for SLR, reducing complications without a significative increase in costs or operating time. Polyglycolide acid and trimethylene carbonate, Seamguard®, is formed into a sleeve that is fitted over the stapler arms and released by pulling the suture that holds the sleeve in place. This material is degraded through a combination of hydrolytic and enzymatic pathways; it is biocompatible and nonantigenic. Seamguard® has been used to assist surgeons performing appendectomies, mesenteric vascular resections, pancreatectomies, and a variety of colorectal procedures [31–35]. Prospective, randomized, clinical trials have shown that Seamguard® minimizes staple-line bleeding and leakage and reduces operating time [15, 36]. To date, it is considered a reliable and useful tool for LSG, even though the high costs have probably reduced its universal application.

Floseal® Haemostatic Matrix is applied to the tissue surface at the staple line. Floseal® granules expand approximately 20 % within 10 minutes and physically restrict the flow of blood. Blood percolates through the spaces and is exposed to thrombin. A clot forms around the mechanically stable matrix provided by the granules. The structural integrity of the gelatin fibrin matrix enables it to remain in place at the tissue surface. Floseal® granules not incorporated in the clot can and should be removed with gentle irrigation without disrupting the hemostatic seal. Floseal® is reabsorbed by the body within 6–8 weeks, consistent with the time frame of normal wound healing [42].

In the present study, no technical difficulties were encountered with the three techniques and no technical intraoperative complications occurred during the procedures. We acknowledge some limitations of the present study: the number of patients is small and no power analysis was performed. Nevertheless, the study was performed in a single center with only one operating surgeon, with no bias regarding the operator and surgical technique. For this reason, we believe that some considerations can be made.

The rate of staple-line postoperative complications was similar in the three groups. Although the number of patients is small, it seems reasonable to conclude, at the moment, that SLR with Seamguard® or Floseal® is faster compared with oversewing. In our study, SLR with Seamguard® or Floseal® was significantly shorter compared with oversewing, and this resulted in a significantly reduced total operative time. Operative time in morbidly obese patients must be reduced to the minimum while providing the same safety of a longer operation. Regarding costs, although difficult to calculate in a complex setting, such as bariatric surgery, they were higher in groups B and C when calculating only the expenses for materials. Operating room occupancy is difficult to calculate at our hospital, but time-saving procedures could be advantageous in different settings, such as private hospitals. In this field, the use of Floseal® seems to be associated with a safe, faster (compared with oversewing) and cheaper technique (compared with Seamguard®) during SLR in LSG. Further and larger randomized studies are obviously needed.

Conclusions

Although the evidence for the need of SLR during sleeve gastrectomy is low, most of the authors recommend it. Actually there are no clear data to support the use of SLR, and most studies conclude that there is no difference. Our thought, based on personal clinical experience, is that SLR is useful to prevent or reduce the risk of staple-line bleeding. The idea of this study came from the need to evaluate the best technique for SLR. For this reason, no control group was included in the study.

Staple-line reinforcement after sleeve gastrectomy can be performed with different techniques. We have experience with all methods with good clinical results. In an effort to find the ideal, safe, fast, and cheap technique, the present randomized study was planned. Of the three techniques presented, Floseal® application is as safe as oversewing and Seamguard® and appeared to be time-saving and cost-saving. Further trials are necessary to improve our knowledge about SLR during LSG.

Disclosures Paolo Gentileschi, Ida Camperchioli, Stefano D'Ugo, Domenico Benavoli, and Achille L. Gaspari have no conflict of interest or financial ties to disclose.

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