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Original article

Comparative use of different techniques for leak and bleeding prevention during laparoscopic sleeve gastrectomy: a multicenter study

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Abstract

Background: Laparoscopic sleeve gastrectomy (LSG) is an approved primary procedure for morbid obesity, but it is associated with serious complications, such as staple line leaks and bleeding. The objective of this study was to assess the effectiveness of staple line reinforcement (SLR) in reducing leaks and bleeding after LSG.

Methods: A total of 1162 patients underwent LSG (305 males, 857 females). The mean age was 43.7 years and the mean body mass index was 48 kg/m^2. The patients were divided into 6 groups based on the type of SLR, including a no-SLR control group, with evaluation of leaking and bleeding risk and correlation of patients' characteristics with complications.

Results: A total of 189 patients underwent LSG without reinforcement. The SLR method was oversewing in 476 patients, bovine pericardium in 312, synthetic polyester in 76, glycolide/trimethylene copolymer in 63, and thrombin matrix in 46. The overall leak frequency was 2.8%; higher with synthetic polyester (7.8%), 4.8% with no reinforcement, and lower with bovine pericardium strips (.3%; $P < .01$). Postoperative hemorrhage occurred in 35 patients (3%), with a higher frequency being observed without SLR (13.7%; $P = .02$). Only diabetes was a risk-factor for a leak ($P < .01$).

Conclusion: SLR with bovine pericardium strips significantly reduced the leak risk. Postoperative bleeding was significantly lower with all SLR-methods, although there was no significant difference among the various techniques. Patients with type II diabetes had a higher risk of staple line leak after LSG. Further randomized, controlled studies are needed to improve our understanding of the efficacy of SLR during LSG. (Surg Obes Relat Dis 2013;▮:00–00.)

Keywords: Bariatric surgery; Sleeve gastrectomy; Staple line reinforcement; Leak; Bleeding

Laparoscopic sleeve gastrectomy (LSG) was pioneered as the restrictive component of the biliopancreatic diversion and duodenal switch and was later proposed as a staged procedure in high-risk patients [1]. Since its first application in 2000, LSG has gained increasing interest in the bariatric community as a stand-alone procedure, because of the

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excellent excess weight loss and improved obesity-related co-morbidities without the addition of a biliopancreatic diversion. In a recent systematic review of LSG as a stand-alone procedure, Gill et al. noted amelioration of type 2 diabetes mellitus (T2 DM) in >90% of patients with excess weight loss of 47% at the 13-month follow-up [2]. LSG effectiveness was comparable to other approved bariatric surgeries through an intermediate term [3,4]; the first long-term data are positive, although they need to be confirmed [5–7]. In 2009 LSG was recognized by the American Society for Metabolic and Bariatric Surgery as a primary procedure for the surgical management of morbid obesity [8]. This technique is also associated with several important benefits, including maintenance of gastrointestinal continuity without an anastomosis, avoidance of malabsorption, absence of implantable nonabsorbable material, and potential convertibility to other operations [9].

Nevertheless LSG is not without complications. The least severe of these are gastroesophageal reflux disease, insufficient weight loss, and stricture or dilation of the gastric tube [10–12]. The most serious and feared complications are bleeding and leakage from the gastric staple line [13,14]. These events can lead to significant morbidity, ranging from a prolonged hospital stay for conservative treatment, stenting, the need for a total gastrectomy, or death [14,15].

The incidence of significant hemorrhage from the staple line, requiring blood transfusion or reoperation, is reported to be 1.1%–8.7% [8]. The most dangerous and life-threatening complication is the staple-line leak; the mean incidence from 24 studies with 1749 patients was 2.7% [16]. Leaks usually occur just below the gastroesophageal junction, perhaps because of the high internal pressure subsequently to the vertical tubularization of the stomach [17].

Staple-line reinforcement (SLR) has been proposed as a method to reduce the occurrence of both bleeding and leak after LSG. SLR can be obtained by several different methods: oversewing the staple-line, buttressing it with specific materials such as bovine pericardium strips (Peri-Strips Dry, Synovis, Deerfield, IL), synthetic polyester (Duet-TRS, Covidien, Dublin, Ireland) or glycolide and trimethylene carbonate copolymer (SeamGuard Bioabsorbable, W. L. Gore & Associates, Newark, DE), or by applying glue or hemostatic agents over the staple-line (Floseal, Baxter, Deerfield, IL). Although a reduction of the complications has been postulated, the published literature has failed to show a definite benefit of these techniques and, to date, no clear consensus exists regarding the efficacy of SLR.

The objective of this retrospective multicenter study was to assess the effectiveness of SLR in reducing staple-line leaks and bleeding in morbidly obese patients undergoing LSG at 4 high-volume bariatric centers. The patients were divided into 5 different groups according to the method of SLR, and the results were compared with those undergoing LSG without SLR. To the best of the authors' knowledge, this is the first multicenter study comparing 5 SLR techniques with each other and with a control group of LSG without SLR.

Materials and methods

Between October 2002 and January 2012, 1162 patients underwent LSG at the participating centers. All the procedures were performed by 4 leading bariatric surgeons, one for each hospital, with a recognized expertise in minimally invasive bariatric procedures.

There were 305 males and 857 females with a mean age of 43.7 ± 9.4 years (range: 17–67 yr) and a mean body mass index (BMI) of 48 ± 6.4 kg/m^2 (range: 35–84 kg/m^2). The patients' demographic characteristics were equally distributed between the study groups (Table 1). The patients met the International Federation for the Surgery of Obesity, the European Association for the Study of Obesity (EASO), and the National Institute of Health indications for bariatric surgery. The Institutional Review Board approved the study.

Each patient had an extensive preoperative evaluation, including consultations with a nutritionist, psychiatrist, and medical internist. An esophagogastroduodenoscopy was performed to screen for *Helicobacter pylori* and incidental pathology. All the patients were extensively informed concerning the surgical procedure and provided written informed consent. Based on the management of the staple-line, the patients were divided into 6 groups: no reinforcement; oversewing; buttressing with Peri-strip Dry, Duet-TRS, or SeamGuard; and reinforcement with Floseal. These procedures were at the choice of the operating surgeon; the patients were not randomized between no-SLR and the other techniques.

Table 1
The demographic data of patients included in the study

Demographics	No-SLR (189)	Oversewing (476)	Peri-Strips Dry (312)	Duet (76)	Seam-Guard (63)	Floseal (46)
Gender (n)						
Female	137	352	228	58	47	35
Male	52	124	84	18	16	11
Mean age (years)	46.3	44.6	43.1	39.8	47.1	41.4
Mean BMI	49	46	51	50	45	47
Type 2 diabetes (n)	53	135	84	23	20	10

BMI = body mass index; SLR = staple line reinforcement.

Surgical technique

The surgical technique was standardized between the 4 centers, both for sleeve gastrectomy that for SLR. The patient was placed in a supine position with the legs open, in the reverse Trendelenburg position. After setting the abdominal insufflation at 15 mm Hg, 5 trocars were placed, including the 30° optical system. Using a 5-mm dissecting coagulator (UltraCision, Smithfield, RI), the greater curvature of the stomach was mobilized, starting at a point 3 cm proximal to the pylorus up to the angle of His. A 32–48 Fr (according to surgeon's preference and patient's characteristics) orogastric tube was inserted to calibrate the size of the gastric sleeve, prevent constriction at the gastroesophageal junction, and provide a uniform shape to the entire stomach. Gastric transection began at a point 3 cm proximal to the pylorus with a mean number of 5.8 (5–9) 60-mm firings using up to 2 cartridges with a staple height of 2.0 mm (green) at the antrum and 1.5 mm (blue) at the gastric body and fundus along the length of the orogastric tube until the angle of His was reached to create an 80–110 mL gastric tube. In the cases of SLR with buttress materials, the stapler was supported by Peri-Strips Dry, Duet-TRS, or SeamGuard, with no modification of the type of cartridge and technique of gastric transection. The entire staple line was inspected for bleeding and tested for leaks with methylene blue. In the group of SLR with oversewing, the staple line was reinforced with a sero-serosal running suture with absorbable material from the last firing of the stapler toward the starting point. In cases of SLR with thrombin matrix, the staple line was covered by Floseal. On the first postoperative day, an upper gastrointestinal series radiographograpy with contrast (Gastrografin, Bracco Diagnostics Inc., Monroe Township, NJ) was obtained, and a clear fluid diet was started in absence of a leak or other problem.

Data collection and statistical analysis

The data collected included age, gender, BMI, comorbidities, SLR method, and operative and postoperative complications, including staple-line leakage, hemorrhage, or abscess development. A postoperative leak was defined as a fluid collection or air adjacent to the staple-line. Staple-line bleeding was defined as the need to transfuse at least 1 unit of blood.

The data were analyzed retrospectively. The results are expressed as the mean ± SD and a range for continuous data and as a percentage and frequency for categorical variables. A multivariate analysis, including age, gender, preoperative BMI, and diagnosis of type II diabetes mellitus, was performed to identify patients at risk of leak or bleeding; whereas, ANOVA was used to compare the efficacy of the different techniques. A P value $<.05$ was considered to be statistically significant, and all reported P values were two-tailed.

Results

Among the 1162 patients undergoing LSG, 189 did not undergo any reinforcement of the staple-line. In the group of 973 LSG with SLR, oversewing was performed in 476, reinforcement with Peri-Strips Dry in 312, Duet-TRS in 76, SeamGuard in 63, and Floseal in 46. The different SLR techniques were equally distributed between the centers, and the operating surgeons performed various methods for SLR.

Perioperative mortality was .5% (7 patients). Three deaths occurred in the no-SLR group: 2 after reoperation for leak, complicated by renal failure and pneumonia, and one due to cardiac complications. Two patients in the oversewing group died: one for myocardial ischemia after staple line leak and one due to pulmonary embolism. Two other deaths, in the Peri-Strips Dry and Duet-TRS groups, were related to early respiratory failure, prolonged intensive care requirement, and septic status. A conversion to open surgery was necessary in 7 cases (.5%): 3 times because of extensive adhesions from previous open operations, 2 for massive hepatomegaly, 1 subsequently to stapler misfiring, and 1 because of a previous band migration. The overall incidence of leak in this group of patients was 2.8% (33/1162).

Regarding SLR and leak frequency, there was a higher risk with Duet-TRS (7.8%), then with no reinforcement (4.8%), SeamGuard (3.2%), oversewing (2.9%), Floseal (2%), or Peri-Strips Dry (.3%) (Table 2). Most leaks (85%) appeared at the level of the gastroesophageal junction or the proximal aspect of the sleeve. The leaks were diagnosed in the first 2 weeks postoperatively by computerized tomographic or upper gastrointestinal scans. In 7 cases (21%), the staple line leak required reoperation and drainage; the remaining patients were treated by percutaneous drainage (n = 12), endoscopic prosthesis (n = 7), total parenteral nutrition (n = 6), and injection of platelet gel (n = 1). The ANOVA test indicated reinforcement with bovine pericardium is significantly more effective than all other techniques in leak prevention ($P < .01$). The multivariate analysis found that only T2 DM was a risk-factor for leak ($P < .01$).

Postoperative hemorrhage was detected in 35 patients (3%). The frequency was higher in patients without SLR

Table 2
The incidence of leak and bleeding in the 6 different groups

Reinforcement technique	Number of patients	Leak	%	Bleeding	%
No reinforcement	189	9	4.8	26	13.7
Oversewing	476	14	3.0	7	1.4
Peri-Strips Dry*	312	1	.3*	0	0
Duet TRS	76	6	7.8	1	1.3
SeamGuard	63	2	3.2	1	1.6
Floseal	46	1	2.2	0	0

*$P < .01$ ANOVA test.

(13.7%) with a significant reduction of bleeding, independent of the SLR method ($P = .02$) (Table 2). Among these patients, 7 (20%) required reoperation and 1 (2.8%) required radiologic embolization to control the hemorrhage. No significant differences were identified comparing the results of each center included in the study.

Discussion

The main potential advantage of SLR is thought to be the improvement of the staple line strength, associated with better sealing of the blood vessels along the gastric wall. Even a small reduction of postoperative leak and bleeding may prevent serious events, such as peritonitis and septic shock, associated with a mortality risk that ranges from 10% to 30% [14,18]. The ideal method of SLR should be simple, with minimal risk of complications or a prolongation of operative time. However, standardization of SLR is still lacking due to the absence of a clear advantage of one method over the others. Several reports demonstrated specific SLR-related complications, including intraluminal migration of bovine pericardium strips, tissue ischemia, or sleeve stenosis after oversewing the staple line [19,20].

In a prospective, randomized trial, Dapri et al. reported no significant difference in leaks between SLR with Seamguard or oversewing compared with a no-SLR group [21]. A reduction in both staple line hemorrhage and leakage using the same buttressing material was documented in a previous study by Consten et al. [18]. Two other groups evaluated the efficacy of Peri-Strips Dry and Duet-TMS; despite a small sample size, they had fewer postoperative complications compared with no-SLR [22,23]. Recently, Choi et al. published a meta-analysis including 8 studies with a total of 1335 patients. These researchers reported a significantly decreased risk of leak associated with SLR; regarding hemorrhage, only reinforcement with buttressing materials was associated with a lower frequency. However, oversewing the staple line seemed to increase postoperative bleeding, although it was not statistically significant [24]. Other studies investigated the potential benefits of hemostatic agents, such as thrombin matrix, during LSG; from results of a preliminary series it appeared that Floseal had the potential to prevent postoperative hemorrhage after LSG [25,26].

From these studies it is clear that SLR needs more analysis. Considering the low occurrence of leaks after LSG, large numbers will be required to detect a significant difference among the various techniques [27].

This retrospective study included patients from 4 high volume centers, considering almost all of the available techniques for SLR, compared with a no-SLR control group. Among the buttressing tools, Peri-Strips Dry is a nonabsorbable vacuum-dried bovine pericardium strip; Seamguard is made from polyglycolide acid and trimethylene carbonate and is degraded through hydrolytic and enzymatic pathways, and both are mounted on the stapler before cutting the stomach. Duet-TRS is a single-use stapler-loading unit with integrated strips of absorbable synthetic polymer. Floseal is a thrombin matrix, which improves hemostasis and is reabsorbed within a few weeks. In our sample of >1000 patients, the present study showed a 2.8% frequency of leak, in line with other studies [24,28].

Postoperative leaks are hypothesized to be caused by compromised blood supply at the staple line, high intraluminal pressure related to the long tubularization of the stomach, and mechanical failure of the stapler with incomplete sealing [17,27]. Leaks most commonly occur in the upper portion of the sleeve, below the gastroesophageal junction, and this was confirmed in the present series. One of the reasons could be the thinner gastric wall at this location that is less resistant to increased intraluminal pressure. Leaks at the body/antrum are believed to be caused by an incomplete closure of the staple line. In both instances, buttressing the staple line might decrease the leak rate.

Comparing the SLR techniques and leak rate, a significant reduction using Peri-Strips Dry (.3%) was observed. Reinforcement with bovine pericardium is significantly more effective than all the other techniques; however, there was a decrease in all the SLR methods compared with the control group, except using Duet-TRS, which was associated with more leaks. Thus, the possibility of a staple line leak persists despite SLR.

The potential effects of other parameters, including age, gender, preoperative BMI, and diagnosis of T2 DM, on postoperative complications was analyzed. Multivariate analysis found that T2 DM was an additional risk factor for staple line leak, which could be due to impaired healing from a peripheral microangiopathy associated with this disease.

In terms of postoperative staple line bleeding, a 3% overall frequency was observed, which is similar to other data in the literature [8]. Overall, reinforcement of the staple line in this series significantly reduced the risk of postoperative bleeding. The control group showed an incidence of bleeding >10 times higher than the SLR group.

Several authors reported that SLR through oversewing might increase the risk of tearing at the point of suture penetration, which may itself increase the risk of bleeding or leak [29]. In our series, this step was performed by imbricating the staple line with an absorbable running suture; no complications specifically related to this method was observed, with no increase of staple line hemorrhage. The various SLR techniques were considered, but the sample size of the present study was not sufficiently large to demonstrate a significant difference between the different techniques in reducing the risk.

The main limitation of this study is that it was retrospective, and in the allocation process, the patients were not randomized with a formal protocol into the study groups. The authors recognize that this can be a bias in the analysis of the results; however, waiting for future prospective

randomized trials, some consideration about SLR can be done from this large series.

Conclusion

SLR, proposed as a method to reduce bleeding and leak after LSG, is advocated by many surgeons. To date, no clear consensus exists regarding its efficacy. The results of this multicenter study indicate SLR with bovine pericardium (Peri-Strips Dry) significantly reduced the risk of postoperative leak compared with all other SLR techniques and with the no-SLR group. Patients with T2 DM had a higher risk of staple line leak. The risk of postoperative staple line bleeding was reduced by all methods of SLR, although our sample size was not sufficiently large to detect any difference among the various methods. Further research with large numbers of patients in randomized, controlled trials are needed to improve our understanding of the efficacy of the different SLR techniques during LSG.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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