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**Georges Nabih Al Hajj & Johnny Haddad**

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# Preventing Staple-Line Leak in Sleeve Gastrectomy: Reinforcement with Bovine Pericardium vs Oversewing

Georges Nabih Al Hajj · Johnny Haddad

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**Abstract** One of the most serious, potentially life-threatening complications of laparoscopic sleeve gastrectomy (LSG) is staple-line leakage. Oversewing the LSG staple line vs buttressing it with bovine pericardial strips (BPS) to reduce perioperative bleeding and postoperative gastric leak was evaluated. From 2006 through 2011, 160 patients underwent LSG with suturing as the only staple-line reinforcement (Group A). From March 2010 through August 2012, 84 LSG patients had BPS incorporated into their last two stapler firings (Group B). Staple lines were evaluated perioperatively for bleeding, and patients were monitored for indications of staple-line leaks (peritonitis, abnormal output from the drain). In preoperative Group A and B, there were 117 (73.1 %) vs 56 (66.7 %) females; mean age, 35.2 years (18.0–68.0) vs 33.8 years (15.0–64.0); mean body mass index (BMI, kilograms per square meter), 42.5 (27.0–76.0) vs 42.0 (30.0–58.0). Three months after surgery, mean BMI for Group A was 37.3 (–5.9); Group B, 35.2 (–7.3); at 6 months, 32.7 (–10.8) and 31.5 (–11.3;  $p < 0.001$ ). Although there was no significant difference in perioperative blood loss, oversewn staple lines in Group A often required electrocautery to stanch bleeding; this was not required for Group B. In Group A, 15 patients (9.4 %) developed complications; in Group B, five (6.0 %;  $p = 0.46$ ). Gastric fistula, verified by barium swallow, occurred in eight Group A patients (5.0 %); in Group B, one (1.2 %;  $p = 0.17$ ). Relative to oversewing, staple-line buttressing with bovine pericardium was readily accomplished, safe, and associated with a lower staple-line leak rate.

**Keywords** Bariatric surgery · Laparoscopic · Sleeve gastrectomy · Morbid obesity · Gastric leak · Staple-line reinforcement · Buttress material · Bovine pericardium

## Introduction

Sleeve gastrectomy (SG) is a restrictive procedure initially developed as part of a staged approach for high-risk, super-obese patients [1, 2]. Since 2006, SG has been increasingly performed as a stand-alone bariatric procedure with good weight loss and resolution of obesity-related comorbidities [3–17].

SG, whether performed by open surgery or laparoscopy (LSG), involves the creation of a small gastric reservoir based on the gastric lesser curvature over an orogastric tube, in addition to removal of a large portion of the greater curvature. LSG produces a decrease in ghrelin levels for up to 1 year, which may reduce the desire for food [18, 19]. Notable advantages of LSG include low rates of complications (3–24 %) and mortality (0.39 %), the ease of performing the procedure, preservation of the pylorus, maintenance of physiological food passage, and avoidance of foreign material [11–13, 20].

The most commonly reported complications of LSG are bleeding, stenosis, and leaks. Bleeding can occur from gastric blood vessels during dissection of the greater curve of the stomach. Most bleeding problems associated with LSG occur from the staple line after transection of the stomach [9, 21]. This bleeding is most likely a result of the large staples used for the thick tissue in the distal stomach. Large staples are not adequate to seal small vessels [22].

Gastric leak after LSG is a serious complication, and reports of its incidence in numerous studies range from 0 % to 5.7 % of patients [6, 9, 23–30]. Many surgeons have investigated the reinforcement of staple lines as a means of reducing gastric leaks after LSG. These efforts have included staple-line oversewing, covering with omentum or jejunum, applying

G. N. Al Hajj (✉) · J. Haddad  
 Middle East Institute of Health (MEIH), Bsalim, Lebanon  
 e-mail: drghage@idm.net.lb

J. Haddad  
 e-mail: raniahaddad@cocogroup.info

fibrin glue, and buttressing the staple line with a material that has been preloaded onto the stapler gun [31–38].

In this study, we investigated the efficacy of treated bovine pericardial strips (BPS) as the buttressing material used in the last two stapler firings administered during construction of the LSG staple line. We compared complication rates with a special focus on fistula in two groups of LSG patients: an initial group of 160 whose staple lines were oversewn, and 84 who received BPS staple-line buttressing. A follow-up qualitative analysis profiled characteristics of patients who developed postoperative gastric fistula.

## Methods

### Patient Eligibility and Informed Consent

Patients seen at the Middle East Institute of Health in Bsalim, Lebanon for treatment of morbid obesity underwent a multi-disciplinary evaluation and preparatory process for bariatric surgery by the various clinicians of the Institute's Obesity Consult Center. Patients were considered eligible for LSG if they met the indications for bariatric surgery of the International Federation for the Surgery of Obesity (IFSO) and the National Institute of Health (NIH) [39, 40]. Informed consent was obtained from all patients.

### Study Design

In this retrospective analysis of prospectively collected data, 244 patients were studied who qualified to receive LSG between 2006 and 2012. Group A was comprised of 160 patients who underwent LSG with continuous oversewing as the only form of staple-line reinforcement (Ti-Cron™ 2–0 suture, Covidien, Mansfield, MA, USA). Group B was comprised of 84 patients who, beginning in March 2010, underwent LSG with oversewing of the staple line and BPS [using Peri-Strips Dry® (PSD) with Veritas® collagen matrix, Synovis/Baxter Healthcare, St. Paul, MN, USA] incorporated into the last two Endo GIA® stapler firings (using the Endo GIA™ Ultra Universal Stapler, Covidien, Mansfield, MA, USA). LSG procedures were performed by the same surgeon and surgical team in an operating room dedicated to obesity procedures.

### Surgical Technique

Antibiotic prophylaxis was administered 30 min prior to the surgical incision and in three doses postoperatively. All patients received venous stasis prophylaxis by external pneumatic compression at the time of surgery and low-molecular heparin 6–8 h after surgery for the duration of hospitalization.

Under general anesthesia, the patient was placed in reverse Trendelenburg lithotomic position, arms and legs abducted,

with the surgeon positioned between the patient's legs, the first assistant on the patient's right, and the second assistant on the patient's left. Closed CO<sub>2</sub> pneumoperitoneum was induced by Veress needle insertion 20 cm below the xiphoid process in the midline. Five trocars were positioned in the usual manner.

We proceeded with a standard SG starting at the distal greater curvature and using the Ligasure as a vessel-sealing device. Serosal attachments of the posterior gastric wall to the pancreatic capsule were kept in order to prevent subsequent gastric rotation. The stomach was calibrated with the help of a 36-Fr orogastric tube.

All of the resection was accomplished by firing green endoscopic linear stapler cartridges (Powered Multifire Endo GIA™ 60 stapler with the Powered Multifire Endo SGIA™ 60–4.8 knifeless single-use loading unit; Covidien). Between five and eight cartridges were used in each operation depending on the length of the resected stomach. In Group A, after electrocautery was used to control small venous oozing along the nonbuttressed transection line, the line of staples was reinforced with a manual, running, nonabsorbable, Ti-Cron 2–0 seroserosal suture. In Group B, PSD BPS was applied to the Endo GIA™ in the last two firings, and the nonbuttressed caudal part of the transected stomach was reinforced and not imbricated in the same fashion as with Group A.

No nasogastric tube was left in place. In rare instances, a methylene blue dye test for determination of staple-line integrity was performed. A 14-Fr thoracic drain was placed under and along the remaining stomach. The resected stomach was removed through the 15-mm trocar, usually without elongating the incision. No fascial defects were closed.

### Data Collection

Baseline patient characteristics, including age, gender, height, weight, BMI, and comorbid conditions, were recorded in the program's bariatric database. Operative time, blood loss, and complications were recorded. In addition, ease of BPS use and, if visible, bleeding from the staple lines was noted.

After discharge, all patients were followed per the protocol established by the Institute's Obesity Consult Center, including initial surgical, medical, and dietetic consultation 10 days after hospital discharge and regular follow-up appointments every 3 weeks thereafter. Although postoperative radiographic or endoscopic studies were not routinely performed, these studies were conducted on patients who returned for a follow-up appointment with any gastrointestinal symptoms, such as pain, vomiting, or inadequate weight loss. Data from the BPS patients were compared retrospectively to those for the patients who underwent the same procedure without BPS.

## Statistical Analysis

Statistical analyses were performed using the SPSS® software package (version 20, IBM SPSS, Chicago, IL, USA). Quantitative demographic variables were reported as mean, standard deviation (SD), and range. Qualitative variables (demographic and outcome variables/complications) were reported as number and percentage. Between-group comparisons along quantitative measures were carried out using the independent samples *t* test. Fisher's exact test was used to assess relationships between qualitative variables. Continuous outcome variables were reported as mean, SD, and 95 % confidence interval (95 % CI). Measures of weight change from baseline at 3 and 6 months were analyzed using the paired-samples *t* test. Alpha was set at  $p < 0.05$ ; all statistical tests were two-tailed.

## Results

### Patient Characteristics, Operative Time, and Hospital Stay

As shown in Table 1, generally, baseline patient characteristics were not significantly different with the exception of Group A reporting more hypertension and Group B reporting a greater number of other comorbidities. For Group A, the mean age was 35.2 years, and 33.8 years for Group B. Mean BMI was 42.5 kg/m<sup>2</sup> for Group A and 42.0 kg/m<sup>2</sup> for Group B. The two groups did not differ with respect to operative characteristics

**Table 1** Preoperative patient characteristics

Variable	Group A (oversewing) <i>n</i> = 160	Group B (BPS) <i>n</i> = 84	<i>p</i> value
	Mean±SD (range)		
Age (years)	35.2±10.5 (18.0–68.0)	33.8±10.3 (15.0–64.0)	NS ( $p = 0.29$ ) <sup>a</sup>
BMI (kg/m <sup>2</sup> )	42.5±7.5 (27.0–76.0)	42.0±5.8 (30.0–58.0)	NS ( $p = 0.59$ ) <sup>a</sup>
Females	117 (73.1)	56 (66.7)	NS ( $p = 0.30$ ) <sup>b</sup>
Prior surgery	37 (23.1)	24 (28.6)	NS ( $p = 0.36$ ) <sup>b</sup>
Comorbidities			
Hypertension	50 (31.2)	16 (19.0)	$p < 0.05$ <sup>b</sup>
T2DM	45 (28.1)	15 (17.9)	NS ( $p = 0.09$ ) <sup>b</sup>
Respiratory disorder	65 (40.6)	38 (45.2)	NS ( $p = 0.50$ ) <sup>b</sup>
Other comorbidities	22 (13.8)	36 (42.9)	$p < 0.001$ <sup>b</sup>

BPS bovine pericardial strips, SD standard deviation, NS nonsignificant, BMI body mass index, T2DM type 2 diabetes mellitus

<sup>a</sup> Independent samples *t* test

<sup>b</sup> Fisher's exact test

and length of hospital stay. Mean operating time was 165 min, mean blood loss was 75 cm<sup>3</sup>, and mean hospital length of stay was 5.6 days.

### Weight Loss

At 3- and 6-month follow-up, both groups had lost significant weight relative to baseline. At 3 months, BMI in Group A had decreased by 5.9±10.3 kg/m<sup>2</sup> (95 % CI, 3.9, 7.9), from 43.2±8.1 to 37.3±12.8 ( $p < 0.001$ ); Group B BMI decreased 7.3±2.3 (6.6, 8.0), from 42.5±6.1 to 35.2±5.4 ( $p < 0.001$ ). At 6 months, Group A BMI decreased 10.8±5.3 (9.6, 11.9), from 43.4±8.7 to 32.7±7.3 ( $p < 0.001$ ); Group B BMI decreased 11.3±3.2 (9.9, 2.7), from 42.8±5.9 to 31.5±4.7 ( $p < 0.001$ ).

### Mortality, Complications, and Leak Rate

No mortality occurred. As shown in Table 2, 15 (9.4 %) patients in Group A experienced complications vs five (6.0 %) patients in Group B (NS,  $p = 0.46$ ). Eight (5.0 %) of the 160 patients in Group A and one (1.2%) of the 84 patients in Group B developed fistula (NS,  $p = 0.17$ ), interpreted as a manifestation of acute staple-line failure. All fistulae occurred in the GEJ close to the angle of His; as all fistulae were proximal, we added buttressing material to the last two Endo GIA firings. In addition, in Group A, one (0.6 %) patient experienced severe bleeding, and numerous others developed minor bleeding from their staple lines. Without exception, BPS-reinforced staple lines had essentially no visible bleeding; however, no significant difference in mean blood loss between groups was observed (NS,  $p = 0.39$ ). Finally, four (2.5 %) Group A patients and one (1.2 %) Group B patient required reoperation (NS,  $p = 0.66$ ).

Table 3 shows characteristics of the patients who developed fistulae. Data on fistulae were analyzed according to patient risk factors, time of occurrence after surgery, manifesting signs and symptoms, location, and medical and surgical management. Both BMI and history of previous surgery appeared to correlate with fistula development: Most fistulae occurred in patients with a BMI > 40 (6/9; 67.0 %), and five of the nine (56.0 %) patients with this complication had undergone previous abdominal surgery.

The nine fistulae developed between 2 and 4 weeks after surgery. Eight of nine patients (89.0 %) with fistula had fever and tachycardia as the first manifesting signs. Left shoulder pain was reported by six of nine patients (67.0 %) with fistula. An external drainage was the only presenting symptom in a 48-year-old female patient; this patient had a BMI of 57 and a history of laparoscopic cholecystectomy and abdominoplasty. Laboratory studies showed an increased white blood cell count and increased CRP in all patients with fistula. Patients with a suspected postoperative leak underwent a barium swallow test to confirm leak/fistula. In most cases,

**Table 2** Comparison of postoperative complications

Complication	Group A (oversewing) <i>n</i> = 160	Group B (BPS) <i>n</i> = 84	<i>p</i> value <sup>a</sup>
Food intolerance, <i>n</i> (%)	1 (0.6)	0 (0.0)	–
Hemorrhage, <i>n</i> (%)	1 (0.6)	0 (0.0)	–
Stenosis, <i>n</i> (%)	1 (0.6)	1 (1.2)	–
Abscess, <i>n</i> (%)	4 (2.5)	2 (2.4)	–
Splenic infarction, <i>n</i> (%)	0 (0.0)	1 (1.2)	–
Fistula, <i>n</i> (%)	8 (5.0)	1 (1.2)	NS ( <i>p</i> = 0.17)
Total	15 (9.4)	5 (6.0)	NS ( <i>p</i> = 0.46)

BPS bovine pericardial strips

<sup>a</sup> Fischer's exact test

a double-contrast abdominal computed tomography scan with intravenous and water-soluble oral contrast was also performed.

**Discussion**

Complications of LSG

Bleeding and staple-line leak, although rare, are the most common complications of LSG [6, 9, 23–30]. Bleeding usually occurs along the staple line, or the greater omentum, once freed from the greater curvature of the stomach [20].

Numerous factors have been implicated in the development of staple-line leaks. Most leaks are due to local factors at the staple line, such as inadequate blood supply and oxygenation,

which can impede healing. Gastric-wall heat ischemia, due to heat generated by the cautery used during dissection of the greater curvature, also may play a role in leaks subsequent to LSG. The LSG procedure produces high intragastric pressure, which can lengthen the amount of time needed for a leak to close [41]. Innate characteristics of the stomach also play a role in post-LSG leaks. Although the blood supply to the stomach is robust, the gastroesophageal junction tends to be an area of decreased vascularity and, thus, is more prone to leaks. In addition, the stomach is typically thinner at the angle of His, and some authors suggest that the large staple height used by many surgeons may not adequately seal this area [22].

Leak after LSG usually appears distal to the gastroesophageal junction, with an incidence between 0 % and 5.7 % [6, 9, 23–30]. Leaks in this area may be related to high intraluminal pressure caused by the vertical tubulization of the stomach [41]. This pressure is amplified by the low compliance of the sleeve, which is ten times less than the compliance of the complete stomach or the resected fundus [42]. These findings, in addition to our own Group A results, influenced our choice to buttress the last two stapler firings at that region in Group B.

Although there was no significant difference in operative blood loss between the current study groups, staple lines without BPS often required electrocautery to stanch minor bleeding, which was not necessary for any buttressed staple lines. Bleeding in the non-BPS group was usually venous ooze but occasionally involved small pumping arterioles. Management of this slight bleeding probably had a marginal effect on case time, but it disrupted operative momentum.

The surgical team readily gained proficiency in the technique of BPS reinforcement (i.e., loading BPS onto stapler cartridges). In some instances, the stapler was found to jam

**Table 3** Patients with acute staple-line leak (fistula)

Age (years)	Sex	BMI (kg/m <sup>2</sup> )	Prior surgery	Time of occurrence after surgery (weeks)	Symptoms	Initial treatment	Secondary treatment	Final treatment (if needed)	Total treatment duration
Group A (oversewing)									
45	M <sup>a</sup>	41	Hiatal hernia	2	PT+LSP	ATB+TPN+D	Endoprosthesis	Total gastrectomy	8 months
21	M <sup>a</sup>	N/A	None	2	PT+LSP	ATB+TPN+D	Fibrin glue coil	None	8 months
26	F	40.1	None	2	PT+LSP	ATB+TPN	None	None	3 weeks
48	F	57	Cholecystectomy+ abdominoplasty	3	External D	ATB+TPN	Endoclip+FJ	RNY	6 months
49	F	44	Endometriosis	3	PT+LSP	ATB+TPN+D	RNY	None	6 months
33	F	32	Gastric banding	2	PT+LSP	ATB+TPN	Surgical D	None	2 months
22	M <sup>a</sup>	76.2	Umbilical hernia	2	PT	ATB+TPN+D	Endoprosthesis coil	RNY	8 months
37	F	NA	None	4	PT	ATB+TPN+D	Coil	FJ	6 months
Group B (BPS)									
52	F	43	None	4	PT+LSP	ATB+TPN	RNY	None	1 month

M male, F female, BMI body mass index, PT pyrexia and tachycardia, LSP left shoulder pain, TPN total parenteral nutrition, ATB antibiotic, D drainage, RNY Roux-en-Y gastric bypass, FJ feeding jejunostomy, N/A not available, BPS bovine pericardial strips

<sup>a</sup> Referred case

secondary to excessive thickness of the stomach wall, or a mechanical problem with the stapler itself. Nevertheless, no meaningful increase in operating time was attributable to BPS buttressing.

Specific patient risk factors may increase susceptibility to staple-line leaks. Of the nine patients who developed fistulae in our study, most had a BMI > 40 and had undergone an earlier abdominal surgery. In our experience, increased BMI and a history of previous abdominal procedure are potential risk factors for leak occurrence after LSG.

### Staple-Line Buttressing

Mechanical staplers are a mainstay of laparoscopic gastrointestinal surgery, and in particular, bariatric surgery. Staple-line failure, although uncommon, can result in significant morbidity and mortality. At our institution, before we began the practice of buttressing, we used suturing to improve the durability of staple lines. Although staple-line buttressing is used in many bariatric operations, the practice has been explored with variable clinical efficacy and no conclusive data in LSG [30–35, 37, 38].

The procedure involves preloading buttressing material onto the stapler gun so that it becomes incorporated into the staple line with firing. The ideal buttress material should be flexible and thin in order to be easily cut by the stapler's blade and should also enhance the strength of the staple line. Buttressing distributes the compressive force of the staples, resulting in decreased bleeding and risk of leak. In animal studies, the practice is known to increase burst pressure and decrease hemorrhage [43, 44], and it has proved beneficial in other types of operations performed in humans [45–50].

Treated BPS are a buttressing material that adds thickness and, potentially, strength to the staple line. The treated strips of pericardium are manufactured to fit the stapler device and are “stapled” onto the tissue when the device is fired. The strips add approximately 1 mm of thickness to the staple line, making it tighter and theoretically stronger. Two dehydrated BPS are secured on each side of a foam spacer by a plastic mounting unit. BPS (PSD) hydrogel creates a temporary bond between the strips and the forks of the stapler, promoting rehydration of the strips.

There is evidence that suggests the benefits of BPS as a buttressing material. Animal research has shown that staple lines incorporated with BPS (PSD product) have higher burst pressures than those without it [51]. In humans, BPS (PSD) has been successfully used to reinforce staple lines in pulmonary resections [45–47]; in that setting, the strips significantly reduced the incidence and duration of postoperative air leaks. The initial experience with BPS (PSD) buttressing of gastric staple lines in laparoscopic gastric bypass showed a trend toward decreased occurrence of hemorrhage and, possibly, of leaks as well [33].

The 2011 Third International Summit publication on sleeve gastrectomy summarized questionnaire responses from 88 experienced LSG surgeons who had performed 19,605 LSGs with a 1.3 % proximal leak rate. Of these practitioners, 57.0 % reinforced the staple line with buttress material and 43.0 % reinforced it with oversewing [52]. As summarized in a 2012 publication of the International Sleeve Gastrectomy Expert Panel (a group of expert surgeons overlapping those in the Third International Summit report), LSG evidence from >12,799 procedures incurring a 1.06 % leak rate led to 100.0 % consensus that staple-line reinforcement (kind unspecified) reduces staple-line bleeding, with consensus that both oversewing and buttressing reinforcement are acceptable choices [53]. Despite the low rate of leak in these expert hands, leak was deemed a highly problematic LSG issue, with neither oversewing nor buttressing yet advocated as the preferred reinforcement methodology.

Use of BPS for gastric staple lines is an attractive concept. The moderate cost per application must be considered; BPS (PSD) sleeves cost approximately \$135.00 per application, and four to seven applications may be necessary to divide the stomach. In our hands, only two BPS applications were required in the last two stapler firings, adding to the cost effectiveness of the procedure and lending support to the high-pressure theory at the angle of His. Application of BPS requires some training and experience. Increased care is necessary to choose the correct cartridge size to fit the tissue thickness; if the staple height is too small to accommodate the tissue and the BPS, or if BPS is improperly loaded, the stapler may misfire. Also, if the BPS become wet from blood or fluid, they may float off the staple cartridge. In rare instances, the stapler jammed secondary to excessive thickness of the stomach wall or a mechanical problem with the stapler itself, a problem not seen in staple lines that were sutured and not buttressed.

Overall, our institution observed that the advantages of BPS buttressing far outweighed the disadvantages. While BPS cost is not negligible, it is a very minor consideration relative to the human and financial cost of staple-line failure. Death may result if leak is not identified and treated rapidly; complications associated with staple-line failure can necessitate the expenditure of hundreds of thousands of dollars. Our surgical team found that BPS buttressing (1) was easy to use; (2) resulted in staple lines with no visible bleeding that were often completely dry; (3) created excellent, sturdy handles that afforded greater and safer retraction than native gastric tissue; and (4) added only a few minutes to procedure length.

### Limitations

There are two important limitations of this study. First, this was not a randomized, prospective trial but rather a comparison of two sequential operative techniques. The 160 patients

whose staple lines were oversewn represented the earlier part of the authors' experience with LSG, and therefore, the results may have been influenced by the significant learning curve of this procedure. Second, the relatively small sample size limited the power of the study.

## Conclusions

Increasingly, primary health-care providers refer obese patients for bariatric surgery; the total number of bariatric procedures is rising. Any technique that reduces the staple-line failure rate will improve patient quality of life and reduce health-care costs. In our study, both groups were comparable in terms of baseline characteristics and early weight-loss outcomes. Also, although the difference in complication rates between LSG procedures with oversewing and those with BPS was not statistically significant, the positive results with regard to leak rate experienced by the BPS group may represent a clinically significant effect. Eight to nine percent of fistula observed in the current study occurred in patients that did not receive BPS. Further study employing greater statistical power is required to quantify and confirm benefits of BPS buttressing.

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