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RESEARCH ARTICLE

Reinforcement Does Not Necessarily Reduce the Rate of Staple Line Leaks After Sleeve Gastrectomy. A Review of the Literature and Clinical Experiences

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Abstract
Background Laparoscopic sleeve gastrectomy (SG) is an accepted bariatric procedure, with an advantaged by a low complication rate. A feared complication is stapler line leak. Buttressing materials have been suggested as a means of reducing staple line leak rates. We analyzed the leak rates from published series to help in demonstrating a potential cause.
Methods The study was institutional review board (IRB) approved retrospectively. A Medline search using the key words *sleeve gastrectomy* and *bariatric surgery* obtained 54 articles. Attention was restricted to 11 articles written in English that listed numbers of gastrectomy procedures and leaks. Poisson regression assessed the possibility that patients who received buttressing materials had a reduced rate of leaks.
Results Thirty-five patients were evaluated from Greece (15) and the United States (20); two patients developed staple line leaks that appeared to be related to problems associated with buttressing materials. Eleven prior studies and the present series yielded 1,589 procedures, 15 (0.94%) of which were complicated by leaks. The leak rate for patients who were known to have received reinforcement of some sort was 1.45 (95% confidence interval 0.41–3.43) times that for other patients. To detect a difference between 1% and 0.5% as statistically significant in 80% of cases, with a two tailed test and alpha set at 0.05, would require 9,346 procedures.
Conclusions There is no reason to believe, at this point, that reduction in leak rates occur because reinforcement is used. Because the leak rate is small, the routine reinforcement of the staple line after sleeve gastrectomy is questionable at best, although a decrease in hemorrhage has been reported.

Keywords Polytetrafluoroethylene · Bovine pericardium · Porcine small bowel · Polyglycolic acid · Trimethylene carbonate · Calcium alginate sleeves · Sleeve gastrectomy · Complications · Leaks · Morbid obesity · Staple line · Review of literature

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Introduction

The lack of implanted nonabsorbable material, the retention of normal gastrointestinal (GI) continuity, the avoidance of malabsorption, and convertibility to other operations makes the laparoscopic sleeve gastrectomy (LSG) a more widely used bariatric procedure [1–2]. According to the American Society for Metabolic and Bariatric Surgery, it is still considered experimental [3]. Stomach dissection usually

requires at least four to five stapler cartridges and a reload of 60 mm staples, preferably green in our experience to resect from the antrum to the gastroesophageal junction, the length of which increases the risk of staple-line bleeding, staple-line leaks, and dehiscence. Attempts to optimize the staple line have included oversewing it with suture, covering it with omentum or jejunum, and reinforcing it with an array of materials [4–8]. Reinforcement has been shown in other operations to increase burst pressure and decrease hemorrhage [6–10] but no final answers have been found for leaks. According to the First International Sleeve Consensus [11], surgeons were divided between those who reinforced with buttress material, those who oversewed, and those who did not do either. Materials used for reinforcement have expanded to polytetrafluoroethylene (ePTFE; W. L. Gore & Associates Inc., Flagstaff, AZ, USA), bovine pericardium (BPS; Peri-Strips Dry, Synovis, St. Paul, MN, USA), small intestinal submucosa (Surgisis; Cook, Inc., Bloomington, IN, USA), and the bioabsorbable polyglycolide acid and trimethylene carbonate (SeamGuard, W.L. Gore & Associates, Inc.) [5–8]. We hypothesized that reviewing the SG series in the literature, after our initial experience, would yield information with respect to the relationship of staple line reinforcement and leak risk.

Materials and Methods

A retrospective study with institutional review board approval was performed in patients who underwent LSG with a minimum of 12-month follow-up. We matched two cohorts of patients from the US (group A) and Greece (group B). A Medline search using the key words *sleeve gastrectomy*, *leak complications*, and *bariatric surgery* made by an independent research fellow (BC) obtained 54 articles. Attention was restricted to articles written in English that listed the number of gastrectomy procedures and the number of procedures complicated by leaks. The meta-analysis of the patients with leaks was conducted with the Poisson regression test. It analyzed the leak rates to determine point estimates and 95% confidence intervals (CI) of the rate ratios of (1) patients who had received buttressing material versus those who either did not receive buttressing material or whose status in this respect was unknown and (2) patients whose status with respect to buttressing was unknown versus patients who did not receive buttressing material. The second comparison was made to take into account the potential for bias in the literature that exists with respect to the lack of reporting of the presence or absence buttressing material in some of the studies. Statistical comparisons of group A and B patients included Fisher's exact test and the Wilcoxon rank sum test, as appropriate. Null hypotheses were rejected when $p<0.05$. *R* was used to perform all statistical analyses and power analysis.

Surgical Technique

Preoperatively, all patients underwent extensive medical clearance and were given 1–2 mg/kg subcutaneous low molecular heparin before starting the operation, as described by a previously reported protocol on morbid obese patients undergoing bariatric surgery [12]. For group A, one 12 mm, one 15 mm, and three 5 mm trocars were used (Ethicon; Cincinnati, OH, USA); for group B patients, three 12 mm and two 5 mm trocars were used. After identifying the gastric antrum by measuring out the distal 10 cm from the pylorus on the greater curvature, an ultrasonic dissector created a window into the lesser sac. Ultrasonic scissors then divided gastrocolic and gastrosplenic ligaments to the gastroesophageal junction. A sleeve was formed over a 36-Fr bougie in group B and over a 29-Fr endoscope in group A. A green stapler (Covidien; Hartford, CT, USA) then resected the stomach, which was then extracted through the umbilicus. The staple line using SeamGuard and Peri-Strips was used for reinforcement. No drains were placed. The stapler line was tested with pneumatic test in both groups. A nasogastric tube was left in place in group B only. Provided an upper GI series with Gastrographin® was normal, the nasogastric tube was removed on the first postoperative day, with discharge from the hospital on a liquid diet occurring between one (group A) and two (group B) days postoperatively. Follow-up after surgery was at 10 days and then every 3 months. The % excess weight loss (EWL) was calculated at 12 months.

Results

Details of Our Cohort Patients' Reinforcement Failures

A 22-year-old American woman with a body mass index (BMI) of 52.3 kg/m^2 underwent SG. One week after surgery, she developed pneumonia and left upper quadrant pain. An upper GI series showed a small leak, which was drained first. At laparoscopic examination, Peri-Strips were not present about the staple line. The peritoneal cavity was carefully washed, and multiple drains were laced. After 6 weeks of total parenteral nutrition, high gastric bypass was performed.

A 32-year-old Greek woman with a BMI of 41 kg/m^2 underwent SG. On postoperative day 2, the patient presented with intra-abdominal hemorrhage and was taken to the operating room for exploration. At open exploration, a small dehiscence at the staple line was found associated with misplacement of the Peri-Strips. A stitch corrected the

Table 1 The patients' demographics and operation data of both studies

Variable (range)	Greek group	US group
Male	9	2
Female	6	18
Age (years)	40.4(17–60)	50(23–62)
Preoperative weight(kg)	138.8(90–189)	140(89–193)
Preoperative BMI (kg/m^2)	47.8(38.6–66.2)	51 (37–71)
Final BMI	37 (34–40)	30 (27–32)
OR time (min)	147.6(90–240)	70(55–85)
Conversion	1 (8.3%)	0
Postoperative complication	1 staple-line leak (8.3%)	1 staple-line leak (5%)
Follow-up (months)	15	18
Mean % EWL (12 months)	36	53*
Mean number comorbidities	5	10

*$p<0.001$

problem, with reinforcement by omentum. A drain was placed and removed within a week. A stricture developed at the level of the leak which required revision surgery 4 weeks later.

The Two Cohorts

Table 1 describes the gender, conversion rate and median (interquartile range) age, number of comorbidities, and percent excess weight loss in the two groups, along with the results of statistical tests that compared them. One leak occurred in one of 20 patients who underwent SG in group A; another leak occurred in one of 18 patients who underwent SG in group B. In group A, the leak was at the crossing between the antrum and the body of the stomach. In group B, it was in the antrum. Both leaks were reinforced with Peri-Strips. The staples started about 8–10 cm from the pylorus.

Review of the Literature

Results of the 11 studies that met our meta-analysis criteria, as well as the current study, are supplied in Table 2 [13–24]. Staple leaks complicated 15 of 1,589 (0.94%) procedures. As displayed in Fig. 1, Poisson regression showed that patients who received reinforcements had a leak rate that was 1.45 (95% CI 0.41–3.43) times that of other patients; there was no reason to believe that reinforcement provided protection against leaks. There was also no reason to believe a difference existed between patients' reinforcement status was unknown and patients who had had no reinforcement; the ratio was 0.65 (95% CI 0.37–1.17). Because the leak rate was less than 1%, the sample size required to detect even relatively large differences in leak rate would be quite large. To detect a difference between 1% and 0.5% as statistically significant in 80% of cases, with a two tailed test and alpha set at 0.05, would require a sample size of 4,673 procedures per group or a total of 9,346 procedures.

Discussion

Results of the Two Cohorts

In our total experience in two centers, we found one leak in 20 patients which was one in group A and one in group B during the learning curve. Therefore, most of the leaks or potential complications happened in the first 20–50 patients

Table 2 Studies of staple line leaks after sleeve gastrectomy

Study	Surgery	Leaks	Procedures	Staple used	Reinforcement
Serra et al. [14]	SG alone or combined DS	6	993	Unknown	Unknown
Givon-Madhala et al. [4]	LSG	0	25	Linear stapler–cutter	Oversewing
Lalor et al. [16]	LSG or SG	2	164	Unknown	Unknown
Bernante et al. [17]	LSG after LAGB	0	8	Linear stapler	Oversewing
Mognol et al. [18]	LSG	0	10	Unknown	Unknown
Cottam et al. [19]	LSG	2	126	Endo-GIA	Unknown
Han et al. [20]	LSG	1	130	Endo-GIA	Unknown
Baltasar et al. [21]	LSG	0	31	Linear stapler	BPS
Consten et al. [13]	LSG/ BPD-DS	1	10	Linear stapler	No reinforcement
Consten et al. [24]	LSG/ BPD-DS	0	10	Linear stapler	SeamGuard
Regan et al. [22]	LSG	0	7	Unknown	Unknown
Ren et al. [23]	SG combined DS	1	40	Linear stapler	Unknown
Current study (2008)	LSG	2	35	Linear stapler	Peri-Strips

SG Sleeve gastrectomy, *LSG* laparoscopic sleeve gastrectomy, *LAGB* laparoscopic adjustable gastric band, *BPD-DS* biliopancreatic diversion with duodenal switch, *BPS* bovine pericardium, *DS* duodenal switch

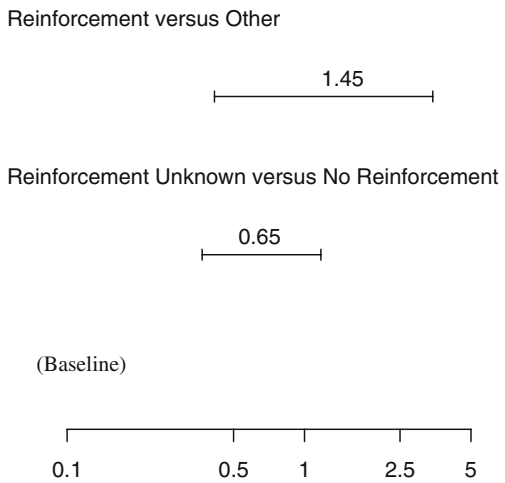

Fig. 1 Poisson regression comparing Medline papers found reporting leak. Point estimates and 95% confidence intervals for leak rate ratios after sleeve gastrectomy from studies in Table 3, as calculated by Poisson regression

and complications tended to decrease over time. On follow-up at 15 months in group B and 18 months in group A, we found that there was a significant difference between the two techniques which gave group A 53% excess weight loss and only 36% EWL in group B ($p<0.001$). Group A seems to be more at risk given the fact that they have an average of ten comorbidities compared to five comorbidities in group B. No conversion was described in group A and the operating time seems to be less. Another notation is that in group A, most of the operations were performed on women while in group B, there were more men than women. If we take the overall results and included the two experiences, a final conclusion of when to use buttress suture remains unclear and that was the reason to look more carefully at the published papers on the subject. Management of the leak was to place a stitch in group B while in group A, the patient was drained surgically first and then a gastric bypass was performed.

The results of this analysis raise questions about the wisdom of using staple line reinforcement in SG. Reported here are the findings that each of two patient's leaks after SG could have resulted from problems with buttressing material. When the current findings are placed in context with those of the literature, a very small, less than 1%, risk of leaks is observed, with no reason to suspect that buttressing material reduces that risk; in fact, the point estimate would suggest an increment. Table 3 reports the available staple-line buttressing materials. Because the risk of leak in sleeve gastrectomy is so small, almost 10,000 procedures would be required to detect the halving of the leak rate. Stapling, more facile than the hand-sewn technique, is the mainstay of gastrointestinal surgery [13]. It is interesting that both leaks came after Peri-Strip usage on a 60-mm green stapler. This was probably due to a lack of position of the Peri-Strips to the stapler by the glue; therefore, we suggest waiting the necessary time before using Peri-Strips. By waiting longer for the glue to work, we did not have any more problems. Another complication found with Peri-Strips was the migration into the stomach and the GI tract [24].

Stapling

Dependable stapling devices have permitted increasingly complex laparoscopic procedures. Current state-of-the art technology allows for cartridges with six rows of staples that can vary in staple height, which allows the same device to work on tissues of varied thicknesses [25]. Mechanical staplers ease transection and re-anastomosis but are no less prone to complications than hand-sewn anastomoses [7, 26]. Because the staple line for SG is quite long, the operation might have been expected to be prone to staple-line hemorrhages and leaks [24]. The patients reported herein, when taken in context of the findings in the literature, permit one to address the nature of staple-line reinforcements that might best prevent such complications.

Buttress Materials

Table 3 displays the currently available buttressing materials. Oversewing with suture, covering with jejunum or omentum, and fibrin glue [4, 17, 27] are of unproven efficacy [10]. Oversewing has been shown to result in

Table 3 Available staple-line buttressing materials

Material	Stapler type	Company
Expanded polytetrafluoroethylene (ePTFE) [40, 42]	Linear	W.L. Gore, Elkton, MD, USA
Bovine pericardium (Peri-Strips Dry) [10, 24, 33, 35, 41]	Circular; Linear	Synovis Life, Technologies, Inc.
Porcine small bowel (Surgisis) [7, 43–45]	Linear	Cook Biotech Inc.
Polyglycolic acid: trimethylene carbonate (SeamGuard) [5, 8–9]	Linear; Circular	W.L. Gore &Associates, Inc.
Knitted calcium alginate (FOREseal) [39]	Linear	Laboratoires Brothier, Nanterre, France

episodes of ischemia [29] and leaks from tears induced by the sutures [28]. The most commonly used staple-line reinforcement material is Peri-Strips made of bovine pericardium, successfully introduced in 1994 to reduce air leaks after lung resections [28–30]. Peri-Strips are inert. The application of the Peri-Strips to the stapler takes 2 min, is readily mastered by OR personnel, and does not increase overall operative time [10, 31]. In fact, operative time is sometimes dramatically reduced because Peri-Strips reduce the time needed to stop staple line bleeding [32]. Peri-Strips increase burst pressure in animal studies [6]. Peri-Strips decrease the risk of acute staple-line failures after laparoscopic Roux-en-Y gastric bypass surgery [10, 33]. Although Peri-Strips have been thought by some to increase the risk of infection [24, 34–35], animal studies of the tissue response to Peri-Strips have shown it to be well integrated into the host tissue, with substantial angiogenesis and collagen deposition that make it indistinguishable from host tissue 4 weeks after implantation [36–37]. Peri-Strips have even been hypothesized to possess antibacterial properties secondary to leaching of retained glutaraldehyde molecules [38].

Nonabsorbable expanded polytetrafluoroethylene is an inert material formed into a sleeve that is slid over both arms of the stapling device; after firing, the surgeon applies ePTFE by pulling a ripcord [38]. In cadaver lungs, ePTFE increases the burst pressure to 55 cm H_2O, as compared with 20 to 25 cm H_2O for the unreinforced staples and 40 to 55 cm H_2O for bovine pericardium [39]. In pulmonary staple lines of dogs [40], ePTFE is superior to Peri-Strips: at 30 days, Peri-Strips specimens show focal chronic inflammation and thin tissue coverage, whereas the ePTFE specimens have no focal inflammation and thick tissue coverage; at 95 and 167 days, Peri-Strips specimens lack inflammation and have only minimal tissue coverage, whereas ePTFE specimens have thick tissue coverage without inflammation.

Porcine small intestine submucosa (Surgisis), a completely resorbable acellular xenograft, has been used to assist the repair of inguinal and large paraesophageal hernias, the treatment of enterocutaneous fistulas, and the reinforcement of gastrojejunal anastomoses of gastric bypass procedures [41–43]. Animal experiments show Surgisis increases the burst pressure of bowel segment and lung staple lines [28, 44]. In pigs, Surgisis is known to reduce the pulmonary staple-line leak rate relative to Peri-Strips, ePTFE, and SeamGuard [45]. In short bowel syndrome animal studies, Surgisis induces the regeneration of mucosa [7]. Surgisis' efficacy in human staple-line reinforcement is undocumented.

Polyglycolide acid and trimethylene carbonate, SeamGuard, are formed into a sleeve that is fitted over the stapler arms and released by pulling the suture that holding 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 [5, 8, 46–48]. Prospective randomized clinical trials have shown SeamGuard minimizes staple-line bleeding and leakage and reduces operating time [24, 49].

Etiology of the Leaks

Etiologies of leaks have been divided into mechanical and ischemic causes, which include tension, ischemia, poor wound healing, technical errors, inappropriate instrument use, iatrogenic injury, and distal obstruction; a leak results when intraluminal pressure exceeds the strength of the tissue and the staple line. Because ischemic leaks are known to occur 5–7 days postoperatively, when wound healing is between the inflammatory and fibrotic phases, the most common causes of the vast majority of leaks, which occur within 48 h, are mechanical [26]. This provides a rationale for buttressing materials, which do not impart a decreased risk of leakage due to ischemia, but do decrease the risk of mechanical failure [50]. Most [6–7], but not all [31], studies have found that buttressing materials increase burst pressure.

It is clearly possible that reinforcing materials may not decrease the risks of leaks in laparoscopic gastric sleeve resections; technical difficulties with respect to staple choice have already been documented. Of the three different sized cartridges (green 4.8 mm, blue 3.5 mm, and white 2.5 mm), the shorter white staple had been recommended for laparoscopic gastric bypass, but the blue, intermediate-sized, staple was recommended for the pouch to provide more compression on transected tissue [51]. With buttressing materials, the need for longer staples is obvious. Moreover, the choice of staple height must take into account the variations in the gastric wall, thinnest at the proximal end near the esophageal junction to thickest near the pylorus [52]. If, in addition to SeamGuard, Peri-Strips are used, an added 1 mm of thickness must be taken into account because two strips are used per staple line. Absent sufficient staple height, gun misfiring can occur, increasing the likelihood of a leak. Moreover, the longer green staple is recommended over the blue one when transecting the antrum because the former is stronger and forms longer leg lengths [24, 26]. The two cases presented herein displayed buttressing material with some degree of misplacement, raising the possibility that even longer staples should be used, if buttressing materials should be used at all. Among the leaks reported in the literature, no deaths were associated with them. The most common described management was

drainage and a second procedure (gastric bypass or duodenal switch as a second stage).

Stapler Misfire

Surgeons creating the SG staple line must watch for and remove the "migratory crotch staple" to avoid a possible staple misfire [26]. This is especially important with respect to the angle of His; in Serra's study, all six gastric leaks occurred at the gastroesophageal junction [14]. To minimize the risk of misfiring from incorrectly applied or "Peri-Strips", the wise surgeon will visually inspect the BPS before firing the gun [32]. From the literature, we found that the leaks were reported in patients with no reinforcement. Unfortunately, some of them did not specify their technique as well [21, 23, 24–26, 28, 49]. Therefore, it is very difficult to make a final conclusion on this matter. The group who was oversewn [22, 53] did not report any leaks. We report leaks with Peri-Strips (BPS). In the sleeve consensus [11], the surgeons were divided about reinforcement versus oversewing; therefore, the decision will be at the surgeon's discretion and experience.

Bleeding

Ideally, reinforcing materials should be easy to use, biocompatible, strong, flexible, and cost-effective [24]. Staple line bleeding is the most common cause of GI hemorrhage after laparoscopic gastric bypass [54]. Intra-abdominal bleeding, by contrast, poses more serious problems because it reduces image definition at laparoscopy, which impedes sharp dissection due to the loss of exposure of the operative field; suction, irrigation, and camera cleansing are often required, prolonging operating time [10]; sometimes a transfusion or an added day in the hospital for observation is required [55]. Far more serious are staple-line leaks, which complicated the course of these two patients. Leaks, which yield peritonitis and septic shock, have 10–30% mortality [14, 24]. In contrast to the 1% risk reported herein for GS, 2.77% of 11,605 gastric bypass procedures yielded staple line leaks [26].

Conclusion

From an evaluation of the current series of 35 patients and the results of eleven reported series of patients who have undergone sleeve gastrectomy, the risk of leak is less than 1%, which is lower than our initial series. The point estimate of the leak rate for patients with reinforcement is greater than that of patients who lack such reinforcement but is not statistically significant; therefore, it is difficult to make a conclusion about the role of reinforcement versus oversewing.

To detect a halving of the leak rate would require almost 10,000 patients. There is no reason to believe, at this point, that reduction in leak rates occur because reinforcement is used. Because the leak rate is small, the routine reinforcement of the staple line after sleeve gastrectomy is questionable at best, although a decrease in hemorrhage has been reported.

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