

Staple Line Reinforcement Methods in Laparoscopic Sleeve Gastrectomy: Comparison of Burst Pressures and Leaks

M. Timucin Aydin, MD, Orhan Aras, MD, Bora Karip, MD, Kemal Memisoglu, MD

ABSTRACT

Background and Objectives: Laparoscopic sleeve gastrectomy is a technically simple and popular bariatric operation with acceptable results. However, leaks can occur in long staple lines, for which various reinforcement methods are used. We compared nonreinforced stapling in laparoscopic sleeve gastrectomy with 3 staple line reinforcement methods: suturing, absorbable buttressing material, and fibrin glue.

Methods: From March 1 until September 30, 2014, 118 patients with body mass index >40 kg/m² underwent sleeve gastrectomy and were enrolled in 4 groups, depending on the type of reinforcement used. The resected stomach specimens were treated with the same methods of reinforcement as used in the surgeries in the corresponding patients and then insufflated until a burst occurred. The burst pressures of the resected stomach specimens and adverse postoperative events were recorded.

Results: Five postoperative leaks occurred in the reinforcement groups (fibrin glue, 2; absorbable buttresses, 2; sutures, 1); no leaks were evident in the no-reinforcement group. Suturing afforded the highest burst pressure and took the longest to perform of the methods. There was no correlation between the leaks and burst pressures. All of the leaks occurred in the proximal fundus in the resected stomach specimens and in the affected patients.

Discussion: Although most surgeons use additional reinforcement on long staple lines in sleeve gastrectomy, there is no consensus about its necessity. We did not show any benefit of such reinforcement methods over proper stapling technique alone.

Conclusion: Laparoscopic sleeve gastrectomy without staple line reinforcement is safe and avoids additional costs for reinforcement materials.

Key Words: Burst pressure, Buttressing, Laparoscopic sleeve gastrectomy, Leak Reinforcement.

INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) is a successful bariatric operation that has gained popularity among surgeons and patients, owing to its relative technical simplicity compared to Roux-en-Y gastric bypass or biliopancreatic diversion and duodenal switch operations and its acceptable results. LSG was defined as the initial step of a double-stage bariatric procedure to avoid difficulties that occur in extremely obese patients. However, LSG alone has provided good short- and long-term results and has become a stand-alone method that has gained in popularity worldwide.^{1,2}

During LSG, the stomach is resected by repeated stapling, forming a tube-shaped stomach known as a sleeve. Leaks in the long staple line are a major concern. Leak rates have been reported to decrease to 2.5% with increasing experience and the development of new techniques.^{3,4} These events are difficult to manage and can lead to prolonged hospitalization.⁵⁻⁷ To avoid or minimize leaks, several reinforcement methods have been used to strengthen the staple line, with variable results, and there is no consensus on the best method. The purpose of the present study was to determine whether any of the reinforcement techniques used on the staple line is effective and whether the bursting pressure measurement of specimens would have an association with the development of leaks.

MATERIALS AND METHODS

After approval of the protocol from the hospital ethics committee and receipt of informed consent from the participants, 118 patients underwent LSG from March 1 through September 30, 2014. The patients were enrolled prospectively into 4 groups according to surgeons' pre-

Department of General Surgery, Fatih Sultan Mehmet Training and Research Hospital, Istanbul, Turkey (all authors).

Address correspondence to: M. Timucin Aydin, MD, Department of General Surgery, Fatih Sultan Mehmet Training and Research Hospital, Fetih Mah, Eski Giflik Yolu Gunyeli Ap 6A D28, 34704 Atasehir, Istanbul, Turkey. Telephone: +902165783000, Fax: +902165750406, E-mail: mtimucina@gmail.com

DOI: 10.4293/JSLS.2015.00040

© 2015 by JSLS, Journal of the Society of Laparoscopic Surgeons. Published by the Society of Laparoscopic Surgeons, Inc.

ferred type of staple line reinforcement: group I: 25 patients, no reinforcement (NoR); group II: 26 patients, fibrin glue (FG) (Tissell; Baxter International, Deerfield, Illinois); group III: 44 patients, suture reinforcement with 2-0 polypropylene sutures (S); and group IV: 14 patients, the biological buttressing material Peri-Strip Dry (PS) (Baxter International).

After resection by repeated stapling, we either applied one of the methods of reinforcement to both the resected and the remnant portions of the stomach or left both portions untouched. The resected stomach specimen was insufflated until a burst occurred and the burst location was noted. The postoperative events, burst pressures, and locations of the first leaks on the specimens in each reinforcement group were recorded and compared.

Surgical Procedure

In all patients, a 5-trocar technique was used for LSG. A midline epigastric 12-mm optical trocar was inserted 25 cm from the xiphoid process. Under laparoscopic view, 2 working trocars were inserted (5 mm on the right and 12 mm on the left) into each midclavicular line, just above the optic trocar level. A subxiphoid 5-mm trocar was used to elevate the left lobe of the liver, and a 5-mm left anterior axillary subcostal trocar was used to retract the stomach. The omentum was liberated from the greater curvature with a vessel-sealing device (LigaSure Atlas; Valleylab, Boulder, Colorado). Starting 5 cm proximal to the antrum to 1 cm lateral to the gastroesophageal junction (GEJ), the stomach was divided with a multiple-firing endoscopic linear stapler. A standard leak test was performed that involves the instillation of 50 mL 0.9% NaCl solution with methylene blue (10 mL methylene blue in 500 mL 0.9% NaCl) and passage of 50 mL of air through an orogastric tube. A drain was placed along the staple line. On postoperative (PO) day 1, the patient was given oral methylene blue. If no gross leak was detected, the patient was placed on a clear liquid diet and subsequently discharged on PO day 3.

Burst Pressure Measurements

The resected stomach specimen was removed from the abdomen after the wound caused by the left midclavicular 12-mm working trocar was enlarged. The resected stomach specimens in group III were sutured with the same material as that used along the staple line. The staple lines of the specimens in group II were sprayed with fibrin glue. Group IV stomach specimens contained PS rein-

forcement along the stapler lines. A small cut was made on the antrum side of the resected fresh stomach specimen, and a Foley catheter was inserted and tightly fastened. The inflator was attached to the catheter and to a manometer through a 3-way stopcock. The specimen was kept under water and inflated with constant air flow. The pressure level of the manometer was recorded as the burst pressure when the first air bubble leak was detected in the staple line. The locations of the leaks along the staple line were also recorded. For this reason, the staple line was subdivided into 3 areas, and leaks were categorized as proximal (fundus), middle (from body to fundus), or distal (from the first staple applied to the body).

Statistical Analysis

The Number Cruncher Statistical System (NCSS) 2007 and Power Analysis and Sample Size (PASS) 2008 Statistical Software (NCSS, Kaysville, Utah) program was used for statistical analysis. In the comparisons of quantitative data and descriptive statistical data (mean, standard deviation, median, frequency, and ratio), 1-way ANOVA was used for the intergroup comparisons of parameters with normal distribution. The Tukey honest significant difference (HSD) test was used to determine the significance of differences among the groups, and the independent-samples *t* test was used for the comparison of 2 groups. The Kruskal-Wallis test was used for the intergroup comparisons of parameters without normal distribution, and the Mann-Whitney U-test was used to determine the significance of differences between 2 groups. The Fisher-Freeman-Halton test and Fisher's exact test were used for the comparison of qualitative data. The results are presented with 95% confidence intervals and at a significance level of $P < .05$.

RESULTS

Nine patients were excluded from the study, owing to the disruption of the resected stomach during extraction from the abdomen. **Table 1** shows the baseline characteristics of the remaining 109 patients. There were no statistically significant differences in the characteristics of the groups. The number of staple cartridges fired and the linearity of the staple line were similar in all groups, but the operating time recorded from the insertion of the optic trocar to the application of reinforcement was significantly longer in the suture group ($P < .001$; **Table 2**). However, there were no significant differences in the burst pressure measurements in groups I, II, and IV ($P > .05$; **Table 3**). There was no correlation between the leaks and burst pressures.

Table 1.
Patient Characteristics

Characteristic	Group I (NoR) (n = 25)	Group II (FG) (n = 26)	Group III (S) (n = 44)	Group IV (PS) (n = 14)	P
Age	38.24 ± 10.52	36.08 ± 10.44	35.79 ± 9.69	33.00 ± 8.51	0.465 ^a
Weight	133.84 ± 6.02	120.38 ± 15.63	128.43 ± 20.66	134.50 ± 18.9	0.085 ^a
Height	167.24 ± 9.57	162.77 ± 6.57	165.28 ± 8.28	166.29 ± 7.08	0.250 ^a
Body mass index (BMI)	47.48 ± 6.33	45.5 ± 5.15	46.58 ± 6.21	48.43 ± 6.88	0.47 ^a
Female, n	19	24	37	12	0.469 ^b
Male, n	6	2	7	2	
Leaks, n	0	2	2	1	0.453 ^b

Data are expressed as the mean ± SD, unless otherwise noted.

^aOne-way ANOVA.

^bFisher-Freeman-Halton test.

Table 2. Surgical Parameters
A. Number of Stapler Cartridges Used and Uniformity of the Staple Line

Group	n	Number of Cartridges				Staple Line Uniformity	
		Min-Max	Mean	SD	Median	Uniform	Not Uniform
I (NoR)	25	4-9	5.12	1.481	5.00	19 (76.0)	6 (24.0)
II (FG)	26	3-6	4.77	0.908	5.00	20 (76.9)	6 (23.1)
III (S)	44	4-7	4.94	0.691	5.00	39 (88.6)	5 (11.4)
IV (PS)	14	4-7	5.07	0.829	5.00	13 (92.9)	1 (7.1)
P		0.668 ^a				0.304 ^b	

Data are number of patients. Uniformity was defined by the surgeon as the linearity or curvilinearity of the staple line that is not distorted or spiralling while stapling.

^aKruskal-Wallis Test.

^bFisher-Freeman-Halton test.

B. Operation Time

Group	n	Min-Max	Mean	SD	P
I (NoR)	25	42-58	48.48	4.46	0.001 ^a
II (FS)	26	52-65	58.42	3.98	
III (S)	44	70-92	81.11	6.53	
IV (PS)	14	52-65	57.50	3.72	

Operating time is expressed in minutes.

^aOne-way ANOVA.

The leak points in the patients were demonstrated by imaging methods, endoscopic evaluation, or laparoscopic reexploration. All leaks in the patients were detected in the proximal stomach within 5 cm of the GEJ. Most the

leaks that occurred on insufflation of the resected stomach specimens were also in the proximal third of the staple line around the fundus (**Table 4**).

DISCUSSION

LSG was primarily developed as the initial step of a double-stage bariatric operation in extremely obese patients, to decrease and prevent operative complications.⁷⁻¹¹ Later, studies supported LSG as an effective, stand-alone, durable bariatric procedure.¹²⁻¹⁶ It does not require that a foreign material such as a laparoscopic gastric band be placed in the patient. The procedure has no effect on gastrointestinal continuity and does not require gastrointestinal anastomosis, which makes it a relatively easier operative technique. Therefore, it has become the most

Table 3.

Burst Pressure Differences Between the Groups

Group	n	Min-Max (mm Hg)	Mean (mm Hg)	SD (mm Hg)	P
I (NoR)	25	21–80	31.80	11.53	0.001 ^a
II (FG)	26	21–50	33.77	7.03	
III (S)	44	30–170	74.95	28.84	
IV (PS)	14	29–42	35.21	4.39	

^aKruskal-Wallis test.

Table 4.

Burst Point in the Staple Line of the Resected Stomach

Group	n	Proximal 1/3 (Fundus)	Middle 1/3 (Corpus)	Distal 1/3 (Antrum)
I (NoR)	25	17 (68%)	6 (24%)	2 (8%)
II (FG)	26	14 (53.8%)	10 (38.4%)	2 (7.8%)
III (S)	44	28 (63.6%)	10 (22.7%)	6 (14%)
IV (PS)	14	8 (57.2%)	6 (42.8%)	0 (0%)
Total	109	67 (61.4%)	32 (29.3%)	10 (9.3%)

Data are the number of patients at each burst point with the percentage of the total patients in the subgroup in parentheses.

frequently performed bariatric operation worldwide during the past decade.²

However, the long staple line used in LSG has created particular concerns about the risk of leaks, which has been reported to range from 0.7% to 5.7%.^{6,17} The leak rate in our study was 4.6% (5 leaks in 109 patients). The use of smaller bougies to augment weight loss and close stapler approximation around the incisura angularis produced functional obstruction, in addition to the natural physiologic obstructive mechanism of the pylorus. Creating a long, tight sleeve leads to increased intraluminal pressure, which may overcome staple line strength and cause leaks.^{6,18} To avoid leaks, most surgeons prefer to reinforce the staple line during LSG, mostly by suturing or using buttressing materials,³ whereas some surgeons leave the staple line untouched.^{16–18}

Studies have shown improved resistance of staple lines to pressure when buttressing materials are used, and this result has been attributed to the possibility that the buttressing materials distribute tension over the high-risk staple line.^{19,20} None of the patients in the 4 study groups differed in age, sex, weight, height, or body mass index (BMI). Leaks were observed in 1 of the male and 4 of the female patients. There was no leak in the control group.

There was no significant difference in the leak rates between the different reinforcement groups; however, the duration of the operation was obviously shorter and the cost was lower in group I. Only 1 complication, an intra-abdominal hemorrhage, was encountered in group I, and the hemorrhage was controlled by a single clip application on the staple line.

As we anticipated, the burst pressures of the staple lines of the resected stomach specimens that were supposed to reflect the staple lines of the remnant stomachs were highest in the suturing group (group III). During evaluation, the most frequent leak site was the proximal stomach, which has been shown to offer the weakest resistance to pressure increases.^{21,22} On the other hand, the fundus had the largest diameter in the resected stomach, which allowed it to distend under higher intraluminal pressure, according to the Laplace law. All of the leaks of the resected stomachs occurred in the staple lines, similar to the results reported by Causey et al.²² A clinical leak just below the GEJ was detected in 1 patient in the suture group.

The second highest burst pressures occurred in the buttressing group (group IV). Similar to those in group I, the leaks were around the fundus. The type of buttressing material used (Peri-Strip Dry; Baxter International) is recommended for the reinforcement of the staple line and to decrease the leak rate. Unlike the only leak in the suturing group, which became clinically evident on the PO day 2, 2 patients in the buttressing group had clinical signs of leaks on PO days 7 and 12. The leaks in both patients were in the fundus area near the GEJ.

Although gastric wall thickness has been reported to vary, it is thick in the antrum (3.1 mm), moderate in the body (2.4 mm), and thin in the fundus (1.7 mm).^{22,23} The choice of staple height is very important when a buttressing material is added. The height of the buttress decreases the actual height of the staple, and a longer staple height should be considered for safe and proper closure.²³ We used Peri-Strips Dry (Baxter International) with gold cartridges (Echelon Flex Endopath 60 mm yellow; Ethicon, Somerville, NJ). Of note, all of the leaks occurred in the proximal stomach and not in the thickest distal part where the actual length of the staple height after buttressing would make it more difficult to form a properly closed B formation. However, even with proper staple height selection, staple-line leaks are unavoidable.^{23–25}

Stapler-related problems or tissue ischemia may lead to impaired tissue healing and dehiscence of the staple line

if higher intraluminal pressures are reached.²⁶ Leaks due to ischemia usually occur around PO days 5 to 7, when the healing is between the inflammatory and fibrotic phases, whereas most leaks occur in the first 48 h, which suggests an additional mechanical cause. There are insufficient data about the causative factors in leaks to support the rationale for the use of reinforcements.²⁵ LSG animal studies have demonstrated increased lactic acid levels along the GEJ, which indicate a predisposition toward tissue ischemia. However, a significant difference could not be verified.²⁷ Experiments on reinforcing the staple lines to avoid leaks have provided variable results, and it is not clear whether the buttressing materials provide any benefit in preventing ischemia.

Fibrin sealants have been used to accelerate wound healing and to achieve hemostasis along staple lines during laparoscopic Roux-en-Y gastric bypass.^{28,29} However, we did not find any benefit in the prevention of leaks after LSG. Two patients in the FG group (group II) had early postoperative leaks from the fundus area. In this study, we did not achieve less perioperative bleeding with fibrin glue than with stapling only (group I). There were no significant differences in the burst pressures between the use of glue with stapling and stapling alone, whereas the costs were higher for glue with stapling.

We are aware that the studied groups were small, a potential cause of bias. A larger number of patients would have produced stronger support for the claim that leaks may be unavoidable, even with reinforcement, but we should emphasize that the leak rate after LSG has been decreasing as experience with the technique has increased.⁴ Most surgeons prefer to use reinforcement along the staple line, and some have described proper technique and suitable stapler sizes.³⁰

CONCLUSION

The routine use of reinforcement methods may not be necessary during LSG, leaks may still occur, and these methods increase the cost of surgery and prolong the operation time. We could not prove any benefit of reinforcement over stapling with no reinforcement. The use of reinforcement increased the burst pressure but did not prevent leaks. Leaving the staple line untouched appears to be safe, although the logic of reinforcement is understandable. However, improved results for reinforcement have not been supported by the statistics.

References:

1. Sarela AI, Dexter SP, O’Kane M, Menon A, McMahon MJ. Long-term follow-up after laparoscopic sleeve gastrectomy: 8–9-year results. *Surg Obes Relat Dis.* 2012;8:679–684.
2. Buchwald H, Oien DM. Metabolic/bariatric surgery worldwide 2011. *Obes Surg.* 2013;23:427–436.
3. Gagner M, Buchwald JN. Comparison of laparoscopic sleeve gastrectomy leak rates in four staple-line reinforcement options: a systematic review. *Surg Obes Relat Dis.* 2014;10:713–723.
4. Gagner M. Decreased incidence of leaks after sleeve gastrectomy and improved treatments. *Surg Obes Relat Dis.* 2014;10:611–612.
5. Tan JT, Kariyawasam S, Wijeratne T, Chandraratna HS. Diagnosis and management of gastric leaks after laparoscopic sleeve gastrectomy for morbid obesity. *Obes Surg.* 2010;20:403–409.
6. Moszkowicz D, Arienzo R, Khettab I, et al. Sleeve gastrectomy severe complications: is it always a reasonable surgical option? *Obes Surg.* 2013;23:676–686.
7. Ren CJ, Patterson E, Gagner M. Early results of laparoscopic biliopancreatic diversion with duodenal switch: a case series of 40 consecutive patients. *Obes Surg.* 2000;10:514–523.
8. Baltasar A, Bou R, Miró J, Bengochea M, Serra C, Pérez N. Laparoscopic biliopancreatic diversion with duodenal switch: technique and initial experience. *Obes Surg.* 2002;12:245–248.
9. Regan JP, Inabnet WB, Gagner M, Pomp A. Early experience with two-stage laparoscopic Roux-en-Y gastric bypass as an alternative in the super-super obese patient. *Obes Surg.* 2003;13:861–864.
10. Milone L, Strong V, Gagner M. Laparoscopic sleeve gastrectomy is superior to endoscopic intragastric balloon as a first stage procedure for super-obese patients (BMI>50). *Obes Surg.* 2005;15:612–617.
11. Silecchia G, Boru C, Pecchia A, et al. Effectiveness of laparoscopic sleeve gastrectomy (first stage of biliopancreatic diversion with duodenal switch) on co-morbidities in super-obese high-risk patients. *Obes Surg.* 2006;16:1138–1144.
12. Baltasar A, Serra C, Pérez N, Bou R, Bengochea M, Ferri L. Laparoscopic sleeve gastrectomy: a multi-purpose bariatric operation. *Obes Surg.* 2005;15:1124–1128.
13. Bohdjalian A, Langer FB, Shakeri-Leidenmühler S, et al. Sleeve gastrectomy as sole and definitive bariatric procedure: 5-year results for weight loss and ghrelin. *Obes Surg.* 2010;20:535–540.
14. Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery. Updated position statement on sleeve gastrectomy as a bariatric procedure. *Surg Obes Relat Dis.* 2010;6:1–5.

15. Fischer L, Hildebrandt C, Bruckner T, et al. Excessive weight loss after sleeve gastrectomy: a systematic review. *Obes Surg.* 2012;22:721–731.
16. Rosenthal RJ. International Sleeve Gastrectomy Expert Panel. International Sleeve Gastrectomy Expert Panel Consensus Statement: best practice guidelines based on experience of >12,000 cases. *Surg Obes Relat Dis.* 2012;8:8–19.
17. Gagner M, Deitel M, Erickson AL, Crosby RD. Survey on laparoscopic sleeve gastrectomy (LSG) at the Fourth International Consensus Summit on Sleeve Gastrectomy. *Obes Surg.* 2013;23:2013–2017.
18. Benedix F, Benedix DD, Knoll C et al. Are there risk factors that increase the rate of staple line leakage in patients undergoing primary sleeve gastrectomy for morbid obesity? *Obes Surg.* 2014;24:1610–1616.
19. Downey DM, Harre, JG, Dolan JP. Increased burst pressure in gastrointestinal staple-lines using reinforcement with a bioprosthetic material. *Obes Surg.* 2005;15:1379–1383.
20. Arnold W, Shikora SA. A comparison of burst pressure between buttressed versus non-buttressed staple-lines in an animal model. *Obes Surg.* 2005;15:164–171.
21. Dapri G, Cadière GB, Himpens J. Reinforcing the staple line during laparoscopic sleeve gastrectomy: prospective randomized clinical study comparing three different techniques. *Obes Surg.* 2010;20:462–467.
22. Causey MW, Fitzpatrick E, Carter P. Pressure tolerance of newly constructed staple lines in sleeve gastrectomy and duodenal switch. *Am J Surg.* 2013;205:571–574; discussion 574–575.
23. Baker RS, Foote J, Kemmeter P, Brady R, Vroegop T, Serveld M. The science of stapling and leaks. *Obes Surg.* 2004;14:1290–1298.
24. Parikh M, Issa R, McCrillis A, Saunders JK, Ude-Welcome A, Gagner M. Surgical strategies that may decrease leak after laparoscopic sleeve gastrectomy: a systematic review and meta-analysis of 9991 cases. *Ann Surg.* 2013;257:231–237.
25. Chen B, Kiriakopoulos A, Tsakayannis D, Wachtel MS, Linos D, Frezza EE. Reinforcement does not necessarily reduce the rate of staple line leaks after sleeve gastrectomy: review of the literature and clinical experiences. *Obes Surg.* 2009;19:166–172.
26. Yehoshua RT, Eidelman LA, Stein M, et al. Laparoscopic sleeve gastrectomy: volume and pressure assessment. *Obes Surg.* 2008;18 :1083–1088.
27. Natoudi M, Theodorou D, Papalois A, et al. Does tissue ischemia actually contribute to leak after sleeve gastrectomy?—an experimental study. *Obes Surg.* 2014;24:675–683.
28. Liu CD, Glantz GJ, Livingston EH. Fibrin glue as a sealant for high risk anastomosis in surgery for morbid obesity. *Obes Surg.* 2003;13:45–48.
29. Sapala JA, Wood MH, Schuhknecht MP. Anastomotic leak prophylaxis using a vapour-heated fibrin sealant: report on 738 gastric bypass patients. *Obes Surg.* 2004;14:35–42.
30. Kasalicky M, Michalsky D, Housova J, et al. Laparoscopic sleeve gastrectomy without an over-sewing of the staple line. *Obes Surg.* 2008;18:1257–1262.