

Review article

Comparison of laparoscopic sleeve gastrectomy leak rates in four staple-line reinforcement options: a systematic review

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Abstract

Objective: The study compared laparoscopic sleeve gastrectomy (LSG) staple-line leak rates of 4 prevalent surgical options: no reinforcement, oversewing, nonabsorbable bovine pericardial strips (BPS), and absorbable polymer membrane (APM).

Background: LSG is a multipurpose bariatric/metabolic procedure with effectiveness proven through the intermediate term. Staple-line leak is a severe complication of LSG for which no definitive method of prevention has been identified.

Methods: The systematic review study design was employed using Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement screening guidelines. Inclusion criteria centered on variables potentially relevant to LSG leak: leak rate, age, gender, calibrating bougie size, distance between pylorus and gastric transection line, overall complication rate, and mortality. Analysis of variance models were used to explore differences in select demographic and surgical technique variables characterizing each reinforcement group. An omnibus χ^2 test followed by independent Fisher's exact tests were used to compare leak rates.

Results: There were 659 articles identified; 41 duplicates removed. Of 618 remaining articles, 324 did not meet inclusion criteria. Of the 294 remaining articles, 206 were eliminated (kin studies, those not reporting staple-line or leak incidence, those reporting discontinued products). There were 88 papers included in the analysis. Statistically significant differences were found between groups across demographic and surgical variables studied ($p < 0.001$). There were 191 leaks in 8,920 patients; overall leak rate 2.1%. Leak rates ranged from 1.09% (APM) to 3.3% (BPS); APM leak rate was significantly lower than other groups ($p < 0.05$).

Conclusion: Systematic review of 88 included studies representing 8,920 patients found that the leak rate in LSG was significantly lower using APM staple-line reinforcement than oversewing, BPS reinforcement, or no reinforcement. (Surg Obes Relat Dis 2014;10:713–724.) © 2014 American Society for Metabolic and Bariatric Surgery. Open access under [CC BY-NC-ND license](#).

Keywords:

Bariatric; Metabolic; Laparoscopic sleeve gastrectomy; LSG; Leak; Staple line; Reinforcement; Systematic review

Laparoscopic sleeve gastrectomy (LSG) has proven highly effective in achieving durable weight loss and comorbidity reduction over the short and intermediate terms;

long-term data are accruing [1–5]. In 1993, Marceau reported a new hybrid procedure, the biliopancreatic diversion (BPD) with duodenal switch (DS) [6], an operation combining a parietal gastrectomy (later termed a SG) with a modified Scopinaro BPD [7] and the DeMeester DS [8]. In 1999, SG was first performed laparoscopically as a portion of a DS by Gagner et al. [9,10]; after observing marked weight loss with LSG, the operation was proposed as a first-

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step procedure for high-risk patients with a second step BPD/DS or RYGB [11,12]. Subsequently, LSG was studied as a definitive operation. The current procedure involves a stapled mostly vertical transection of the stomach and removal of the left gastric fundus body and proximal left antrum to create a tubular alimentary channel along the stomach's lesser curvature. Food restriction, early satiety, decreased production of the appetite-stimulating hormone ghrelin, and increased production of GLP-1 and PYY-36 have been associated changes after LSG [13,14].

An assessment of the global distribution of metabolic/bariatric surgery procedures found that, after Roux-en-Y gastric bypass (RYGB) SG/LSG was the most performed metabolic/bariatric procedure, trending upward from 0% in 2003 to 5.3% in 2008 to 27.8% (94,689 procedures) in 2011 [15]. Between 2008 and 2011, the regional trend of SGs performed increased dramatically by 571.8% in Europe, 121.4% in the United States and Canada, 561.7% in South America, and 2,255.4% in the Asia/Pacific region [15]. LSG was recently recognized as a primary metabolic/bariatric surgical operation by the American Society for Metabolic and Bariatric Surgery and the American College of Surgeons [16,17].

According to a recent meta-analysis, LSG has been associated with 57.6% mean excess weight loss (EWL) at 1 year and 70.1% EWL at 3 years [1], superior to that of restrictive procedures and comparable to malabsorptive-restrictive and primarily malabsorptive procedures over the intermediate term. Other advantages of LSG include its relative procedural simplicity; no need to introduce a foreign body; absence of an enteric anastomosis; maintenance of gastrointestinal continuity; no or low risk of ulceration and internal hernia; lower rates of dumping syndrome; lowered ghrelin levels; improved quality of life; and no need to perform postoperative adjustments [2,26,27]. The overall complication rate in large medical centers is $\leq 15\%$; the irreversibility of LSG and risk of gastroesophageal reflux pose potential issues [18]. Overall LSG mortality is .3% with a leak-related mortality of .1% [1]. The .0–5.5% incidence of staple-line leak is perhaps the most salient concern and target for improvement associated with the procedure [16,17,20,21].

In 1993, the most significant complication of BPD/DS was gastric leak and fistula [6]; in 2013, leaks continue to detract from LSG outcomes, at times resulting in a high rate of morbidity and revisional procedures [22]. Most LSG staple-line leaks are proximal (89%) [19] and may be related to ischemic or mechanical issues caused by intraluminal pressures sufficient to exceed tissue and suture-line resistance [23]. A variety of surgical options, including staple-line reinforcement, suture invagination, and biological sealant have been used to try and reduce leak incidence. The aim of the present study was to employ the systematic review (SR) study design to collect relevant evidence for comparison of the staple-line leak rates of 4 prevalent surgical options in LSG: no reinforcement,

reinforcement by oversewing, reinforcement with nonabsorbable bovine pericardial strips, and reinforcement with absorbable polymer membrane.

Methods

Search strategy, inclusion criteria, variables of interest

An electronic literature search of the National Library of Medicine's PubMed database was performed. The search strategy followed the identification and screening guidelines established by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA) [24]. Articles were identified by the keywords: "sleeve gastrectomy," laparoscopic sleeve gastrectomy," and "vertical gastrectomy," and were limited to research papers of all designs on human patients in the English language. The search included records from no beginning date through March 2012.

Electronic results were screened by title to exclude duplicate studies resulting from collecting e-publications that were followed several months later by print publications. The remaining records were screened by reading abstracts. Studies that reported on LSG were included if the study included leak data and if the type of staple-line reinforcement used, or lack thereof, was clarified. Comments, Letters to the Editor, articles with no actual staple-line reinforcement or leak data, or with no focus on LSG, were excluded from eligibility in the analysis, as were case reports, animal studies, abstracts, series with < 5 patients, and review articles without accompanying data. Of eligible full-text articles, those not describing a form of reinforcement studied (e.g., a reinforcement material, oversewing, or no reinforcement); kin studies (i.e., reports discovered to contain overlapping data, or the same author group reporting outcomes for similar periods of time); and those articles not focused on percentage leak incidence were excluded.

Data collection objectives centered on variables potentially relevant to leak in LSG, including: prior bariatric/metabolic surgery, gender, age, BMI, staple height, intraoperative and postoperative leak tests, the calibrating bougie size, the distance between the pylorus and gastric transection line, overall complications, mortality, and %EWL.

Abbreviated terms

No reinforcement = "N". Reinforcement by oversewing alone = "O". Reinforcement with nonabsorbable bovine pericardial strips (Peri-Strips Dry, Baxter Healthcare, St. Paul, MN) = "BPS". Reinforcement with absorbable polymer membrane (GORE SEAMGUARD Reinforcement, W. L. Gore & Associates, Elkton, MD) = "APM".

Statistical analysis

All data were extracted from original sources to fields within an Excel (Microsoft, Redmond, WA) database. Data

manipulation and analysis was conducted using JMP statistical software, version 8.0.1 (SAS Institute Inc., Cary, NC), “R” open source statistical software, version 2.15.0 (R Foundation for Statistical Computing, Vienna, Austria), and SPSS software, version 20 (IBM SPSS, Chicago, IL). Criteria-based data were aggregated from selected studies representative of the 4 LSG reinforcement options of interest. Select demographic (i.e., age, % females, body mass index [BMI, kg/m²]) and surgical technique (i.e., bougie size, distance from pylorus) variables were summarized using mean, SD, range, and the percentage of studies reporting on each variable. One-way ANOVA tests were performed on study summary data using reinforcement method as the grouping variable. Post hoc pairwise *t* tests were used to determine where statistically significant differences existed. Pearson’s χ^2 test was used to determine whether there were any differences in the distribution of gender by reinforcement method; a permutation test was used to identify where significant differences existed. The overall leak rate for LSG patients, as well as, patient leak

rates within each of the 4 reinforcement categories were calculated. An omnibus χ^2 test in conjunction with independent Fisher’s exact tests were used to compare the number of patients with and without leaks for the different reinforcement options. In addition, weighted-mean rates of overall complications and excess weight loss were calculated for each reinforcement method. For studies reporting weight loss in terms of BMI reduction, %EWL was calculated as: [(BMI change)/(baseline BMI – 25)] X 100. All statistical tests were 2-tailed and alpha was set at $p < 0.05$.

Results

Study characteristics

Figure 1 presents the results of the systematic review of the literature through record identification, screening, and analysis using the PRISMA diagram format. A total of 659 articles were identified in the initial search. Forty-one

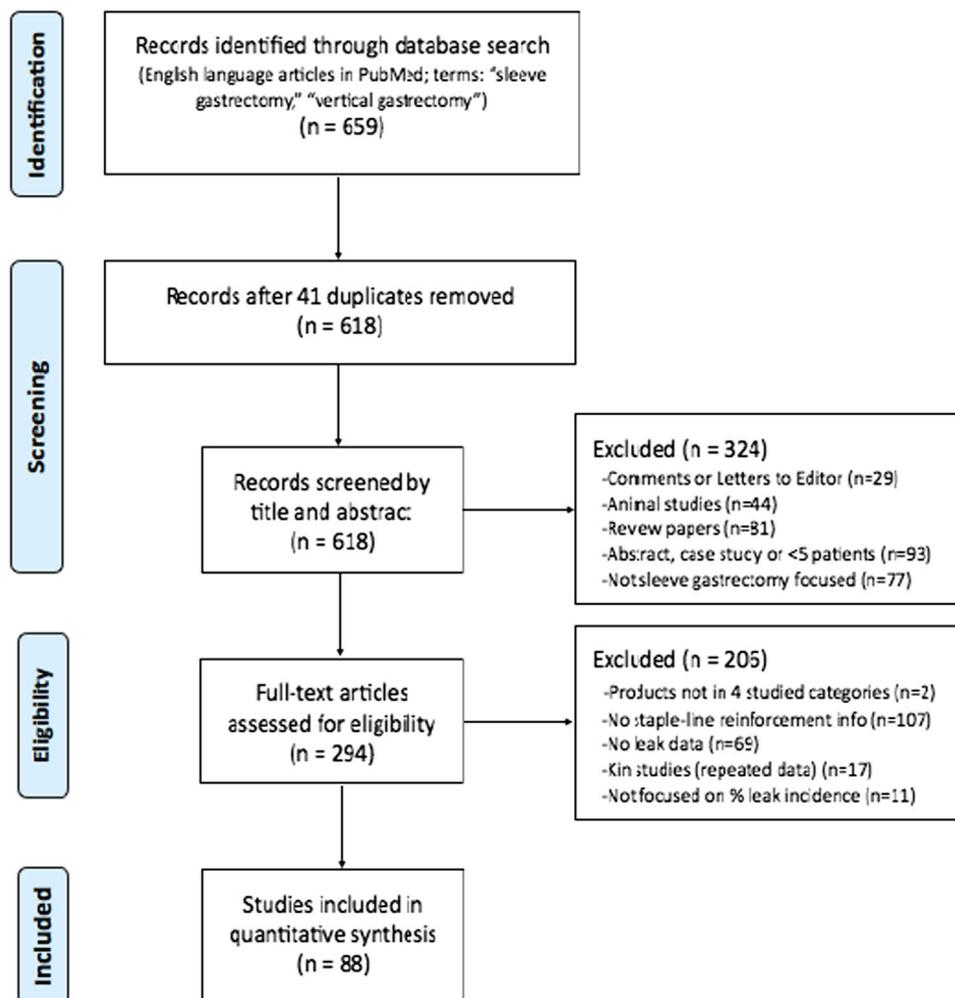


Fig. 1. Results of the systematic review of the literature by article identification, screening, and analysis using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA) flow diagram format.

duplicates were removed. Of the 618 articles remaining to be screened by title and abstract, 324 did not meet search strategy criteria and were excluded. Of the remaining 294 full-text articles assessed for eligibility, 206 were eliminated as either not presenting staple-line reinforcement information ($n = 107$), not presenting leak data ($n = 69$), kin studies ($n = 17$), those not focused on percentage leak incidence ($n = 11$), or papers that reported the Duet TRS™ Reload reinforcement product (Covidien, Mansfield, MA), recalled in 2012 ($n = 2$). A porcine small intestinal submucosa reinforcement product manufactured by Cook Biotech (West Lafayette, IN), was not included in this analysis because there were no clinical publications describing its use in LSG.

A final set of 88 papers was included in the SR. Of these, 32 papers were counted in the N category [23–56]; 42, in the O category [3,18,20,26–29,47,48,57–89]; 9 in the BPS category [26,28,48,57,59,90–93]; and 22 in the APM category [25–27,46,48,58,91,94–109]. (In the analysis of characteristics of the above accepted studies [Table 1], certain papers were counted in >1 category if they included data on ≥ 2 reinforcement options of interest.)

Table 1 displays the general characteristics of included studies by reinforcement option. The publication date of studies ranged from 2001 to 2012. The predominant designs across LSG reinforcement options were prospective (48.0%) and retrospective (42.0%) case series. A total of

8.0% of studies were randomized controlled trials (RCTs). Four studies (4.0%) did not report study design. Countries in Europe were the origin of the greatest number of LSG articles (56.0%) relative to the Americas (28.0%), Asia (15.0%), and Oceania (1.0%). A method of LSG staple-line reinforcement was the main study focus in 29.0% of articles included in the analysis. The mean study duration across all papers reviewed was 2.8 ± 1.7 years (median 3.0 years).

Patient characteristics

The final analysis incorporated 8,920 LSG patients (71.1% females) with data on reinforcement methods and leak rate. Overall, mean patient age was 41.0 years, pooled SD: 10.9 years; and mean patient BMI was 45.6 ± 7.3 . Approximately 40.0% of all studies included patients with previous bariatric/metabolic surgery, with each study group comprised of $\leq 10.0\%$ revision patients. In addition, a significant proportion of patients who had prior bariatric surgery underwent procedures that incurred fewer complications than major revisional procedures, e.g., band removals.

As reported in Table 2, ANOVA models comparing staple-line reinforcement methods along demographic variables indicated the presence of multiple significant differences. With regard to age, pairwise *t* tests revealed that LSG patients receiving APM were significantly older than patients

Table 1
Characteristics of accepted studies

Reinforcement method	Publication date range	Study design type = N (%)	Continent of article origin Article N (%)	Reinforcement as a main focus N (%)
No reinforcement	2001–2012	P = 14 (44.0) R = 16 (50.0) RCT = 2 (6.0) NR = 0 (.0)	Asia = 10 (31.0) Americas = 4 (13.0) Europe = 18 (56.0) Oceania = 0 (0)	9/32 (28.0)
Oversewing (suture)	2005–2012	P = 19 (45.0) R = 17 (40.0) RCT = 4 (10.0) NR = 2 (5.0)	Asia = 4 (10.0) Americas = 11 (26.0) Europe = 26 (62.0) Oceania = 1 (2.0)	9/42 (21.0)
Bovine pericardium	2009–2012	P = 4 (44.0) R = 5 (56.0) RCT = 0 (.0) NR = 0 (.0)	Asia = 0 (.0) Americas = 1 (11.0) Europe = 8 (89.0) Oceania = 0 (.0)	6/9 (67.0)
Absorbable membrane	2004–2012	P = 12 (55.0) R = 6 (27.0) RCT = 2 (9.0) NR = 2 (9.0)	Asia = 2 (9.0) Americas = 13 (59.0) Europe = 7 (32.0) Oceania = 0 (.0)	6/22 (27.0)
Total	2001–2012	P = 49 (47.0) R = 44 (42.0) RCT = 8 (8.0) NR = 4 (3.0)	Asia = 16 (15.0) Americas = 29 (28.0) Europe = 59 (56.0) Oceania = 1 (1.0)	30/105 ^a (29.0)

NR = not reported; P = prospective; R = retrospective; RCT = randomized controlled trial.

Asia includes articles from: Israel, India, Singapore, China, Saudi Arabia, Korea, Taiwan, and Japan. The Americas includes articles from: United States, Canada, Chile, Venezuela. Europe includes: France, Netherlands, United Kingdom, Austria, Greece, Italy, Czech Republic, Belgium, Switzerland, Sweden, Spain, and Germany. Oceania include: New Zealand.

^aA denominator of 105 was used for total percentage calculations (rather than the actual number of studies [88]), as several studies included data on ≥ 2 reinforcement options of interest.

Table 2
Demographic data by reinforcement method

Reinforcement method	Variable mean ± SD (Range ^a) [% Reported ^b]		
	Age	% Female	BMI
No reinforcement	40.9±10.6 (27.0–47.1) [93.8]	73.0±11.0 (43.0–100.0) [90.6]	46.5±7.7 (28.5–68.0) [96.9]
Oversewing (suture)	40.8±11.1 (33.9–54.0) [90.5]	72.0±10.0 (10.0–97.0) [95.2]	43.1±6.5 (34.0–58.2) [95.2]
Bovine pericardium	38.9±10.3 (34.3–45.9) [77.8]	67.0±9.0 (51.0–76.0) [77.8]	48.5±8.2 (43.2–56.7) [88.9]
Absorbable	43.0±10.9 (37.6–47.3) [86.4]	66.0±22.0 (21.0–93.0) [86.4]	50.0±8.8 (44.0–60.1) [90.9]
P-value	< .001	< .001	< .001

BMI = body mass index (kg/m²); SD = standard deviation.

^aRange = minimum to maximum.

^bPercentage of studies reporting on variables.

comprising the remaining three reinforcement groups, 43.0±10.9 [APM] versus 40.9±10.6 [N], 40.8±11.1 [O], 38.9±10.3 [BPS] (all differences significant at $p < 0.001$). Conversely, BPS patients were found to be significantly younger than all other patient groups ($p < 0.001$).

The overall mean percentage of female LSG patients across reinforcement methods was 71.1%. APM and BPS patient groups were statistically similar in gender distribution (66.0% versus 67% female); however, both groups were comprised of significantly fewer females than the N (73.0%) and O (72.0%) groups (differences significant at $p < 0.001$). The N and O groups were not significantly different in gender distribution.

Significant BMI differences between the four reinforcement groups were observed (all differences significant at $p < 0.001$). The heaviest patients were in the APM group with a mean baseline BMI of 50.0±8.8; whereas, the O group presented with the lowest relative mean BMI (43.1±6.5).

Surgical technique

Table 3 presents summary data for relevant surgical technique variables specific to LSG staple-line reinforcement methods. Again, ANOVA indicated the presence of significant differences among the reinforcement methods studied. With regard to bougie size (overall model mean: 40.2 [Fr], pooled SD: 8.9), O group patients had a significantly greater mean bougie size than patients in the remaining 3 reinforcement groups, 44.4±10.6 [O] versus 36.5±8.8 [N], 37.3±4.6 [BPS], 36.1±3.3 [APM] (all differences significant at $p < 0.001$). Conversely, a significantly smaller mean bougie size was used in the APM group relative to the other reinforcement groups ($p < 0.001$).

Significant differences in the distance of the transection line from the pylorus were also evident. The overall model mean distance (and pooled SD) was 4.9±1.5 cm. Although the APM and O reinforcement groups were statistically similar, both showed significantly greater mean distances from the pylorus compared to the N and BPS groups, 5.4±0.9 [APM] and 5.4±1.3 [O] versus 4.1±1.5 [N] and 4.6±2.6 [BPS] ($p < 0.001$). Also, a significantly smaller distance between the transection line and pylorus was used in the N group compared to all other groups ($p < 0.001$).

Mobilization of the greater curvature and fundus before the resection was performed in all but three studies. Heterogeneity of staple heights between studies precluded meaningful statistical analysis; however, the most common stapling technique used across reinforcement methods (approximately 50.0%) was a combination of staple cartridges—a green load (4.8 mm), used at the antrum, and a blue load (3.5 mm), applied at the gastric corpus and fundus. The most common form of intraoperative leak test used across reinforcement methods studied was the methylene blue dye test; approximately 60.0% of all studies employed this test. The second most commonly used test (approximately 30%) was the air-leak test.

Staple-line leak rate

Approximately 80% of all studies reporting on post-operative leak determination performed a water-soluble upper gastrointestinal contrast study; the most commonly referenced contrast agent was gastrografin. In total, 191 leaks were reported in 8,920 patients (overall incidence: 2.1%). As reported in Table 4, leak rates after LSG ranged from 1.1% ($n = 16/1,462$) in patients reinforced with APM,

Table 3
Bougie size and distance from pylorus by reinforcement method

Reinforcement method	Variable mean ± SD (Range ^a) [% Reported ^b]	
	Bougie size (Fr)	Distance from pylorus (cm)
No reinforcement	36.5±8.8 (32.0–60.0) [90.6]	4.1±1.5 (2.5–7.0) [53.1]
Oversewing (suture)	44.4±10.6 (30.0–60.0) [95.2]	5.4±1.3 (2.5–7.0) [54.8]
Bovine pericardium	37.3±4.6 (32.0–48.0) [100.0]	4.6±2.6 (3.0–9.0) [67.0]
Absorbable membrane	36.1±3.3 (29.0–60.0) [90.9]	5.4±0.9 (3.0–8.0) [64.0]
P-value	< .001	< .001

Fr = French; SD = standard deviation.

^aRange = minimum to maximum.

^bPercentage of studies reporting on variables.

Table 4
Leak rates by reinforcement method

Reinforcement method	Leaks	Number of Patients w/o leaks	% Leaks	P-value compared to APM ^a
Absorbable membrane	16	1,446	1.09	—
Oversewing (suture)	86	4,128	2.04	.02
No reinforcement	67	2,512	2.60	.001
Bovine pericardium	22	643	3.30	.0006
Total	191	8,729	2.14	—

APM = (Seamguard) absorbable polymer membrane; PSD = (Peri-Strips Dry) bovine pericardial strips.

^aTwo-tailed Fisher's exact test.

to 3.3% (n = 22/665) in patients reinforced with BPS. A 2 x 4 contingency table χ^2 test indicated that significant differences in the leak rate existed among reinforcement methods ($X^2 = 14.7$, $p < 0.005$). Fisher's exact tests demonstrated that the leak rate of 1.1% for the APM group was significantly lower than that attained by the 3 other reinforcement options (all differences significant at $p < 0.05$). In addition, there was a marginally significant difference in leak rate between the O and BPS groups (2.0% versus 3.3%, $p = 0.046$).

Overall complications

Overall mortality rate was .1% (n = 9/8,920 patients). Total sample weighted-mean rate of overall complications was 7.01%. Independent weighted-mean overall complication rates for each reinforcement method are presented in Figure 2. The APM group was found to have the lowest rate of overall complications (5.5%), and the no reinforcement group, the highest (8.9%).

Weight loss

All reinforcement option groups experienced significant weight loss at 1 year (>50% EWL). Overall weighted-mean EWL across reinforcement methods was 64.5% at 1 year. The oversewing group (lowest baseline BMI, 43.1) had the highest weight loss at 1 year, with a weighted-mean EWL of 73.1%. The BPS group had the second highest weight loss, 65.7% EWL, followed by the no reinforcement group, 60.9% EWL, and the APM group (highest baseline BMI, 50.0%), 58.4%.

Discussion

Current LSG review findings and the literature

In this study, 88 systematically reviewed articles relating LSG staple-line reinforcement methodology and leak rates were analyzed. Within a total sample size of 8,920 patients, 191 leaks were recorded for an overall leak rate of 2.1%. Four reinforcement options were studied: no reinforcement, oversewing, bovine pericardial strip reinforcement (BPS, Peri-Strips Dry), and absorbable polymer membrane reinforcement (APM, Seamguard). APM patients were found to have a leak rate of 1.1%, which was statistically

significantly lower than the other reinforcement options studied. This was true despite the fact that the APM group was characterized by use of smaller bougie sizes and a greater baseline BMI—factors that have been previously linked to higher leak rates [1,19]. The APM group was also found to be significantly older and to have had the LSG transection performed at a distance from the pylorus (5.4 cm) \geq to that of the other groups. In addition, the APM group was found to have the lowest overall weighted-mean rate of complications (5.5%).

During the past decade, the time frame in which almost all LSG evidence has been published, 90.0% of articles included in the current SR were prospective and retrospective case series, with 8.0% RCTs. The current analysis comprised data from 88 papers; yet, 187 LSG papers were excluded because they did not report staple-line leak rates or key surgical techniques that may affect leak. Standards for reporting LSG do not yet exist; without them, it is difficult to include a wide, and perhaps more representative, array of reports in a pooled analysis and to compare data across studies. Numerous individual LSG series included in this SR compared leak rates between no reinforcement, oversewing, and/or ≥ 2 reinforcement options with conflicting results. Several reinforcement technique and product categories are available, each with multiple specific brand and composition options, further complicating pooled

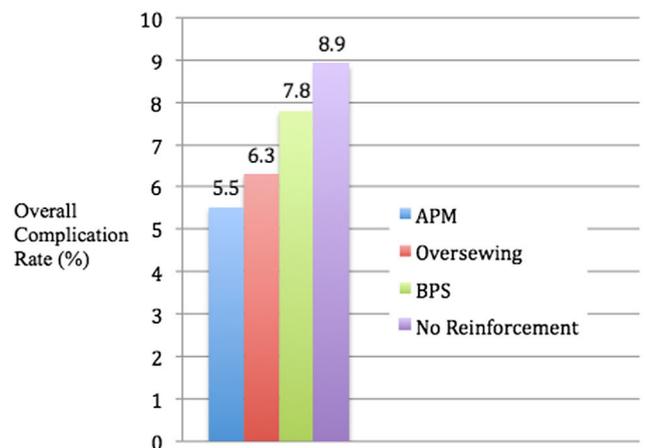


Fig. 2. Weighted-mean overall complication rates for each of the four reinforcement options. APM (Seamguard) absorbable polymer membrane, PSD (Peri-Strips Dry) bovine pericardial strips.

comparison within the reinforcement category. Identifying definitive evidence regarding the safest and most effective techniques for preventing staple-line leak is also problematic without observational studies that report LSG outcomes in a standardized manner and a greater volume of RCTs.

To our knowledge, there are only three randomized trials (RTs) [27,58,110], 1 of which was controlled [27]. Three SRs [1,19,111] (2 of which are SRs with more rigorous meta-analysis [MA]) have focused on LSG staple-line reinforcement and may be compared to the current SR findings. While these conflict in their conclusions as to the optimal staple-line reinforcement option, they are in agreement that the leak rate for LSG is relatively low—generally, <2.4%¹⁹ and <1.3% [112,113] in experienced hands—and that reinforcement does not significantly differ from no reinforcement in reducing staple-line leak.

An RCT reported by Dapri et al. in 2010 [27], and RTs published in 2012 by Albanopoulos et al. [58] and Gentileschi et al. [110], resulted in similar outcomes regarding prevention of staple-line leak in LSG. In a study of 75 comparable morbidly obese patients randomized to LSG with either no reinforcement (control), staple-line oversewing, or buttressing with APM, Dapri et al. noted a significant reduction in operative blood loss with APM, but no significant difference between the 2 options and the control in preventing postoperative staple-line leak [27]. Albanopoulos et al. randomized 90 morbidly obese patients with like characteristics to either an APM or oversewing treatment group. Comparable to the complication rate for APM in the current SR (5.5%), Dapri et al. reported a total complication rate of 6.2% in the APM group, with 2 patients developing postoperative staple-line leak under the gastroesophageal junction (4.2%). There were .0% complications in the oversewing group; however, there was no statistically significant difference between the 2 methods in preventing leak [58]. In a RT of 120 morbidly obese patients randomized to an oversewing group, an APM group, or a group that received a staple-line roofing matrix (developed from a bovine-derived gelatin matrix of thrombin derived from humans mixed with additional components; Floseal, Baxter Biosurgery, Deerfield, IL) used for the first time in this LSG study, Gentileschi et al. recorded, respectively, 1 bleed and 1 leak; 1 bleed; and 1 leak, with no statistically significant difference between the methods of leak prevention [110]. Gentileschi et al. remarked that reinforcement of the staple-line significantly increases hemostasis, possibly strengthens the staple line, and may reduce leak, although there is no conclusive evidence to support reinforcement in LSG.

Three SRs published by Parikh et al. [1], Aurora et al. [19], and Choi et al. [111] in 2012 focused on staple-line leak in LSG. Parikh et al. reported results of a SR that included 112 studies and employed a general estimating equation to analyze the leak odds ratio (OR) relative to bougie size, distance of the transection from the pylorus,

and staple-line reinforcement (or no reinforcement). Parikh et al. identified an overall leak rate of 2.2% (198 leaks in 8,922 patients), comparable to that of the current SR (2.1%). Reinforcing the staple line was not found to have a significant effect on leak rate; however this may be because in their definitive analysis, all absorbable reinforcements were included, whereas in the present study, a significant difference was found between absorbable and nonabsorbable reinforcement. As observed in other studies focused on bougie size [114,115], Parikh et al. calculated a significant diminution of the leak rate up to 3-year follow-up (with no impact on weight loss) when a ≥ 40 Fr bougie was used to size the gastric sleeve. In addition, leak rate was not shown to be affected by the distance of the pylorus from the gastric transection line [1]. An SR by Aurora et al. found a similar overall leak rate of 2.4% (115 leaks in 29 studies encompassing 4,888 patients), higher in the super-obese (2.9%). Eighty-nine percent of leaks were identified at the esophagogastric junction. Like Parikh et al. and unlike the present study, Aurora et al. combined reinforcement methods and concluded that reinforcement did not have a significant effect on leak rate. Aurora et al. found, as did Parikh et al., that the risk of leak was higher when the bougie size used was <40Fr¹⁹. Choi et al.'s SR/MA included 8 studies incorporating 1,345 patients. The OR comparing staple-line reinforcement (either buttressing or oversewing or both) to no reinforcement for hemorrhage was .559 (95% CI, .247–1.266), and for leak, .425 (95% CI, .226–0.799). Contradictory to the previous 2 SRs, Choi et al. found that reinforcement with oversewing and/or buttressing material had a statistically significant effect on reduction of leak rate and overall complications [111].

Three sequential international consensus summits [112,113,116] and 1 international expert panel summary [117] published during the last decade ratify the value of LSG as a staged and stand-alone procedure. Although, based on the 2011 Oxford Centre for Evidence-Based Medicine “Levels of Evidence” [118], reports of expert opinion carry less evidentiary weight than RCTs, RTs, SRs, and MAs, the Third International Consensus Summit for Sleeve Gastrectomy convened experts with a substantial combined experience of 19,605 LSG cases with a proximal leak rate of 1.3% [112]. Of the 67.1% majority of expert surgeons who used reinforcement in LSG, 43.0% oversewed the staple line (sutures applied seromuscularly or through-and-through), and 57.0% used a buttressing product (21.0% BPS; 42.0% APM; 33.0% Duet [discontinued in 2012]). Mean bougie size was 36 ± 4.8 Fr (median 34.5Fr, range 32–60Fr).

In practice guidelines developed through consensus voting and published recently in the International Sleeve Gastrectomy Expert Panel Consensus Statement [113], recommendations were derived from data and knowledge based on a collective experience of 12,799 LSG cases in which the leak rate was 1.1%. With respect to reinforcing the staple line, the Expert Panel achieved consensus on

most topics, notably, that staple-line reinforcement reduces bleeding along the staple line, and that either buttressing or oversewing the staple line are valid options. No consensus was reached on whether reinforcement reduces leak rate or should be routinely performed; whether the smaller bougie sizes create smaller sleeves and a greater incidence of leaks; and whether the gastric transection should begin 4–6 cm from the pylorus.

In a 2009 review of reinforcement of the staple line in LSG, Chen et al. suggested that a sample size of nearly 10,000 LSG procedures would be required to detect a statistically significant difference between the typically low leak rates associated with reinforcement options [91]. The current SR sample ($n = 8,920$) approaches this volume; however, the current finding that use of APM staple-line reinforcement results in a significantly lower leak rate compared to 2 other reinforcement options and to no reinforcement is contradictory to the findings of 5 of the 6 aforementioned RTs and SRs, but is in agreement with Choi et al, who found that reinforcement had a statistically significant effect on leak rate reduction. These contradictory findings may be the result of confounding by factors that relate significantly to leak and/or to factors inherent in the design or conduct of the studies. If further study confirms definitively that there is no difference between APM (or another reinforcement option) and no reinforcement, it may also be the case that reinforcement is a superior choice in LSG for certain patients. The international LSG Consensus Groups' and Expert Panels reports that reinforcement of the LSG staple line is not only a valid option, but the method practiced by the majority of surgeons; reinforcement may have been historically aimed at leak prevention but may prove to more definitively minimize hemorrhage.

Limitations

The analytic power of the current SR was limited by the paucity of experimental studies (RCTs) and the lack of reporting standards in the LSG literature. Variables essential to accurately and completely report LSG procedures, particularly details surrounding the staple-line reinforcement method selected, distinctions between oversewing techniques, bougie size, distance of the transection line from the pylorus, and leak data, were absent from a marked number of studies identified, limiting the sample of evaluable records and the power of review results. Future studies that employ a multivariate analysis controlling for potential confounding variables would further our understanding of the differences between reinforcement materials. Achieving consensus regarding optimal surgical technique requires completeness and clarity of reported variables as summarized by SRs and MAs; these designs require the capacity to pool standardized data from many studies; when not available, the opportunity to provide guidance for safer, more effective LSG procedures is reduced.

Conclusion

Short- and mid-term evidence on the effectiveness of LSG is promising. LSG is a multipurpose operation that has the advantage of convertibility to alternative surgical solutions. The procedure's safety overall is good; developing proven surgical strategies to minimize the risk of potentially life-threatening staple-line leak after LSG is of critical importance.

The current SR is aligned with findings of prior SRs, SR/MAs, RTs, RCTs, and international consensus and expert panel reports that suggest the need for longer-term (≥ 5 -year) data; standardization of the LSG procedure and LSG reporting; and studies focused on demonstration of the value of staple-line reinforcement options versus no reinforcement. The current systematic review of 88 studies representing 8,920 patients found that APM staple-line reinforcement was associated with a significantly lower leak rate than oversewing, BPS reinforcement, and no reinforcement.

Disclosures

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Editorial comment

Comment on: Comparison of laparoscopic sleeve gastrectomy leak rates in 4 staple-line reinforcement options: a systematic review

In an effort to further elucidate the role of staple-line reinforcement on leak rates after laparoscopic sleeve gastrectomy, Gagner and Buchwald compared 4 techniques, specifically no reinforcement, oversewing of the staple line, and reinforcement of the staple line using bovine pericardium or absorbable polymer membrane strips. After appropriate screening of the literature, the authors conducted a systematic review of 88 articles (8,920 patients) published before April 2012 and concluded that staple-line reinforcement, in particular reinforcement using absorbable polymer membrane strips, yielded a significantly lower staple-line leak rate after laparoscopic sleeve gastrectomy [1].

As with any systematic review of the literature, the data must be interpreted cautiously. The pooled comparison of techniques for staple-line reinforcement is made difficult by the variability in patient factors, operative technique, surgeon training and proficiency, biomaterial form and function, as well as reporting of patient outcomes. For example, 187 potentially informative articles ultimately were excluded from analysis based on incomplete reporting of patient demographic characteristics, operative technique, or outcomes data [1]. Some factors that may affect staple-line leak rates, like surgeon training and experience, could not be analyzed, as these metrics are infrequently noted in