A Systematic Review of Staple-Line Reinforcement in Laparoscopic Sleeve Gastrectomy

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ABSTRACT

Background and Objectives: Laparoscopic sleeve gastrectomy is gaining popularity as a bariatric procedure, with outcomes similar to gastric band and gastric bypass. Staple-line disruption is a significant source of morbidity and death. We aim to evaluate the effect of staple-line reinforcement on the gastric leak rate, morbidity, and mortality rate.

Methods: A systematic review was performed using title key words "sleeve gastrectomy," and articles were reviewed for description of operative technique and postoperative outcomes including staple-line leak. Rates of leak, bleeding, surgical-site infection, reintervention, readmission, and mortality were analyzed. We calculated pooled event rates and 95% confidence intervals using fixed-effects modeling to determine differences between the reinforcement group (group A) and non-reinforcement group (group B).

Results: We identified 390 articles, and 30 met the inclusion criteria. Group A had 3293 patients, and group B had 1588 patients. After heterogeneity calculations, 9 variables met the criteria to be analyzed. The leak rate was 3.9% (95% confidence interval, 2.9%–5.5%) in group A and 3.2% (95% confidence interval, 2.8%–4.1%) in group B. The mortality rate was 0.8% (95% confidence interval, 0.4%–1.5%) in group A and 0.7% (95% confidence interval, 0.4%–1.1%) in group B. Our results also showed no statistical difference for any of our other 7 outcome variables.

Conclusion: Our study shows a lack of statistical difference in leak rate, overall morbidity, or mortality rate in laparoscopic sleeve gastrectomy with or without staple-line reinforcement. Because of study limitations, we propose that prospective trials are needed to determine the effect of staple-line reinforcement on leak rates.

Key Words: Sleeve gastrectomy, Staple line, Reinforcement.

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INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) has gained increasing acceptance among bariatric surgeons and patients because of encouraging excess weight loss and resolution of comorbidities. Initially established as the first stage of a 2-stage bariatric approach, it is now used as a primary bariatric procedure because of documented excellent weight loss and an acceptable risk of complication. Advantages include the avoidance of implantable material, maintenance of gastrointestinal continuity, avoidance of malabsorption, and convertibility to other operations.

The major disadvantage of LSG is the severity of the major postoperative complications of bleeding and staple-line leakage. Staple-line disruption is the most life-threatening complication after LSG, with a mean incidence of 2.7% from 24 studies with 1749 patients.[1] Leaks after sleeve gastrectomy (SG) commonly occur at the proximal aspect of the staple line immediately below the gastroesophageal junction because of the creation of a high internal pressure.

Staple-line reinforcement has been advocated by many surgeons but not well studied through prospective or retrospective methodology. Moreover, surgeon practice with respect to staple-line reinforcement varies widely. Options for staple-line reinforcement include non-reinforcement, oversewing, and use of buttressing within the stapler load.

We performed a systematic review of retrospective studies (and one prospective study) to analyze the effect of staple-line reinforcement on leak rate, mortality rate, and overall morbidity of SG.

METHODS

A thorough literature search of the Medline online database was combined with reference checks of articles involving LSG for the past 15 years. Search phrases used were made of combinations of the following key words: "sleeve," "gastric," and/or "gastrectomy." Secondary inclusion criteria used included reporting of (1) a description of the operative technique including whether reinforcement was applied, (2) the type of reinforcement applied, and (3) outcomes including staple-line leak and bleeding.

The selected articles were then thoroughly evaluated for the presence or absence of staple-line reinforcement within the operative technique and associated outcomes, including staple-line leak rate, bleeding, surgical-site infection, operative reintervention, readmission, conversion to laparotomy, abdominal fluid collection, postoperative venous thromboembolic complications, 30-day mortality rate, inpatient length of stay, and excess weight loss. Most included publications were retrospective chart reviews. Articles that included most or all of the desired outcomes reported were included for further analysis and possible inclusion in the study.

The statistical methods used were as follows. We compiled data from all eligible studies and grouped data into 2 groups: those studies or patients where reinforcement was used and those studies or patients where reinforcement was not used. All studies were retrospective, 1-group studies (with the exception of Casella[2] et al., Sanchez-Santos[3] et al., Ser[4] et al., and Dapri[5] et al.) that provided details of the outcomes of patients undergoing SG. The aforementioned studies had groups of patients with and without staple-line reinforcement. For the purposes of data analysis, we separated the information for these separate groups and analyzed their data as part of their respective group. Statistical analysis followed recommendations from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins and Green)[6]. To determine heterogeneity between studies, we calculated χ^2 values (Q) as well as an inconsistency statistic (I^2). Taken together, we used Q and I^2 to make judgments about heterogeneity of specific outcome variables and the usefulness of further data analysis. Finally, we used pooled fixed-effects models to determine differences in effect size.

According to Higgins and Green, "A low P value (or a large chi-squared statistic relative to its degree of freedom) provides evidence of heterogeneity of intervention effects (variation in effect estimates beyond chance)." We used a P value less than .10 or a large χ^2 value (Q) relative to degrees of freedom to determine evidence of statistical significance against the null hypothesis that the studies are not heterogeneous. In addition, we evaluated the I^2 statistic as recommended by Higgins and Green, where 0% to 40% indicates that the inconsistency might not be important; 30% to 60% indicates that the inconsistency may represent moderate heterogeneity, 50% to 90% indicates that the inconsistency may represent substantial heterogeneity, and inconsistency values of 75% to 100% indicate considerable heterogeneity. However, Higgins and Green suggest that "the importance of the observed value of I^2 depends on (i) magnitude and direction of effects and (ii) strength of evidence for heterogeneity (e.g., P value from the chi-squared test, or a confidence interval for I^2)."

After determining heterogeneity of our variables, we calculated pooled event rates and 95% confidence intervals (CIs) using fixed-effects modeling to determine significant differences in rates between our two treatment groups.
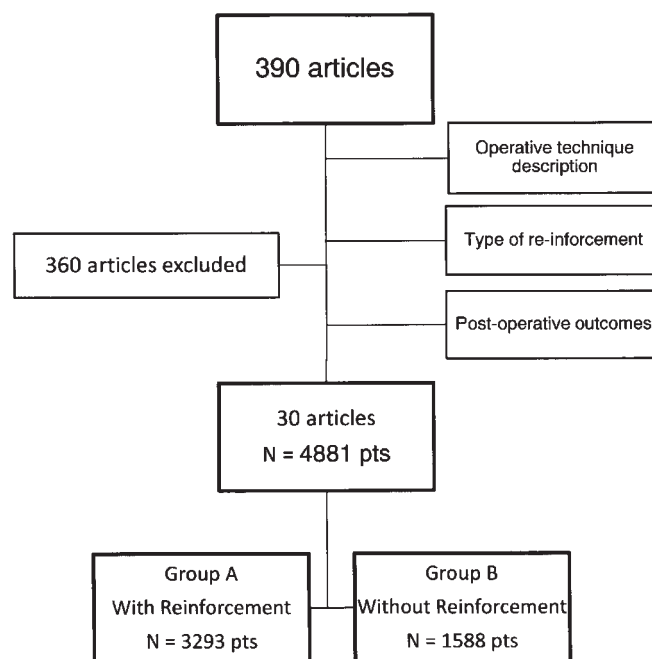
Figure 1. Flowchart of study selection methodology.

Table 1.
Characteristics of Included Studies

Author	Year	Study Type	Group A[a]	Group B[a]	Group A (Reinforcement)			Group B (Non-Reinforcement)		
					Leak, %	Bleed, %	Mortality, %	Leak, %	Bleed, %	Mortality, %
No reinforcement										
1 Casella et al.[b2]	2009	Retrospective	100					2.0	0.0	0.0
2 Sanchez-Santos et al.[b3]	2009	Retrospective	159					5.3	1.0	0.3
3 Sammour et al[6]	2010	Retrospective	100					3.0	2.0	0.0
4 Magee et al.[7]	2011	Retrospective	68					0.0	0.0	0.0
5 Bellanger et al.[8]	2011	Retrospective	529					0.0	0.4	0.2
6 Sabbagh et al.[9]	2010	Prospective	59					1.7	0.0	0.0
7 Nienhuijs et al.[10]	2010	Retrospective	74					5.4	1.3	0.0
8 Armstrong et al.[11]	2010	Retrospective	185					0.0	1.1	0.0
9 Ser et al.[b4]	2010	Retrospective	40					1.0	0.0	0.0
10 Triantafyllidis et al.[12]	2011	Retrospective	85					3.5	3.5	0.0
11 Dapri et al.[b5]	2010	RCT[c]	25					4.0	0.0	0.0
12 Rice et al.[13]	2010	Retrospective	115					3.5	0.0	0.9
13 Kiriakopoulos et al.[14]	2009	Prospective	15					6.7	6.7	0.0
14 Behrens et al.[15]	2011	Retrospective	34					2.9	2.9	0.0
Reinforcement										
1 Chowbey et al.[16]	2010	Retrospective	75		0.0	0.0	1.3			
2 Burgos et al.[17]	2009	Prospective	214		3.3	0.0	0.0			
3 Leyba et al.[18]	2011	Prospective	42		0.0	2.4	0.0			
4 Daskalakis et al.[19]	2011	Retrospective	144		2.1	2.8	0.0			
5 Menenakos et al.[20]	2010	Retrospective	261		3.8	1.9	0.3			
6 Albanopoulos et al.[21]	2010	Retrospective	353		3.4	2.5	0.8			
7 Alley et al.[22]	2010	Retrospective	85		0.0	2.3	0.0			
8 Gluck et al.[23]	2010	Retrospective	204		0.0	1.0	0.0			
9 Ayloo et al.[24]	2011	Retrospective	30		0.0	0.0	0.0			
10 Casella et al.[b2]	2009	Retrospective	100		4.0	0.0	0.0			
11 Arias et al.[25]	2009	Retrospective	130		0.8	0.0	0.0			
12 Diamanitus et al.[26]	2010	Retrospective	25		0.0	0.0	0.0			
13 Jacobs et al.[27]	2010	Retrospective	157		1.3	0.0	0.6			
14 Basso et al.[d28]	2011	Retrospective	100		4.0	8.0	1.0			
15 Basso et al.[d]	2011	Retrospective	200		2.5	2.5	0.5			
16 Lakdawala et al.[29]	2010	Retrospective	50		2.0	0.0	0.0			
17 Ser et al.[b4]	2010	Retrospective	78		0.0	2.5	0.0			

Author	Year	Study Type	Group A[a]	Group B[a]	Group A (Reinforcement)			Group B (Non-Reinforcement)		
					Leak, %	Bleed, %	Mortality, %	Leak, %	Bleed, %	Mortality, %
18	Dapri et al.[b,e5]	2010	RCT	50	50	6.0	0.0	0.0			
19	Dapri et al.[b,e]	2010	RCT	50		6.0	0.0	0.0			
20	Angrisani et al.[30]	2011	Retrospective	121		0.0	0.0	0.0			
21	Sanchez-Santos et al.[b3]	2009	Retrospective	381		2.6	0.8	0.6			
22	Csendes et al.[31]	2010	Prospective	343		4.7	2.3	0.0			

Table 1. (continued)
Characteristics of Included Studies

[a]Group A comprises patients with reinforcement of the staple line, whereas group B comprises patients with non-reinforcement of the staple line.

[b]Studies with reinforced and non-reinforced cohorts.

[c]RCT = randomized controlled trial.

[d]Basso et al. included 300 patients who all underwent staple-line reinforcement: 100 underwent Peri-Strip (Synovis Surgical Innovations, Deerfield, IL USA) reinforcement, whereas 200 underwent suture reinforcement.

[e]Dapri et al. included 3 cohorts: 1 non-reinforced and 2 reinforced (suture and Seamguard [W. L. Gore and Associates, Flagstaff, AZ, USA]).

RESULTS

Search Results and Demographics

The initial key word search returned 390 articles. After review with inclusion and exclusion criteria (**Figure 1**), 30 articles were identified for the actual systematic review (**Figure 1**). Group A (reinforcement) included 3293 patients and group B (non-reinforcement) included 1588 patients, for a total of 4881 patients. There were 25 single-cohort studies (15 reinforcement only and 10 non-reinforcement only) and 5 multiple-cohort studies. In terms of study design, there were 24 retrospective reviews, 5 prospective cohort studies, and 1 randomized controlled trial (**Table 1**). The overall female-to-male ratio was 3:1. The body mass index ranged from 30 to 85 kg/m^2 for group A and 32 to 103 kg/m^2 for group B. The ranges for percent of estimated weight loss after 12 months' follow-up were 30.6% to 81.1% for group A and 47.2% to 81.1% in group B.

Heterogeneity Results

Our results indicate that the variables length of stay and excess weight loss are heterogeneous among studies. The P values in both cases were calculated to be <.001, whereas the χ^2 values for length of stay and excess weight loss were 135 times and 100 times the degrees of freedom, respectively. In addition, the I^2 value for each variable was 99%. Taken together, this is sufficient evidence to exclude these variables from further analysis. The variable reintervention has a Q of 61, with 32 df; a P value of <.0013; and an I^2 value of 42%. The variable readmission has a Q of 84, with 34 df; a P value of <.001; and an I^2 value of 59%. Although the significant χ^2 value indicates heterogeneity, the ratios of Q to degrees of freedom are only 2 and 2.5 times for reintervention and readmission, respectively. In addition, the I^2 value for each is 47% and 59%, respectively. Given the low Q–to–degrees of freedom ratio and because the inconsistency statistic indicates that there may be moderate heterogeneity, we decided to continue to analyze these variables further.

In all, we further evaluated the following variables: leak rate, bleed rate, infection rate, reintervention rate, readmission rate, conversion rate, abdominal fluid collection rate, thromboembolic event rate, and mortality rate. In each study the authors reported numbers of patients who had each of these situations. As such, we were able to determine event rates for each study for

each variable, broken out by our 2 predetermined groups: reinforcement and no reinforcement. We used fixed-effects model analysis to determine pooled event rates and 95% CIs for each group.
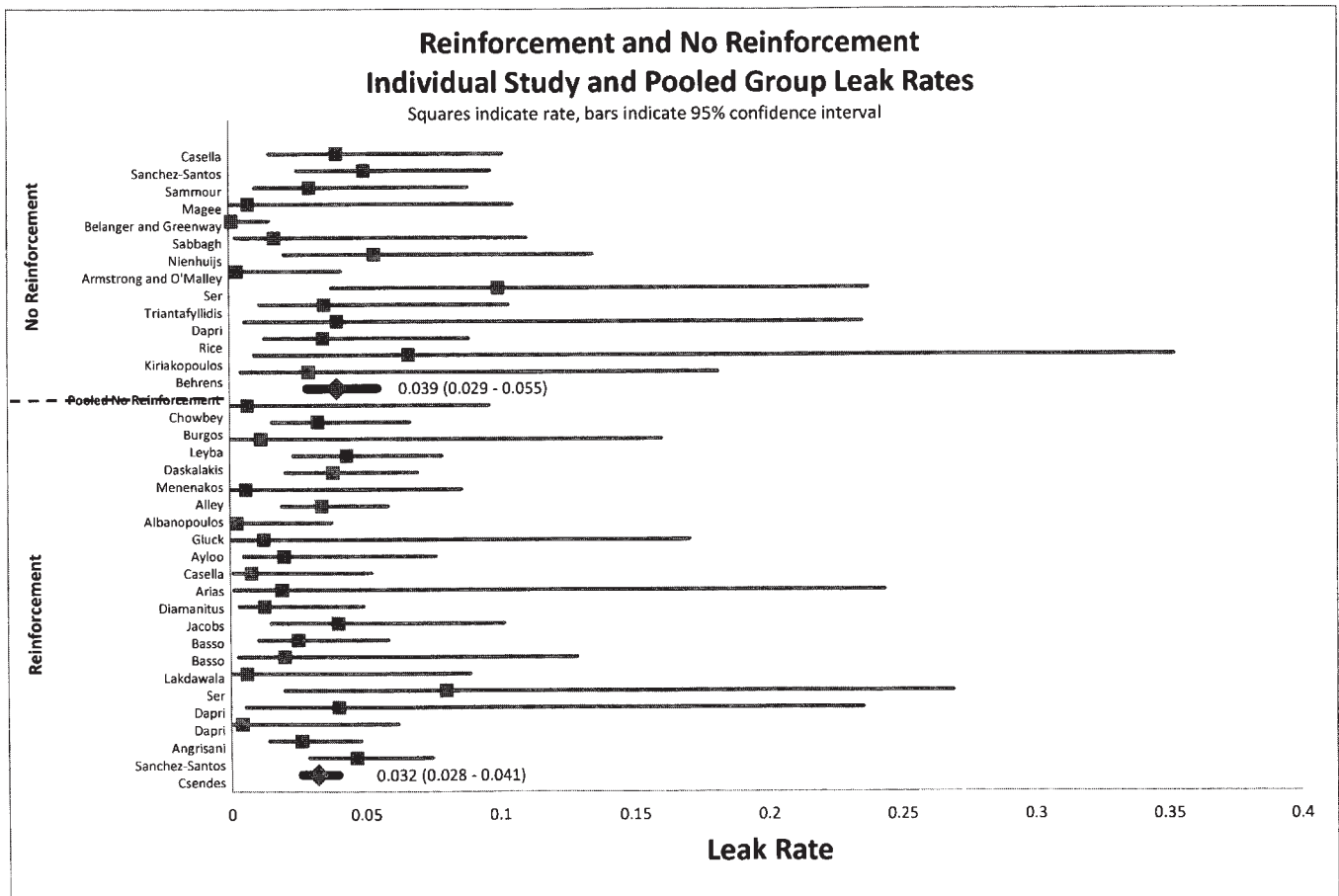
Leak Rates

Leak rates were not affected by reinforcement. **Figure 2** presents a forest plot for leak rate. Our results indicate that there is no statistical difference in the pooled event rate for leak rate. The statistical leak rates (**Figure 2**) for group A and group B were 3.2% (95% CI, 0.028−0.041) and 3.9% (95% CI, 0.029−0.055), respectively, indicating no difference. Both leak rates show agreement with currently published studies.
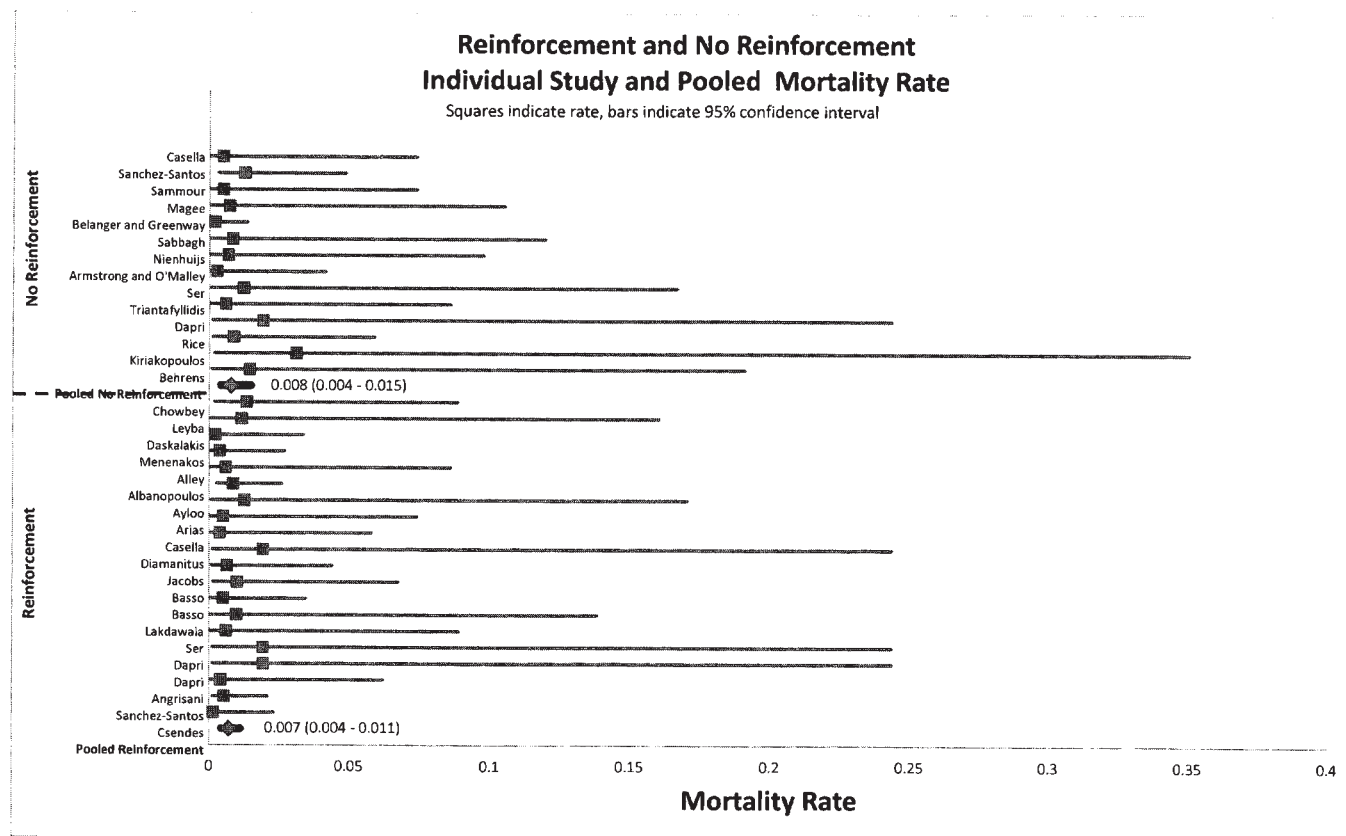
Mortality, Bleeding, and Reintervention Rates

Mortality, bleeding, and reintervention rates were not affected by reinforcement. **Figures 3**, **4**, and **5** indicate that there is no statistical difference in the pooled rate of mortality, bleeding, or reintervention. The statistical mortality rates (**Figure 3**) for the reinforcement group and non-reinforcement group were 0.7% (95% CI, 0.004−0.011) and 0.8% (95% CI, 0.004−0.015), respectively, indicating no difference. For bleeding and reintervention, the results were similar: 2.6% (95% CI, 0.020−0.033) and 1.7% (95% CI, 0.011−0.027), respectively, for bleeding and 3.1% (95% CI, 0.023−0.040) and 3.2% (95% CI, 0.021−0.047), respectively, for reintervention. Data for mortality, bleeding, and reintervention rates after LSG show agreement with currently published studies.

Similar results for infection, readmission, conversion to open surgery, abdominal fluid collection, and venous thromboembolism were found (data not shown). Summary results of the 9 outcome variables compared between groups A and B are shown in **Table 2**.

Figure 2. Forest plot of pooled event rates of odds ratios for gastric leak rates of group A (reinforced) and group B (non-reinforced) for each article. The squares indicate the event rates, and the lines indicate the extent of the 95% CI. Summative pooled event rates are shown with 95% CIs in parentheses.

**Reinforcement and No Reinforcement
Individual Study and Pooled Mortality Rate**
Squares indicate rate, bars indicate 95% confidence interval

Figure 3. Forest plot of pooled event rates of odds ratios for mortality rates of group A (reinforced) and group B (non-reinforced) for each article. The squares indicate the event rates, and the lines indicate the extent of the 95% CI. Summative pooled event rates are shown with 95% CIs in parentheses.

DISCUSSION

Sleeve gastrectomy is gaining popularity whether as a primary, staged, or revision operation. In 2009 the American Society for Metabolic and Bariatric Surgery endorsed the SG for its potential value as a first-stage operation for high-risk patients.[32] In June 2012 Medicare affirmed to reimburse and recognize SG as an appropriate weight loss procedure for patients who met National Institutes of Health guidelines for weight loss surgery candidacy.[33,34] Despite LSG's success, staple-line leakage and bleeding after the procedure continue to be the most serious complications (1%–3% in large published series)[8,13,20,28,35] and are the most frequent causes of death after bariatric surgery including LSG.[19] Theoretically, staple-line reinforcement should increase its strength and help decrease the incidence of complications associated with staple lines. Though a relatively standardized operation, the reinforcement step in SG is quite often a matter of surgeon preference. We there-

fore report the largest systematic literature review investigating staple-line reinforcement, subsequent leak rate, and other outcomes in LSG.

The pathophysiology of staple-line leaks after LSG is unclear. Compromise of blood supply, especially at the angle of His near the crura, stapler device failure, poor technique, and postoperative gastroparesis with an intact pylorus causing increasing intragastric pressure have all been implicated.[37] Although 3 of 5 bariatric surgeons surveyed at an international conference reported reinforcing the sleeve staple line, many still believe that the aforementioned pathophysiologic factors cannot be overcome with simple staple-line reinforcement.

Our analysis showed an overall leak rate and mortality rate comparable with most published large series. However, we found no statistical difference in 9 different outcome variables between the use of staple-line reinforcement
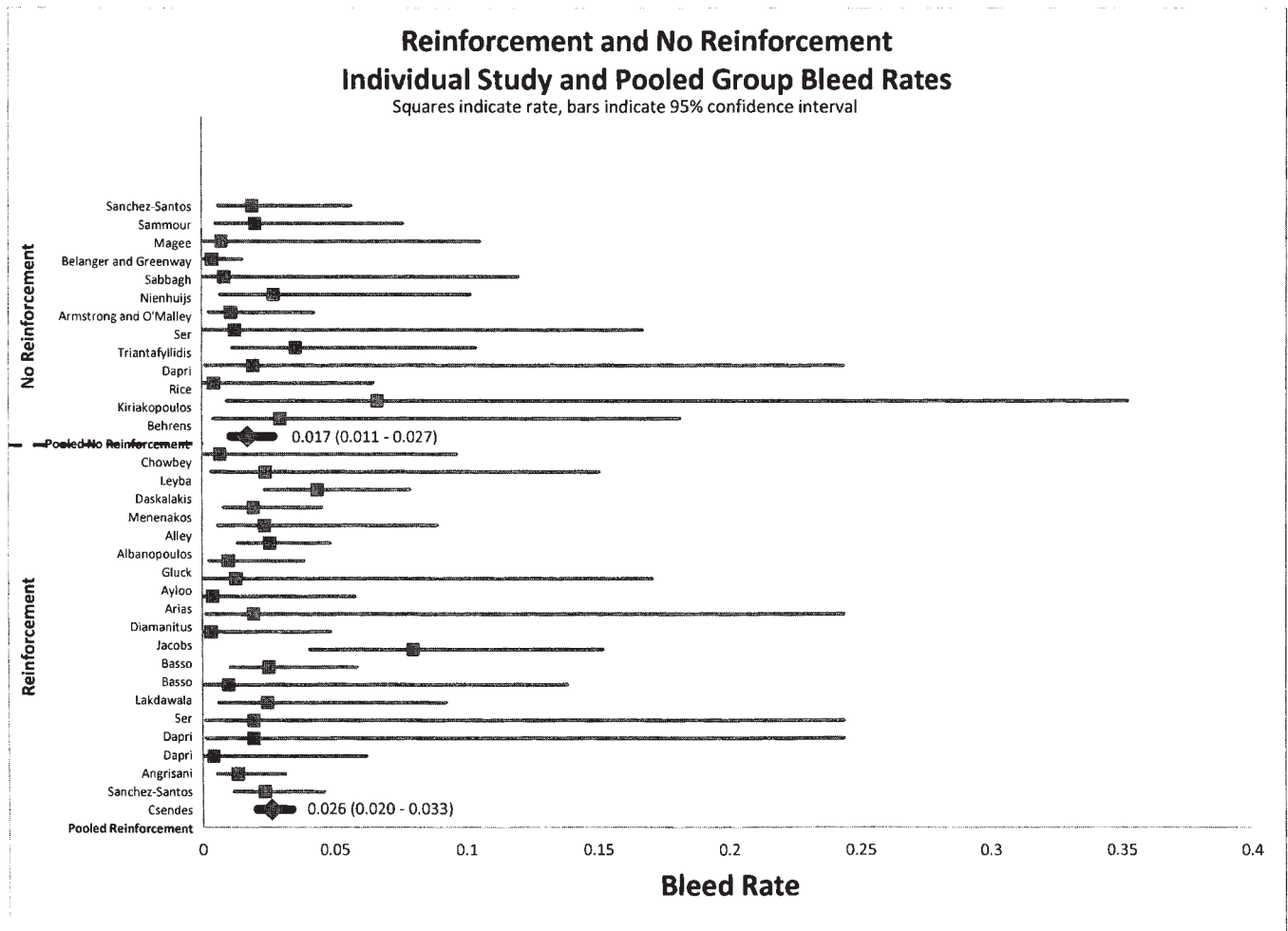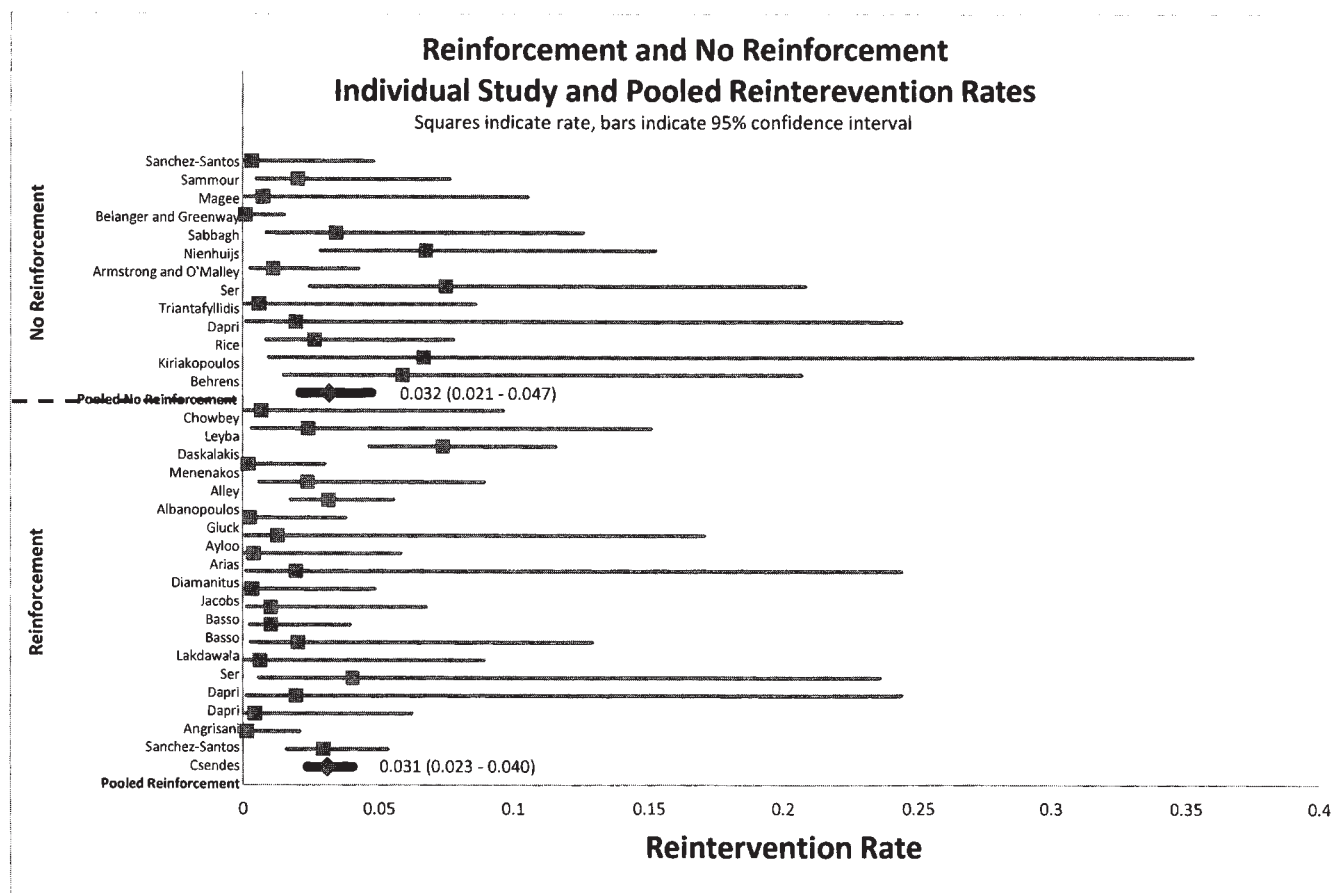
Figure 4. Forest plot of pooled event rates of odds ratios for perioperative bleeding rates of group A (reinforced) and group B (non-reinforced) for each article. The squares indicate the event rates, and the lines indicate the extent of the 95% CI. Summative pooled event rates are shown with 95% CIs in parentheses.

and non-reinforcement. This is in contrast to Choi et al.,[38] who reported through a meta-analysis of 8 studies that staple-line reinforcement had the advantages of decreased postoperative leak and overall complications. This may very well be because of differences in study design (systematic review vs meta-analysis) and, therefore, types of articles included in the analysis. Ser et al.,[4] in their experience in 118 consecutive patients, found a statistically significant difference between their 2 groups, citing a 0% leak rate in their reinforced group versus 10% in the non-reinforced group, which is one of the greatest differences of any large cohort study performed to date.

Our overall initial article review yielded close to 400 articles, of which 2 were randomized controlled trials, one by Dapri et al.[5] and one by Musella et al.[39] Dapri et

al. showed, through a prospective randomized trial, with 3 treatment arms (non-reinforced, suture reinforced, and stapler-load buttressing), a difference in intraoperative blood loss parameters, but no difference for leak rate, after staple-line reinforcement. They did not report any deaths in their study, and their overall leak rate was 4% to 6%, which is consistent with the overall leak rate of 3% to 4% in our systematic analysis. According to their study, the additional cost and time of staple-line reinforcement may be justified by reduced intraoperative bleeding complications.

In another randomized prospective study published later, Musella et al.[39] showed no difference in the rate of leak or bleeding but did show a higher rate of stenosis with staple-line reinforcement. Their study included

Figure 5. Forest plot of pooled event rates of odds ratios for reintervention rates of group A (reinforced) and group B (non-reinforced) for each article. The squares indicate the event rates, and the lines indicate the extent of the 95% CI. Summative pooled event rates are shown with 95% CIs in parentheses.

two arms: non-reinforced and suture reinforced. Compared with the prior randomized controlled trial, there were some minor differences in technique, such as the type of cartridge load and bougie size, and it is unclear whether these differences contributed to the differences in overall outcomes with respect to staple-line bleeding. As before, their overall staple-line leak rate of 2.5% to 5% agrees with the general literature on this topic, as well as with our systematic review results.

Our study possesses a number of limitations. First, our analysis was purely retrospective and based on pooled results of heterogeneously constructed studies. Not all of the studies consistently reported all outcomes that we wanted to analyze. To offset this inconsistency, we performed a detailed heterogeneity analysis to pick the most appropriate outcome variables as reported; however, this methodology is fraught with retrospective bias even in the best-case scenario. In addition, we were unable to stratify

our results based on the type of reinforcement used (e.g., stapler-load reinforcement vs suture reinforcement). This was because many of the studies actually did not report the exact type of reinforcement used. We are therefore unable to make any conclusions about the superiority of one reinforcement method or another. Finally, because of the retrospective methodology used, we were not able to perform a multivariate risk factor analysis to determine which variables predispose patients to worse outcomes with and without reinforcement.

Given the previously mentioned limitations, we propose that rigorous, level I, prospective trials are needed to determine the true effect of staple-line reinforcement on leak rates and overall morbidity in LSG. Because of the rarity of the complication, as well as the number of different types of reinforcements available, a large number of patients will be required in each arm of the study for meaningful, clinically relevant results.

Table 2.
Summary of Comparison of Reinforced and Non-Reinforced Groups Across All 9 Measured Variables

Variable	Reinforced, % (%)[a]	Non-Reinforced, % (%)[a]
Leak rate[b]	3.9 (CI, 2.9–5.5)	3.3 (CI, 2.8–4.1)
Bleed rate[b]	1.7 (CI, 1.1–2.7)	2.6 (CI, 2.0–3.3)
Infection rate[b]	1.3 (CI, 0.7–2.3)	1.5 (CI, 0.9–2.3)
Reintervention rate[b]	3.2 (CI, 2.1–4.7)	3.1 (CI, 2.3–4.0)
Readmission rate[b]	3.2 (CI, 2.0–4.8)	3.5 (CI, 2.7–4.7)
Conversion rate[b]	1.4 (CI, 0.8–2.5)	0.7 (CI, 0.4–1.2)
Abdominal collection rate[b]	1.9 (CI, 1.1–3.2)	1.7 (CI, 1.2–2.4)
Thromboembolic complication rate[b]	0.7 (CI, 0.4–1.3)	0.7 (CI, 0.4–1.1)
Mortality rate[b]	0.8 (CI, 0.4–1.5)	0.7 (CI, 0.4–1.1)

[a]Values represent overall percentage pooled rates (CI = 95% confidence interval).

[b]No statistically significant difference in pooled rate.

CONCLUSION

Our systematic review shows a lack of statistical difference for staple-line leak in LSG with or without staple-line reinforcement, as well as other major complications. Future prospective randomized trials are needed to determine the true effect of staple-line reinforcement on leak rates and overall morbidity in LSG.

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