

Reinforcing the Staple Line During Laparoscopic Sleeve Gastrectomy: Does It Have Advantages? A Meta-analysis

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Published online: 2 June 2012
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Abstract

Background This study aims to identify whether reinforcing the staple line during laparoscopic sleeve gastrectomy (LSG) has advantages.

Methods We searched MEDLINE (PubMed; till August 2011), EMBASE (till August 2011), and the Cochrane Central Register of Controlled Trials (Central) in the Cochrane Library (till August 2011) using common keywords related to sleeve gastrectomy and reinforcement. The keywords were as follows: “sleeve gastrectomy” and “reinforcement,” or “reinforcing,” or “reinforce,” or “leak,” or “leakage,” or “staple,” or “stapling,” or “oversew,” or “oversewing,” or “oversewed.” The language of publication was limited to English only.

Results Of the 358 articles meeting our initial criteria, eight full texts (two randomized control trial [RCT] and six cohort studies), involving 1,345 participants (828 patient cases and 517 controls) were included in the final analysis. Comparing the reinforcement of the staple line to no reinforcement of the staple line, the odds ratio (OR) for overall complications was 0.521 (95 % confidence intervals [CI], 0.349–0.777). In addition, the OR for staple line leak was 0.425 (95 % CI,

0.226–0.799) and for staple line hemorrhage was 0.559 (95 % CI, 0.247–1.266).

Conclusion The current study showed that reinforcing the staple line during LSG has the following advantages: decreased incidence of postoperative leak and overall complications. More prospective studies with better evidence are needed.

Keywords Sleeve gastrectomy · Leak · Reinforcement

Introduction

Laparoscopic sleeve gastrectomy (LSG) was originally performed as a bridge procedure to laparoscopic Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch [1–3]. Recently, LSG has gained more popularity as an independent bariatric procedure because LSG was reported to be an effective, safe, and time-saving procedure [4, 5] leading to adequate weight loss for morbidly obese patients [6]. Leak and staple line hemorrhage are the least desirable complications after LSG as there is a long staple line after LSG. Although lots of surgeons reinforce the staple line during LSG, the effect of doing so is still controversial. The aim of the present study was to identify the effect of reinforcing the staple line during LSG, by reviewing published articles with meta-analysis.

Materials and Methods

Literature Search

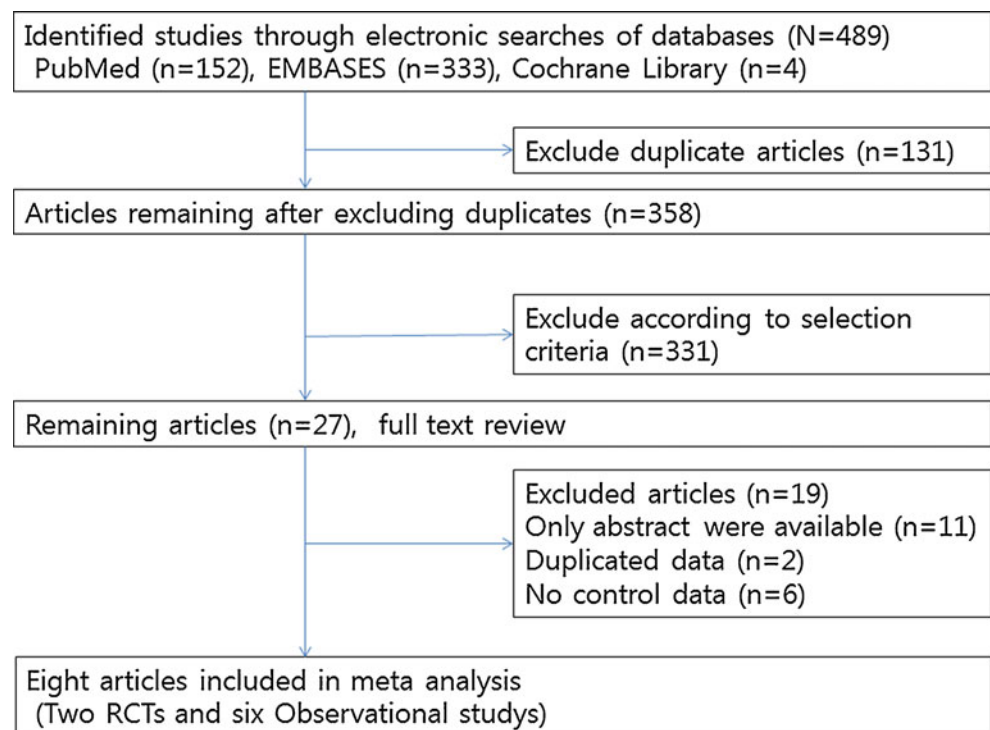
We searched MEDLINE (PubMed; till August 2011), EMBASE (till August 2011), and the Cochrane Central Register of Controlled Trials (Central) in the Cochrane Library

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Fig. 1 Flow diagram for identification of selected studies. One article (Dapri et al. [13]) was divided into two studies as it compared two different methods of reinforcing the staple line (buttress and oversewing) with the control group



(till August 2011) using common keywords related to sleeve gastrectomy and reinforcement. The keywords were as follows: “sleeve gastrectomy” and “reinforce*,” or “leak*,” or “staple*,” or “oversew*.” The language of publication was limited only to English.

Selection Criteria

Two of the authors (Y.Y.C. and J.B.) independently evaluated the eligibility of all of the studies collected from the databases based on the selection criteria, which were as follows: the publication was a cohort study or an RCT, which investigated the relationship between reinforcing the

staple line and postoperative complications after LSG such as leak or staple line hemorrhage; values in cells of a 2×2 table were available; and the odds ratios (OR) could be calculated or described. If the data were duplicated in more than one study, the first published study or the more reasonable study was selected for analysis. If there was any disagreement, it was resolved by discussion.

Assessment of the Methodological Quality

We assessed the methodological quality of each study according to the Newcastle–Ottawa Scale [7] for case–control studies and cohort studies and the Jadad scale [8] for RCT.

Table 1 Characteristics and outcomes of the included trials

Trials	Country and year	Type of study	Reinforcement			Type of reinforcement	Control		
			Leak	Hemorrhage	Overall		Leak	Hemorrhage	Overall
Consten et al. [9]	USA, 2004	Cohort	0/10	0/10	0/10	Buttressing	0/10	2/10	3/10
Silecchia et al. [10]	Italy, 2009	Cohort	–	–	4/29	Oversewing	–	–	10/56
Sanchez-Santos et al. [11]	Spain, 2009	Cohort	10/381	2/381	14/381	Combined	8/159	2/159	14/159
Ser et al. [12]	Taiwan, 2010	Cohort	0/78	2/78	8/78	Oversewing	4/40	0/40	6/40
Dapri et al. [13]	Belgium, 2010	RCT	1/25	–	3/25	Oversewing	1/25	–	5/25
			2/25	–	6/25	Buttressing	1/25	–	5/25
Daskalakis et al. [14]	Germany, 2011	Cohort	3/144	4/144	9/144	Buttressing	7/86	6/86	14/86
Stamou et al. [15]	Greece, 2011	Cohort	2/96	0/96	2/96	Buttressing	4/91	3/91	12/91
Musella et al. [16]	Italy, 2011	RCT	1/40	4/40	9/40	Oversewing	2/40	2/40	4/40

Table 2 Methodological quality assessment of included trials

Type of trials	Trials	Selection (0–4)				Comparability(0–2)		Outcome (0–3)			Total
		REC	SNEC	AE	DO	SC	AF	AO	FU	AFU	
Cohort studies	Consten et al. [9]	★	★	★	★	★			★	★	7
	Silecchia et al. [10]		★	★	★				★	★	5
	Sanchez-Santos et al. [11]	★	★	★	★			★	★	★	7
	Ser et al. [12]	★	★	★	★	★			★	★	7
	Daskalakis et al. [14]		★	★	★	★			★	★	6
	Stamou et al. [15]	★	★	★	★	★		★	★	★	8
Type of trials	Trials	Randomization			Blinding			An account of all patients			Total
		Mentioned		Appropriated	Mentioned		Appropriated				
RCTs	Dapri et al. [13]	1		1	0		0		1		3
	Musella et al. [16]	1		0	0		0		0		1

REC representativeness of the exposed cohort, SNEC selection of the non-exposed cohort, AE ascertainment of exposure, DO demonstration that outcome of interest was not present at start of study, SC study controls for age, sex, and marital status, AF study controls for any additional factors, AO assessment of outcome, FU follow-up long enough for outcomes to occur, AFU adequacy of follow-up of cohorts, RCTs randomized controlled trials

All searched abstracts were evaluated by two authors for subject relevance. The full publication of each relevant abstract

was reviewed and included in the meta-analysis. If there was no full publication, with only an abstract available, it was excluded.

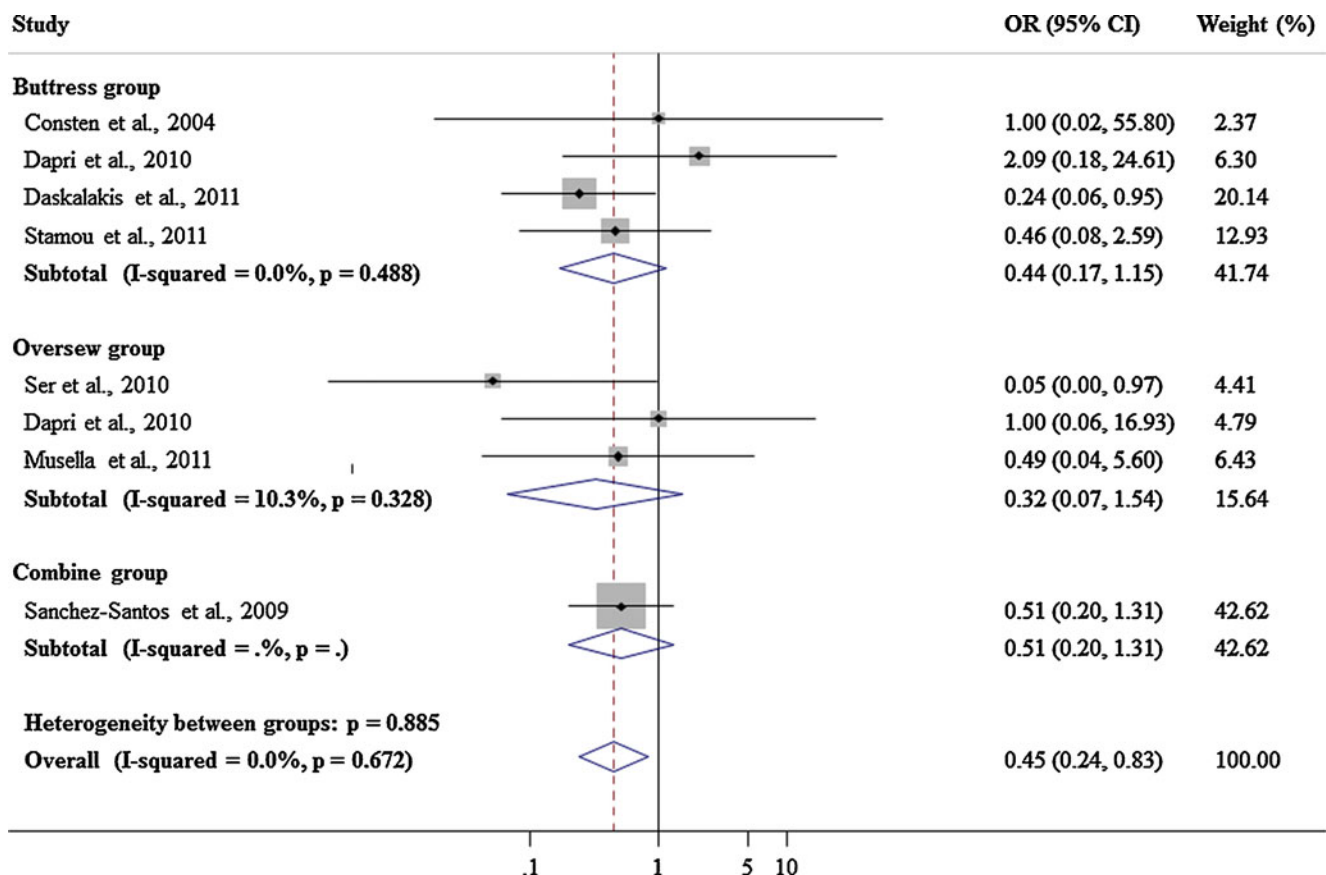


Fig. 2 The forest plot showed the OR of leak after LSG of the reinforcing the staple line group and the control group with fixed-effects model meta-analysis. OR odds ratio

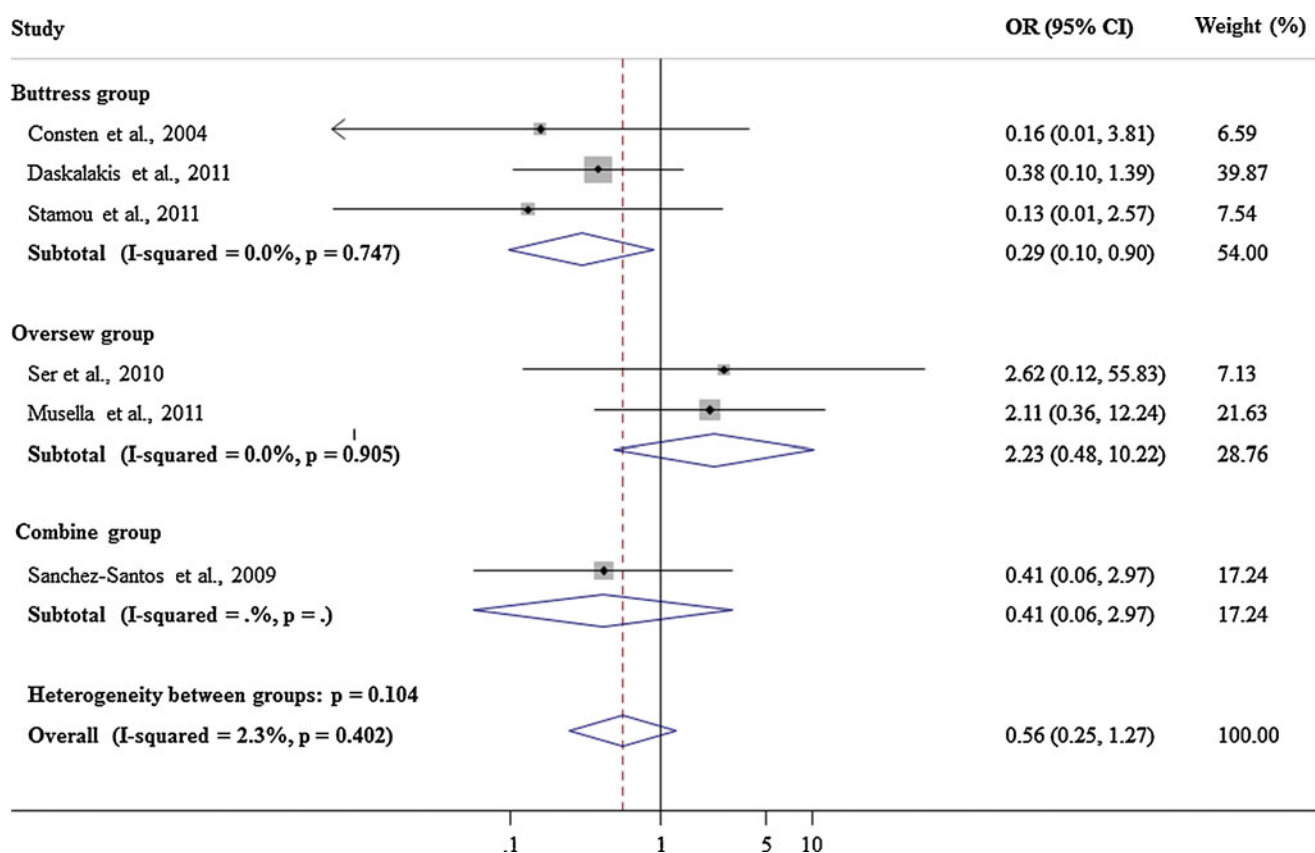


Fig. 3 The forest plot shows the OR of staple line hemorrhage after LSG of the reinforcing the staple line group and the control group with fixed-effects model meta-analysis. OR odds ratio

Statistical Analysis

We performed meta-analysis with Stata version 11.0 software package (StataCorp, College Station, TX, USA). We calculated the effect sizes as the OR with 95 % confidence intervals (CI) for dichotomous variables. We evaluated heterogeneity in results across studies using Higgins I^2 and chi-square. We considered a chi-square <0.10 and an I^2 value >50 % as indicative of substantial heterogeneity. If it was considered that there was no heterogeneity, we applied the fixed-effects model with Woolf's (inverse variance) method. If there was a "zero cell" in which one arm of a study contained no events or all events, we added 0.5 to each cell of the 2×2 table for the trial.

The publication bias of studies was estimated by Begg's funnel plot with Egger's test. If there was asymmetry of Begg's funnel plot or the $p < 0.05$ with the Egger's test, we considered it as publication bias.

Results

As Fig. 1 shows, 489 articles were identified by researching three electronic databases. After exclusion of articles based on the selection criteria, 27 articles remained. Finally, eight articles [9–16] (two RCTs and six cohort studies) were left after full text

review, and these were included in the final meta-analysis. There were 1,335 participants in the eight studies (507 patients in the control groups, and 828 patients in the intervention groups). For studies describing age and sex, the mean age was 36.7 years, and 65 % of the participants were women.

Table 1 shows the characteristics and outcomes of the included trials. Two of the eight trials were RCT, and the others were cohort studies. One trial [13] compared three different techniques (buttressing, oversewing, and no reinforcement), and it was divided into two studies. There were four trials comparing the buttressing and control groups and four other trials comparing the oversewing and control groups. One trial [11] did not contain detailed information about the number of cases that was in the buttressing group or in the oversewing group.

The methodological quality of included trials is described in Table 2. There were six cohort studies, and the mean stars of these trials were seven. Two RCTs that were included in the meta-analysis had 3 and 1 point, respectively, so the mean point was 2.

Leak After LSG

As shown in Fig. 2, reinforcement of the staple line during LSG was significantly associated with a decreased risk of leak

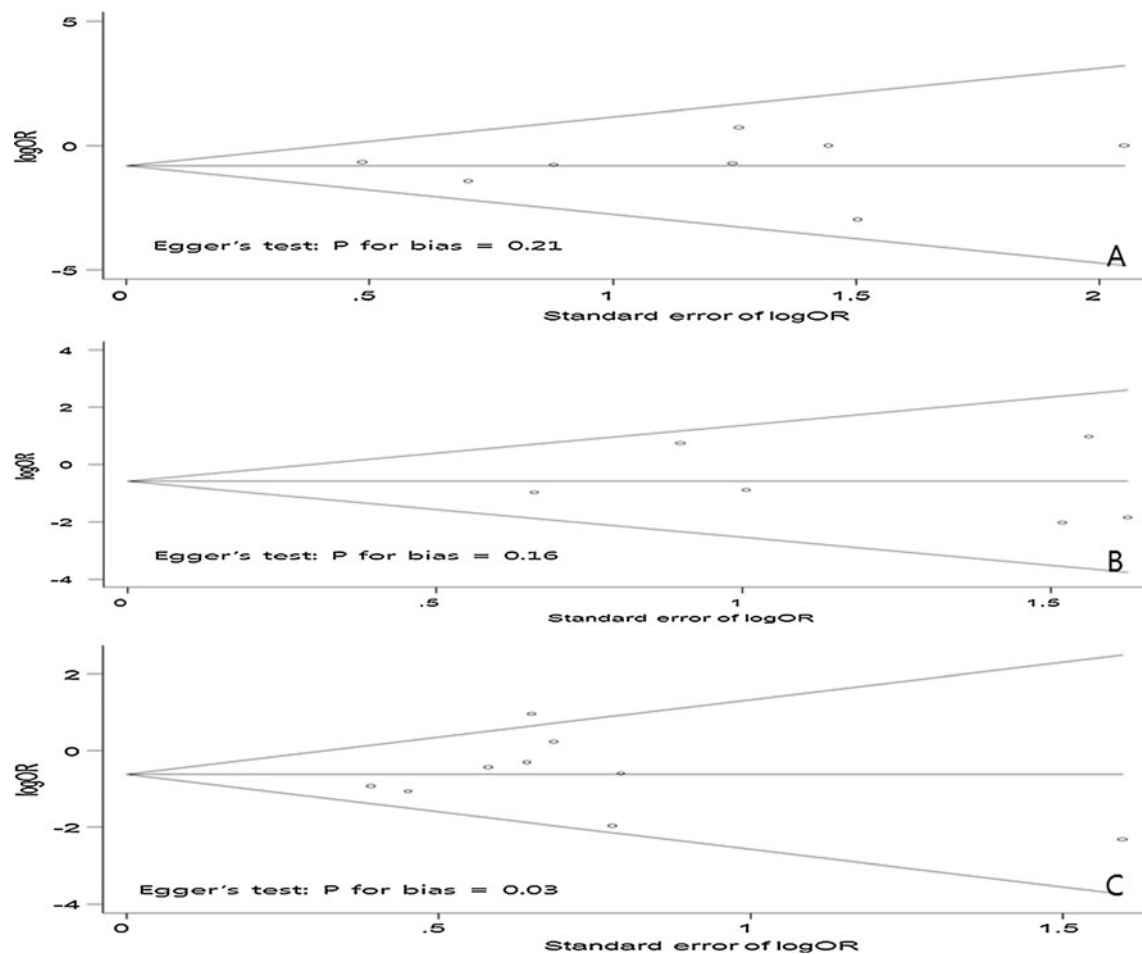


Fig. 4 Begg's funnel plots and Egger's test for identifying publication bias for **a** the leak, **b** the staple line hemorrhage, and **c** the overall complications

in a fixed-effects model ($I^2=0\%$ and $p=0.672$) meta-analysis (OR=0.45; 95 % CI, 0.24–0.83) of eight trials (one trial [10] was excluded because there was no detailed information about the leak). No publication bias was detected in the trials (Begg's funnel plot was symmetric and Egger's test, p for bias=0.21; Fig. 4a).

A subgroup meta-analysis of the two different methods of staple line reinforcement (buttressing and oversewing) showed some positive relationships to leak after LSG, but the findings were not statistically significant (buttress group: OR=0.44; 95 % CI, 0.17–1.15; oversewing group: OR=0.32; 95 % CI, 0.07–1.54).

Staple Line Hemorrhage After LSG

Figure 3 shows the relationship between reinforcing the staple line during LSG and staple line hemorrhage. Overall, reinforcing the staple line seemed to be associated with a decreased risk of staple line hemorrhage, but this result had no statistical significance in a fixed-effects model ($I^2=2.3\%$ and $p=0.402$) meta-analysis (OR=0.56;

95 % CI, 0.25–1.27) of six trials (two trials [10, 13] were excluded as there were no detailed information about the staple line hemorrhage). In addition, there was no publication bias in the selected trials (Begg's funnel plot was symmetric and in Egger's test, p for bias=0.16; Fig. 4b).

Despite this, a subgroup analysis showed that reinforcing the staple line with buttressing was associated with a decrease in the risk of staple line hemorrhage after LSG (OR=0.29; 95 % CI, 0.10–0.90). Contrary to this, oversewing the staple line seemed to increase the risk of staple line hemorrhage after LSG, but this result was not statistically significant (OR=2.23; 95 % CI, 0.48–10.22; Fig. 5).

Overall Complications After LSG

The overall complications was defined as the full spectrum of complications, which were described in each trial such as wound complication, intra-abdominal abscess, intra-abdominal bleeding except staple line hemorrhage, stenosis, and reflux. Overall, reinforcement of the staple line was associated with a decrease in the risk

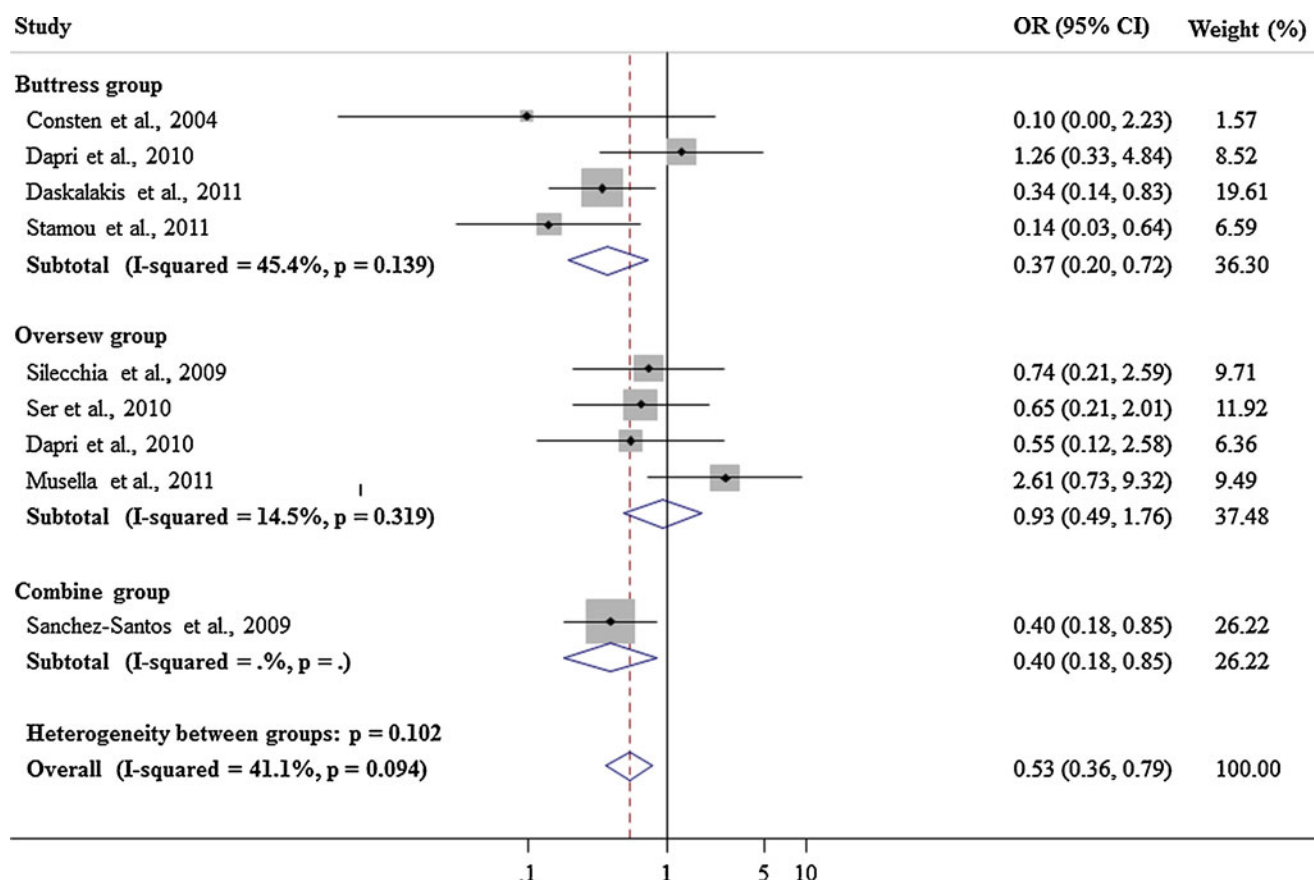


Fig. 5 The forest plot showed the OR of the overall complications after LSG of the reinforcing the staple line group and the control group with fixed-effects model meta-analysis. OR odds ratio

of overall complications after LSG in a fixed-effects model ($I^2=41.1\%$) meta-analysis (OR=0.53; 95 % CI, 0.36–0.79) of all trials. The Begg's funnel plot was not symmetric and the p value of Egger's test was lower than 0.05 (Fig. 4c), so it was suspected that there was publication bias (a study with a small sample size showing a lack of an association with overall complications of reinforcing the staple line tends not to be published).

In the subgroup analysis, reinforcing the staple line with buttressing was associated with a decrease in the risk of overall complications after LSG (OR=0.37; 95 % CI, 0.20–0.72), but oversewing was not associated with a decreased risk (OR=0.93; 95 % CI, 0.49–1.76).

Discussion

Laparoscopic stapling devices have become pivotal tools in the field of laparoscopic bariatric surgery. However, they are also associated with complications such as leak, bleeding, fistula, and technical failure, even though these complications are not common [17]. In theory, reinforcing the staple line should increase its strength

and help decrease the incidence of complications associated with staple lines. Furthermore, there seemed to be no reason to believe that reinforcement would lead to harmful effects. However, some authors have claimed [18, 19] that reinforcing the staple line has no effect and is, therefore, a useless procedure. Hence, it is obvious that reinforcing the staple line needs more analysis.

In practice, according to Gagner's report [20], 65.1 % of 106 surgeons who participated in The Second International Consensus Summit for Sleeve Gastrectomy in 2009 answered that they reinforced the staple line of the gastric tube. Of these, 50.9 % reinforced the staple line with oversewing, 42.1 % used a buttress, and 7 % did both.

The incidence of leak after LSG, which every surgeon wants to avoid, has been reported to be 0–8 % [21–23]. Compromised blood supply, high pressure due to preservation of the pylorus, and failure of the stapling devices are believed to be some of the causes of leak after LSG [18, 23]. In this meta-analysis, reinforcing the staple line seemed to decrease staple line leak after LSG (Fig. 2). However, closer examination of the individual methods, which initially seemed to show an association with a lower incidence of leak, showed that the associations were not statistically significant.

The incidence of staple line hemorrhage has been reported to be 0 to 8.7 % [20]. The reinforcing material may compress the transected tissue, and this could help reduce staple line hemorrhage after LSG [24]. Although there was no significant effect of overall reinforcement of the staple line in this meta-analysis, reinforcement with a buttress seemed to decrease staple line hemorrhage (Fig. 3). On the other hand, reinforcing the staple line with oversewing may increase the risk of staple line hemorrhage after LSG, although this result had no statistical significance. We thought that there could be two reasons for this finding: First, only two trials were available, and one of them [16] had very low methodological quality, although it was an RCT; second, oversewing the staple line may increase the risk of tearing at the sutured point [25, 26], which could cause hemorrhage.

In a subgroup analysis of this meta-analysis, reinforcing the staple line with a buttress may decrease the risk of staple line hemorrhage and overall complications, but it is not clear whether it decreases the risk of staple line leak after LSG. Some authors [9, 27, 28] reported that reinforcing the staple line with a buttress helps prevent staple line complications such as leak and hemorrhage; however, this procedure is expensive. On the other hand, if it can decrease the incidence of staple line complications, resulting in shorter hospital stays, it can lead to a decrease in the overall cost [27, 29].

It is disappointing that reinforcing the staple line with oversewing did not show any advantage compared with the control group in leak, hemorrhage, and overall complications. In addition, it could lead to stricture of the gastric sleeve [3, 30] and leak from tears caused by the sutures [18].

The present study has some limitations. The total number of trials that were included in the final meta-analysis was only eight, and only two RCTs were included. Moreover, some trials had low methodological quality. The asymmetry of the funnel's plot in overall complications may be caused by low methodological quality or publication bias. In addition, 11 trials were excluded by the selection criteria because only the abstract was available in these cases. Several RCTs were included in these excluded trials, so these ongoing trials may change the results of the meta-analysis of this subject.

Conclusion

In summary, this meta-analysis indicated that reinforcing the staple line with a buttress during LSG seemed to decrease the risk of staple line hemorrhage and overall complications. The effect of reinforcing the staple line with oversewing was unclear. More research is needed to provide clearer

information about the effects of each method of reinforcing the staple line.

Conflicts of Interest All authors have no commercial interest.

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