Staple line oversewing during laparoscopic sleeve gastrectomy

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ABSTRACT

INTRODUCTION This meta-analysis was performed to assess the possible benefits of staple line oversewing during laparoscopic sleeve gastrectomy.

METHODS A comprehensive search up to February 2017 was conducted on PubMed, the Web of Science™ and Embase™. All eligible studies were included, and the outcomes of staple line bleeding and leak, overall complications and operative time were pooled.

RESULTS A total of 7 randomised controlled trials involving 845 patients (428 cases and 417 controls) were analysed. There was no significant difference in staple line bleeding (relative risk [RR]: 0.858, 95% confidence interval [CI]: 0.343–2.143, $p=0.742$), leak (RR: 0.650, 95% CI: 0.257–1.644, $p=0.363$) or overall complications (RR: 0.913, 95% CI: 0.621–1.342, $p=0.644$) between the oversewing group and the patients who did not have oversewing. Oversewing of the staple line was associated with a longer operative time (weighted mean difference: 14.400, 95% CI: 7.198–21.602, $p=0.000$).

CONCLUSIONS Oversewing the staple line during laparoscopic sleeve gastrectomy does not decrease the risk of staple line bleeding, leakage or overall complications but it does prolong the operative time.

KEYWORDS

Sleeve gastrectomy – Laparoscopic – Oversewing

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Laparoscopic sleeve gastrectomy (LSG) was introduced into bariatric surgery as a first step approach followed by Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch.¹ In the early 2000s bariatric surgeons began to use it as a standalone procedure for morbidly obese patients. LSG has lower operative risks and a simpler methodology than other well established procedures.² It has now gained worldwide popularity owing to its satisfactory mid-term results of weight loss and resolution of co-morbidities.³

The major complications of LSG in the early postoperative course are staple line bleeding and leakage. Bleeding from the staple line is the most common complication and exists in about 1.1–8.7% of cases.^{4,5} This cannot always be treated conservatively and may require reoperation. The most dangerous and life threatening complication is staple line leakage, with the reported incidence ranging from 0.5% to 2.7%.^{6,7} Staple line reinforcement (SLR) has been proposed to decrease the risk of these complications. SLR can be achieved with several options: oversewing the staple line with a running absorbable suture, buttressing it with specific materials or roofing the staple line. Although it has been postulated that there are fewer complications, SLR remains controversial and its effectiveness is still unclear.

Recently, several studies have examined the effects of oversewing the staple line during LSG but their findings have been inconsistent. In order to be able to draw more comprehensive conclusions, we therefore performed a meta-analysis of randomised controlled trials (RCTs) to evaluate the possible benefits.

Methods

A comprehensive search was performed of English language publications listed in PubMed, the Web of Science™ and Embase™ from the inception dates of each database up to February 2017. The following search terms comprised “laparoscopic OR laparoscopy”, “sleeve gastrectomy”, “reinforcement”, “leak OR leakage OR fistula” and “bleed OR hemorrhage”. Our search was limited to clinical studies. Reference lists from original studies were also examined manually to identify additional publications. If studies from the same investigators contained overlapping data, the most recent article with the largest sample size was used.

In order to be included in our meta-analysis, studies had to compare the outcomes of staple line oversewing versus no reinforcement during LSG. Furthermore, they had to

report at least one of the following outcomes: postoperative staple line bleeding, leak, other complications or operative time. Studies were excluded if they were not RCTs, did not concern human research and there were no available data.

Data extraction

Two investigators (ZW and JL) separately extracted data from the included studies, using a standardised form. Factors examined comprised first author, publication year, country in which the trial was conducted, number of participants, staple line haemorrhage, leak, overall postoperative complications, operative time and follow-up duration. Disagreements were resolved by discussion with a third reviewer.

Assessment of study quality

The methodological quality of each study was evaluated using the Jadad composite scale, which assesses descriptions of randomisation, blinding, withdrawals and dropouts.⁸ The quality scale ranged from 0 to 5 points. A study with a score of ≥3 points was regarded as high quality whereas a score of <3 indicated a low quality report.

Statistical analysis

Relative risks (RRs) were calculated with 95% confidence intervals (CIs) to compare dichotomous variables.

Continuous variables were analysed using weighted mean differences and 95% CIs. Heterogeneity between the studies was assessed with Cochran’s Q test.⁹ If the studies were shown to be homogeneous with a *p*-value of >0.10 for the Q test, the RRs for each study were pooled by means of a fixed effects model (Mantel–Haenszel method).¹⁰ If the studies were not homogeneous, a random effects model (DerSimonian and Laird method) was employed.¹¹ Sensitivity analysis was performed to assess the stability of the results by removing a single study from the meta-analysis sequentially to reflect the influence of that individual dataset on the summary RR. Publication bias was assessed using both funnel plots and Egger’s linear regression test.¹² All analyses were performed with Stata® version 13.1 (StataCorp, College Station, TX, US), using two-sided *p*-values.

Results

The electronic search strategy identified 571 publications that mentioned oversewing the staple line during LSG. By examining title, abstract and full text, articles were selected based on the inclusion and exclusion criteria (Fig 1). Eight studies were eligible for analysis after careful screening. Finally, the Jadad scale was used to assess the quality of each trial; one was excluded for its low score.¹³ As a result,

Figure 1 Flowchart of studies included in review

Table 1 Summary of trials included in the meta-analysis							
Study	Country	Number of patients		Follow-up duration	Jadad score		
		OS	NOS		Randomisation	Blinding	Withdrawals / dropouts
Dapri, 2010 ¹⁴	Belgium	25	25	6 months	2	0	1
Musella, 2011 ¹⁵	Italy	40	40	1 year	2	0	1
Aggarwal, 2013 ¹⁶	India	30	30	1 year	2	0	1
Sroka, 2015 ¹⁷	Israel	49	67	3 months	2	1	1
Albanopoulos, 2015 ¹⁸	Greece	84	62	30 days	2	0	1
Carandina, 2016 ¹⁹	France	150	150	36 months	2	1	1
Kwiatkowski, 2016 ²⁰	Poland	50	43	30 days	2	0	1
OS = oversewing; NOS = no oversewing							

seven RCTs with high quality were included in our meta-analysis.^{14–20}

Study characteristics

All articles were published between 2010 and 2016 (Table 1). A total of 845 patients were included (428 patients who underwent staple line oversewing and 417 who received no reinforcement). The size of the trials ranged from 50 to 300. Five studies were published by European investigators and two were reported by Asian scholars. All seven RCTs were evaluated as high quality, with a Jadad score of 3 or 4.

Quantitative synthesis

Six studies provided data on staple line bleeding. Oversewing the staple line did not seem to reduce the rate of staple line haemorrhage (RR: 0.858, 95% CI: 0.343–2.143, *p*=0.742) in a fixed effects model (Fig 2).

All seven RCTs compared the frequency of staple line leak for the oversewing (OS) and no oversewing (NOS) groups although in the study of Albanopoulos *et al*, there were no cases of leakage in either cohort.¹⁸ The combined results indicated that oversewing the staple line seemed to decrease the risk of leakage but this was not statistically significant (RR: 0.650, 95% CI: 0.257–1.644, *p*=0.363) (Fig 3).

Figure 2 Forest plot for staple line bleeding

Figure 3 Forest plot for staple line leakage

Figure 4 Forest plot for overall complications

All of the studies reported the incidence of overall complications, which included sleeve stenosis, intra-abdominal haematoma, bleeding from vessels other than the staple line and wound complications. There was no obvious difference between the two cohorts in a fixed effects model (RR: 0.913, 95% CI: 0.621–1.342, $p=0.644$) (Fig 4). Six trials offered data on the operative time. The operative time of the OS group was significantly longer in a

random effects model (weighted mean difference: 14.400, 95% CI: 7.198–21.602, $p=0.000$).
Test of heterogeneity
The results of heterogeneity testing are summarised in Table 2. No significant heterogeneity was observed in staple line bleeding ($p=0.727$, $I^2=0.0\%$), leak ($p=0.906$, $I^2=0.0\%$) or overall complications ($p=0.190$, $I^2=31.2\%$). Heterogeneity

Table 2 Meta-analysis of the outcomes in all included trials

Outcomes	Quantitative synthesis			Heterogeneity		Publication bias
	RR / WMD	95% CI	p-value	I ²	p-value	p-value
Bleeding	0.858	0.343–2.143	0.742	0.0%	0.727	0.093
Leak	0.650	0.257–1.644	0.363	0.0%	0.906	0.979
Overall complications	0.913	0.621–1.342	0.644	31.2%	0.190	0.308
Operative time	14.400	7.198–21.620	0.000	92.2%	0.000	0.152

RR = relative risk; WMD = weighted mean difference; CI = confidence interval

did, however, exist between studies in terms of operative time ($p=0.000$, $I^2=92.2\%$).

Sensitivity and publication bias

Sensitivity analysis was performed by removing a single study from the meta-analysis sequentially to assess the influence of each individual study on the pooled RRs. The results indicated that no single study influenced the pooled RR qualitatively, suggesting the results of this meta-analysis were stable.

Begg's funnel plot and Egger's test were used to assess publication bias. These showed no evidence for publication bias regarding postoperative staple line haemorrhage ($t=6.80$, $p=0.093$), leakage ($t=-0.03$, $p=0.979$), overall complications ($t=1.23$, $p=0.308$) or operative time ($t=1.77$, $p=0.152$).

Discussion

LSG is an approved definitive approach in bariatric surgery. Its main advantages include maintained gastrointestinal continuity without anastomosis, lack of malabsorption, absence of implantable materials and potential conversion to multiple bariatric procedures.²¹ Despite this, LSG is associated with worrisome complications such as staple line bleeding and leakage. Even a small reduction in postoperative bleeding and leak could prevent serious events such as peritonitis and septic shock.^{22,23} While increased surgical experience and higher quality laparoscopic staplers would also help to reduce these complications, SLR was thought to improve the staple line strength. It has been applied in many obesity centres even though there has been no high grade evidence in the literature. Various methods of SLR have been practised but no clear consensus exists regarding the benefits of these techniques and standardisation is still lacking.

Oversewing the staple line with a continuous suture has been used widely to reduce postoperative complications after LSG. D'Ugo *et al* conducted a multicentre retrospective trial in which 476 of 1,162 patients underwent staple line oversewing.²⁴ The bleeding and leak rates were 1.4% and 3.0% respectively, lower than for the NOS group.

There has been one meta-analysis involving two RCTs and six cohort studies that evaluated the efficacy of SLR

(oversewing and buttressing).²⁵ The findings suggested that oversewing could reduce the frequency of leak but that it might increase the risk of bleeding after LSG although the results were not statistically significant. Nevertheless, some of the studies included in the meta-analysis were of poor methodological quality and only three evaluated the effects of oversewing. As the decision regarding whether to perform staple line oversewing during LSG remains debatable, we undertook our meta-analysis in an attempt to provide some evidence for bariatric surgeons. To our knowledge, a meta-analysis of RCTs on staple line oversewing versus no oversewing during LSG has not been performed previously.

Given that the staple line of LSG is long in length and close to the lesser curvature blood supply, it is prone to bleeding postoperatively. Haemorrhage is more likely to occur with episodes of hypertension, ketorolac use, heparin use and renal failure.²⁶ Sroka *et al* found that oversewing of the staple line minimised haemorrhagic complications¹⁷ while in the study by Dapri *et al*, no significant evidence of this advantage was detected.¹⁴ In terms of staple line leakage, the compromised blood supply, high intraluminal pressure, the shape and functionality of the sleeve, and mechanical failure of the stapler might contribute to its occurrence.^{27,28} Parikh *et al* also reported that a bougie size of <40Fr would increase leak rates.²⁹ Aggarwal *et al* demonstrated that oversewing of the staple line during LSG could lead to a reduced leak rate.¹⁶ However, Musella *et al* concluded that oversewing did not prevent fistula formation.¹⁵

Oversewing itself could potentially be dangerous. Tearing at the point of suture penetration may increase bleeding and leak, and the running suture could cause sleeve stricture and tissue ischaemia.^{30,31} On the one hand, Musella *et al*¹⁵ and Albanopoulos *et al*¹⁸ found that the rates of sleeve stenosis and haematoma formation respectively were significantly higher in the OS group. On the other hand, the study by Dapri *et al* showed that no significant difference existed regarding overall complications, irrespective of whether oversewing was performed.¹⁴

The results of our meta-analysis of seven RCTs suggest that there is no significant difference in the frequency of staple line bleeding, leak or overall complications between the OS and NOS groups. Furthermore, oversewing increases the operative time. Evidence in support of oversewing of the staple line during LSG is therefore lacking. No publication bias

analysis was detected, which suggests the results of this meta-analysis are stable. As a meta-analysis of homogeneous RCTs constitutes high grade evidence, our findings may provide assistance when surgeons are making a decision with regard to oversewing.

Some limitations of this meta-analysis should be addressed. First, the use of blinding was not mentioned in five of the studies^{14–16,18,20} and this lowered the methodological quality of those RCTs. Further high quality studies evaluating the efficacy of staple line oversewing in the future might change the results of a meta-analysis. Second, heterogeneity was observed between the studies in the analysis of operative time. Differences in surgeons, patients and procedures might have contributed to this heterogeneity. Third, as the raw data of the reviewed trials were not available, this limited any further evaluation such as the effects of oversewing on postoperative hospital and total costs.

Conclusions

The results of our meta-analysis indicate that oversewing the staple line during LSG does not decrease the risk of staple line bleeding, leakage or overall complications but it does prolong the operative time. Further well designed, large RCTs are warranted to validate our findings.

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