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Review

The efficacy of staple line reinforcement during laparoscopic sleeve gastrectomy: A meta-analysis of randomized controlled trials

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HIGHLIGHTS

- Buttress or roof improved safety.
- Oversew showed no advantage.
- The first meta-analysis.

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ABSTRACT

Objective: This study was performed to evaluate the effects of staple line reinforcement during laparoscopic sleeve gastrectomy.
Methods: Relevant articles published in English (up to July 25, 2015) were identified by searching PubMed, Embase, Web of Knowledge. The outcomes of staple line hemorrhage and leakage, overall complications, operative time were pooled. Data synthesis and statistical analysis were performed using Stata 13.1 software.
Results: Eight randomized controlled trials involving 791 patients (453 cases and 338 controls) were analyzed. Compared to performing no reinforcement, staple line reinforcement was associated with a lower risk of staple line hemorrhage (RR = 0.609, 95%CI = 0.439–0.846, $P = 0.003$) and overall complications (RR = 0.673, 95%CI = 0.507–0.892, $P = 0.006$). No significant difference was observed regarding postoperative leakage (RR = 0.654, 95%CI = 0.275–1.555, $P = 0.337$). Oversewing of the staple line took longer operative time (WMD = 13.211, 95%CI = 6.192–20.229, $P = 0.000$).
Conclusion: Staple line reinforcement using buttressing or roofing materials could reduce staple line hemorrhage and overall complications. No obvious advantages of oversewing the staple line were found and it took longer operative time. No significant reduction in leak rate was evidenced after reinforcement.

1. Introduction

Obesity is becoming a worldwide problem and can increase the risk of related diseases including hypertension, diabetes, sleep apnea and sexual disorder [1,2]. Laparoscopic sleeve gastrectomy (LSG) has been widely accepted for morbid obesity and gained popularity since it was first applied as a bariatric procedure in 2000 [3]. Due to the long staple line, the main complications of LSG are postoperative hemorrhage and gastric leak with reported incidence of about 13.7% and 4.5% respectively [4,5].

Staple line reinforcement (SLR) is extensively debated and highly recommended by most surgeons in an attempt to reduce postoperative complications [6,7]. Staple line reinforcement (SLR) is not well standardized and involves different options: oversewing of the staple line [8,9], application of buttressing or roofing (B/R) materials including specific biologic tissue and hemostatic sealants [10,11].

To date, many studies have investigated the safety and efficacy of SLR. The results of these studies however remain inconsistent rather than conclusive. And only a limited number of well-designed randomized controlled trials (RCTs) have focused on this research.

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In order to estimate the effects of SLR and to help surgeons make a better decision in the management of the staple line during LSG, we carried out this meta-analysis on all the eligible randomized controlled trials.

2. Materials and methods

A protocol was drafted before the initial search was started. The meta-analysis was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement issued in 2009 [12].

2.1. Search strategy

We searched the electronic literature from PubMed, Embase and Web of Knowledge for all relevant reports (the last search update was July 25, 2015), using the search terms “laparoscopic or laparoscopy”, “sleeve gastrectomy”, and “reinforcement”, or “leak or leakage or fistula”, or “bleed or hemorrhage”. The search was limited to English language papers. Appropriate adjustments were required according to the database. In addition, studies were identified by a manual search of the reference lists of original studies. Of the studies with the same or overlapping data published by the same investigators, the most recent or complete articles with the largest sample sizes were included.

2.2. Inclusion and exclusion criteria

In our meta-analysis, studies met the following inclusion criteria: (a) compared the safety and efficacy of SLR with that of no reinforcement of staple line during LSG, (b) contained at least one of these outcomes: postoperative staple line bleeding, leakage, other complications, operation time for both groups, and (c) used the RCT design.

Studies were mainly excluded for the following reasons: (a) not designed in randomized controlled trials, (b) duplicated the previous publication, and (c) not for human research.

2.3. Data extraction and quality assessment

Two of the authors (Wang and Dai) independently extracted data from each study complying with the inclusion criteria by using an electronic data sheet. In the present study, the following variables were collected for each study: the first author's last name, year of publication, country of participating institution, the number of participants, type of reinforcement, duration of follow-up, staple line hemorrhage, leakage, overall postoperative complications, and operative time. In the cases of conflicting evaluation, agreement was reached after discussion.

We used the Jadad's rating scale to evaluate the methodological quality of each included study [13]. RCT randomization that was performed using a computer generated number and concealed in a sealed envelope (or similar method) was considered appropriate. Blinding was performed so that the reporting of results was not affected by the involving participants. Withdrawals and dropouts were described by the results of follow-up.

2.4. Statistical analysis

We used relative risks (RRs) with 95% confidence intervals (CIs) to calculate the effect sizes for dichotomous data. Weighted mean differences (WMD) with 95% confidence intervals (CIs) were used for analyzing continuous variables. The heterogeneity between the studies was assessed by the Cochran's Q-test [14]. If the studies were shown to be homogeneous with a $P > 0.10$ for the Q test, the summary of RR estimate of each study was calculated using a fixed-effects model (the Mantel–Haenszel method) [15]. Otherwise, the random-effects model (the DerSimonian and Laird method) was used [16]. Stratified analyses were carried out by the type of reinforcement. Sensitivity analyses were performed to assess the stability of the results by deleting a single study in the meta-analysis each time to reflect the influence of the individual data set to the summary RR. To test the publication bias, both Funnel plots and Egger's linear regression test were used [17]. All analyses were performed with Stata software (version 13.1; StataCorp LP, College Station, TX), using two-sided P values.

3. Results

3.1. Literature search results

The search of three electronic databases retrieved 562 results according to the initial strategy. After screening the titles, abstracts, full texts, or a combination of these, we selected articles based on the inclusion and exclusion criteria. The PRISMA [12] flow diagram for this meta-analysis is presented in Fig. 1. Finally, a total of eight eligible articles [8–11,18–21] were included in our meta-analysis.

3.2. Study characteristics and quality screening

The characteristics of the selected studies are summarized in Table 1. These included eight randomized clinical trials were published between 2010 and 2015, involving 791 participants among which 453 patients were in the intervention groups, and 338 patients were in the control group. The SLR options were oversewing the staple line and using buttressing or roofing (B/R) materials including Gore SeamGuard, Peri-Strips Dry with Veritas, Tisseel and Evicel. The sample size of the studies ranged from 60 to 165. Four studies were carried out in Europe (two in Italy, one in Belgium and one in Turkey), and three studies were done in Asia (two in India and one in Israel).

As shown in Table 2, six studies [8,10,11,19–21] used adequate random allocation sequences; the exact method of randomization was unclear in other trials, which stated only that allocation had been randomized. Because of the nature of the clinical surgery trials, it was impossible to perform exact blinding except for the statistician. One trial [10] mentioned the statistician and one [20] used single blinding. As the results of this study were recorded by objective parameters and almost unaffected by the researchers and patients, the role of blinding should be less emphasized in our case. All the RCTs did follow-up and contained withdrawal information.

4. Quantitative synthesis

The pooled results of postoperative staple line hemorrhage, leakage, overall complications and operative time were summarized in Table 3.

4.1. Postoperative staple line hemorrhage

Six included studies [8,10,11,18–20] reported the incidence of staple line bleeding. The combined results of these studies (Fig. 2) suggested that staple line reinforcement during LSG had a lower risk of hemorrhage than no reinforcement (RR = 0.609, 95% CI = 0.439–0.846, $P = 0.003$). No significant heterogeneity was observed among these studies ($P = 0.385$, $I^2 = 5.5\%$).

The subgroup analysis showed that the application of buttressing or roofing materials could statistically reduce the hemorrhage rate (RR = 0.543, 95%CI = 0.387–0.761, $P = 0.000$). But no