Is hand sewing comparable with stapling for anastomotic leakage after esophagectomy? A meta-analysis

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Abstract

AIM: To compare the outcome of hand sewing and stapling for anastomotic leakage after esophagectomy.

METHODS: A rigorous study protocol was established according to the recommendations of the Cochrane Collaboration. An electronic database search, hand search, and reference search were used to retrieve all randomized controlled trials that compared hand-sewn and mechanical esophagogastric anastomoses.

RESULTS: This study included 15 randomized controlled trials with a total of 2337 patients. The results revealed that there was no significant difference in the incidence of anastomotic leakage between the methods [relative risk (RR) = 0.77, 95% confidence interval (CI): 0.57-1.04; P = 0.09], but a subgroup analysis yielded a significant difference for the sutured layer and year of publication (Ps < 0.05). There was also no significant difference in the incidence of postoperative mortality (RR = 1.52, 95%CI: 0.97-2.40; P = 0.07). However, the anastomotic strictures rate was increased in the stapler group compared with the hand-sewn group (RR = 1.45, 95%CI: 1.11-1.91; P < 0.01) in the end-to-side subgroup, while the incidence of anastomatic strictures was decreased (RR = 0.34, 95%CI: 0.16-0.76; P < 0.01) in the side-to-side subgroup.

CONCLUSION: The stapler reduces the anastomotic leakage rate compared with hand sewing. End-to-side stapling increases the risk of anastomotic strictures, but side-to-side stapling decreases the risk.

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Key words: Anastomotic leakage; Esophagectomy; Hand-sewn sutures; Mechanical sutures; Meta-analysis

Core tip: This was an important meta-analysis comparing the results of hand-sewn and stapling techniques for esophagogastric anastomosis after esophageal cancer resection. We performed some subgroup analyses that suggested some associations with anastomotic leakage: (1) the number of layers sutured (single or double); (2) year of publication (before 2003 vs 2003-2013); and (3) anastomotic sites (intrathoracic or cervical). A better understanding of this may yield a consensus for comparison of anastomotic leakage rate following the two methods of esophagogastric anastomosis after esophageal cancer.

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INTRODUCTION

Esophageal carcinoma is a multifaceted and complex disease process of rapidly rising incidence that exerts an in-
creasing social and financial burden on global healthcare systems[1-3]. Currently, esophagectomy continues to be the standard treatment for esophageal cancer. After esophageal resection for carcinoma, the stomach is commonly used for restoring alimentary continuity. The success of esophagogastrectomy anastomosis is closely correlated with the patient’s outcome, including anastomotic leakage and stricture. Anastomotic leakage is a feared and frequent complication leading to increased hospital stay, and is a significant cause of early postoperative morbidity. Different anastomotic techniques have been described in order to minimize this risk.

Since the development of the mechanical stapler in the 1990s, there have been many reports showing that the stapler decreases the rate of leakage after esophagogastrostomy[4-7]. However, several meta-analyses recently conducted to compare hand-sewn and stapler anastomosis methods have revealed that there is no significant difference in the risk of developing anastomotic leakage, and the stapler method more frequently contributes to the development of anastomotic strictures[8-10]. These meta-analyses had some limitations: (1) they did not include all published randomized controlled trials (RCTs); and (2) the clinical heterogeneity among the included RCTs indicates that several subgroup meta-analyses are needed.

We conducted a systematic review and meta-analysis of RCTs that compared stapler and hand-sewn methods for esophagogastrectomy anastomosis after esophagectomy, and examined the contribution of each method to the occurrence of anastomotic leakage, 30-d mortality, and anastomotic strictures. Subgroup analyses were also performed to evaluate the anastomotic leakage rate between the two methods related to the sutured layers, the anastomotic sites, and the year of publication. Through this pooled analysis, we hope to gain a consensus about treatment options for clinicians regarding esophagogastrectomy anastomosis after esophagectomy.

MAterials and METHODS

Study selection

The rigorous study protocol was established according to the recommendations of the Cochrane Collaboration. Before the meta-analysis, we pre-specified all the objectives, exclusion and inclusion criteria, major outcomes, and the methods used for synthesis to ensure the high quality of this meta-analysis.

Two investigators independently searched the Cochrane Library database, EMBASE, Chinese Biomedical Database and Chinese Scientific Journals Database (up to December 2013). All RCTs involving patients with esophageal cancer who underwent esophagogastrectomy anastomosis after esophagectomy were included in the analysis. The search terms were “esophagectomy”, “anastomosis”, “esophagus”, “hand-sewn”, “manual”, “stapled”, “mechanical” and “gastric” and MeSH headings “anastomosis”, “hand-sewn”, “manual”, “stapled”, “mechanical” and “esophagectomy” were used in combination with the Boolean operators AND or OR. The electronic search was supplemented by a hand search of published abstracts from conference proceedings including the International Society for Diseases of the Esophagus, the China Esophageal Society Meeting, United European Gastroenterology Week, and some Surgery Associations. In reference searches, we scanned lists of trials that were selected from electronic searching to identify further associative trials. The two investigators independently obtained and reviewed copies of these full articles according to the inclusion criteria of this study. When disagreement occurred in the trial criteria, it was discussed with another author to reach consensus.

Data collection and outcomes

Data were extracted by the two investigators using standardized forms. The quality of all selected articles was ranked in accordance with the Jadad composite scale[11]. According to this scale, low quality studies had a score ≤ 2 and high quality studies had a score ≥ 3.

The primary outcome measure for the meta-analysis was anastomotic leakage. The secondary outcome measures were 30-d mortality and anastomotic strictures (developing within 6 mo of operation and requiring endoscopy).

Statistical analysis

Statistical analysis was performed by RevMan version 5.2.9 (provided by the Cochrane Collaboration, Oxford, United Kingdom). The data extracted from the included trials were combined and the relative risk (RR) was calculated with 95% confidence intervals (CIs). The Cochran’s Q statistic (Q test) and the Higgins I² statistic were used to determine the percentage of total variations across studies due to heterogeneity. If the I² statistic was ≤ 50%, the fixed effect model was used to pool studies, otherwise, the random effects model was used. To examine clinical heterogeneity, the following subgroup analyses were conducted to evaluate the anastomotic leakage: (1) the site of anastomosis (intrathoracic vs cervical); (2) year of publication (2003-2013 vs before 2003); and (3) double or single suture layer for the hand-sewn method. For obvious clinical heterogeneity, we performed two subgroup analyses (side-to-side stapler vs hand-sewn, and end-to-side stapler vs hand-sewn) to evaluate the anastomotic stricture.

RESULTS

Characteristics of included trials

Fifteen RCTs (2337 patients) that met the inclusion criteria were identified; all were performed between 1990 and 2013[5,12-26] (Figure 1). Table 1 shows the details for each trial, including baseline characteristics, year of publication, anastomotic method, and Jadad score.

Anastomotic leakage

All 15 trials reported the incidence of anastomotic leak-
age following surgery. There was no significant difference in anastomotic leakage between the two groups (RR = 0.77, 95%CI: 0.57-1.04; P = 0.09) (Figure 2). Statistical heterogeneity was not detected ($I^2 = 17\%$, $\chi^2 = 16.8$, $df = 14$; $P = 0.27$). The subgroup analyses yielded significant differences for the number of suture layers for the hand-sewn method and the year of publication (Figure 3). One subgroup analysis found that the stapler method had an obvious benefit over the single-layer hand-sewn method in reducing the incidence of postoperative anastomotic leakage (RR = 0.37, 95%CI: 0.18-0.76; $P < 0.01$); however, there was no benefit when compared with the double-layer hand-sewn method (RR = 1.01, 95%CI: 0.66-1.53; $P = 0.98$). Another subgroup analysis showed that during the latest decade, the stapler method was superior to the hand-sewn method in preventing anastomotic leakage (RR = 0.66, 95%CI: 0.45-0.96; $P = 0.03$). The subgroup analysis of anastomotic site yielded no significant difference in anastomotic leakage between the two groups (RR = 1.23, 95%CI: 0.70-2.18; $P = 0.47$).

Thirty-day mortality
Fourteen trials reported the incidence of 30-d mortality, with no significant difference observed following stapled vs hand-sewn anastomosis (RR = 1.52, 95%CI: 0.97-2.40; $P = 0.07$) (Figure 4). There was no evidence of statistical heterogeneity ($I^2 = 0\%$, $\chi^2 = 8.17$, $df = 9$; $P = 0.52$).

Anastomotic strictures
Fourteen studies reported the incidence of anastomotic stricture following surgery. Because there was obvious clinical heterogeneity present in these studies, we performed two subgroup-analyses. In one analysis, there was a significant increase in the incidence of anastomotic stricture following end-to-side stapled anastomosis compared with hand-sewn anastomosis (RR = 1.45, 95%CI: 1.11-1.91; $P < 0.01$) (Figure 5). However, in the other analysis, side-to-side stapled anastomosis contributed to reducing the incidence of anastomotic stricture compared with hand-sewn anastomosis (RR = 0.34, 95%CI: 0.16-0.76; $P < 0.01$).

DISCUSSION
Since the 1990s, the use of the stapler for esophagogastric anastomosis has become increasingly popular. How-
my\textsuperscript{6,7,27,28}. Also, several RCTs have shown that mechanical suturing is as adequate as manual suturing, leading to a lower incidence of anastomosis leakage.

The results of this study revealed that there is no significant difference between the hand-sewn and stapler groups in the incidence of developing anastomotic leakage. However, the subgroup analyses revealed two

### Table 1 Study characteristics

| Ref.         | Year | Anastomotic methods | No. of patients | Male/female | Mean age (yr) | Jadad score |
|--------------|------|---------------------|-----------------|-------------|---------------|-------------|
| Fok et al\textsuperscript{[4]} | 1991 | Hand-sewn           | 25              | Details unknown | 63.7      | 2           |
| Valverde et al\textsuperscript{[26]} | 1996 | Hand-sewn           | 74              | 67/7        | 59           | 3           |
| Craig et al\textsuperscript{[25]} | 1996 | Hand-sewn           | 50              | 27/23       | 65           | 2           |
| Law et al\textsuperscript{[24]} | 1997 | Hand-sewn           | 61              | 54/7        | 64           | 2           |
| Laterza et al\textsuperscript{[23]} | 1999 | Hand-sewn           | 21              | 4/17        | 50.9        | 3           |
| Walther et al\textsuperscript{[22]} | 2003 | Hand-sewn           | 41              | 28/13       | 68           | 3           |
| Hsu et al\textsuperscript{[21]} | 2004 | Hand-sewn           | 32              | 27/5        | 63           | 2           |
| Okuyama et al\textsuperscript{[18]} | 2007 | Hand-sewn           | 18              | 16/2        | 64.3        | 2           |
| Luechakiettisak et al\textsuperscript{[17]} | 2008 | Hand-sewn           | 59              | 50/9        | 63.6        | 2           |
| Aquino et al\textsuperscript{[7]} | 2009 | Hand-sewn           | 15              | Details unknown | 45.6      | 3           |
| Zhang et al\textsuperscript{[15]} | 2010 | Hand-sewn           | 244             | 142/102     | 60           | 2           |
| Wu et al\textsuperscript{[20]} | 2005 | Hand-sewn           | 154             | 158/114     | 59           | 3           |
| Saluja et al\textsuperscript{[13]} | 2012 | Hand-sewn           | 125             | 92/33       | 56           | 2           |
| Cai et al\textsuperscript{[12]} | 2013 | Hand-sewn           | 52              | 27/5        | 60.8        | 3           |

### Figure 2 Forest plot for anastomotic leakage.

Fifteen studies were included.

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**ever, compared with the routine hand-sewn method, the superiority of the stapler method is still controversial.** Anastomotic leakage is one of the main postoperative complications that is associated with a high mortality rate. Since the development of the mechanical stapler, there have been many reports to show that the stapler can decrease the rate of leakage after esophagogastros-
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| Study or subgroup | Stapler Events | Hand-sewn Total | Weight M-H, fixed, 95%CI | Risk ratio | Risk ratio |
|------------------|---------------|------------------|--------------------------|------------|-----------|
| **1.1.1 anastomotic double layer** |
| Aquino 2009      | 1 15          | 5 15             | 2.4%                     | 0.20 (0.03, 1.51) |          |
| Hsu 2004         | 8 31          | 7 32             | 3.4%                     | 1.18 (0.49, 2.86) |          |
| Laterza 1999     | 4 20          | 1 21             | 0.5%                     | 4.20 (0.51, 34.44) |          |
| Okuyama 2007     | 1 14          | 3 18             | 1.3%                     | 0.43 (0.05, 3.69) |          |
| Saluja 2009      | 16 87         | 14 87            | 6.8%                     | 1.14 (0.59, 2.20) |          |
| Walther 2003     | 0 42          | 1 41             | 0.7%                     | 0.33 (0.01, 7.77) |          |
| Wu 2005          | 2 162         | 6 154            | 3.0%                     | 0.32 (0.06, 1.55) |          |
| Zhang 2010       | 6 272         | 1 244            | 0.5%                     | 5.38 (0.65, 40.39) |          |
| **Subtotal (95%CI)** | 643 | 612 | 18.7% | 1.01 (0.66, 1.53) |          |
| **Total events** | 38            | 38               |                          |             |          |

Heterogeneity: $\chi^2 = 10.05, df = 7 (P = 0.19); I^2 = 30%

Test for overall effect: $Z = 0.03 (P = 0.98)$

| **1.1.2 anastomotic single layer** |
| Cayi 2012         | 0 0           | 0 0              | Not estimable            |          |          |
| Craig 1996        | 3 102         | 18 105           | 7.9%                     | 0.20 (0.06, 0.67) |          |
| Law 1997          | 4 50          | 3 50             | 1.5%                     | 1.33 (0.31, 5.65) |          |
| Luechakietisak 2008 | 2 58       | 4 59             | 1.9%                     | 0.51 (0.10, 2.67) |          |
| Wang 2013         | 1 92          | 3 52             | 1.9%                     | 0.19 (0.02, 1.77) |          |
| **Subtotal (95%CI)** | 302 | 286 | 13.2% | 0.37 (0.18, 0.76) |          |
| **Total events** | 10            | 28               |                          |             |          |

Heterogeneity: $\chi^2 = 4.46, df = 3 (P = 0.22); I^2 = 33%

Test for overall effect: $Z = 2.72 (P = 0.008)$

| **1.1.3 anastomotic leakage (2003-2013)** |
| Aquino 2009      | 1 15          | 5 15             | 2.4%                     | 0.20 (0.03, 1.51) |          |
| Cayi 2012        | 3 102         | 18 105           | 7.9%                     | 0.20 (0.06, 0.67) |          |
| Hsu 2004         | 8 31          | 7 32             | 3.4%                     | 1.18 (0.49, 2.86) |          |
| Luechakietisak 2008 | 2 58       | 4 59             | 1.9%                     | 0.51 (0.10, 2.67) |          |
| Okuyama 2007     | 1 14          | 3 18             | 1.3%                     | 0.43 (0.05, 3.69) |          |
| Saluja 2009      | 16 87         | 14 87            | 6.8%                     | 1.14 (0.59, 2.20) |          |
| Walther 2003     | 0 42          | 1 41             | 0.7%                     | 0.33 (0.01, 7.77) |          |
| Wang 2013        | 1 92          | 3 52             | 1.9%                     | 0.19 (0.02, 1.77) |          |
| Wu 2005          | 2 162         | 6 154            | 3.0%                     | 0.32 (0.06, 1.55) |          |
| Zhang 2010       | 6 272         | 1 244            | 0.5%                     | 5.38 (0.65, 40.39) |          |
| **Subtotal (95%CI)** | 875 | 827 | 29.9% | 0.66 (0.45, 0.96) |          |
| **Total events** | 40            | 62               |                          |             |          |

Heterogeneity: $\chi^2 = 15.68, df = 9 (P = 0.07); I^2 = 43%

Test for overall effect: $Z = 2.16 (P = 0.03)$

| **1.1.4 anastomotic leakage (-2003)** |
| Craig 1996       | 4 50          | 3 50             | 1.5%                     | 1.33 (0.31, 5.65) |          |
| Laterza 1999     | 4 20          | 1 21             | 0.5%                     | 4.20 (0.51, 34.44) |          |
| Law 1997         | 3 61          | 1 61             | 0.5%                     | 3.00 (0.32, 28.04) |          |
| Valverde 1996    | 12 78         | 12 74            | 6.0%                     | 0.95 (0.46, 1.98) |          |
| WSHASG 1991     | 0 27          | 1 25             | 0.8%                     | 0.31 (0.01, 7.26) |          |
| **Subtotal (95%CI)** | 236 | 231 | 9.2% | 1.23 (0.70, 2.18) |          |
| **Total events** | 23            | 18               |                          |             |          |

Heterogeneity: $\chi^2 = 3.15, df = 4 (P = 0.53); I^2 = 0%

Test for overall effect: $Z = 0.72 (P = 0.47)$

| **1.1.5 anastomotic site (Thoracic)** |
| Craig 1996       | 4 50          | 3 50             | 1.5%                     | 1.33 (0.31, 5.65) |          |
| Valverde 1996    | 12 78         | 12 74            | 6.0%                     | 0.95 (0.46, 1.98) |          |
| Wang 2013        | 1 92          | 3 52             | 1.9%                     | 0.19 (0.02, 1.77) |          |
| Wu 2005          | 2 162         | 6 154            | 3.0%                     | 0.32 (0.06, 1.55) |          |
| **Subtotal (95%CI)** | 382 | 330 | 12.4% | 0.73 (0.41, 1.27) |          |
| **Total events** | 19            | 24               |                          |             |          |

Heterogeneity: $\chi^2 = 3.64, df = 3 (P = 0.30); I^2 = 18%

Test for overall effect: $Z = 1.12 (P = 0.26)$
important findings. First, the use of a stapler method contributed to a reduced anastomotic leakage rate over the last decade. Second, the stapler was superior to the single-layer hand-sewn method in preventing postoperative anastomotic leakage.

For this study, we made attempts wherever possible to follow the recommendations of the Cochrane Collaboration. A rigorous study protocol was pre-specified and several electronic databases, references, and international conference abstracts for relevant trials, were searched without restrictions on language. Several pooled analyses on this topic have demonstrated a similar incidence of anastomotic leakage between the two groups. These pooled analyses either did not attempt to produce subgroup analyses or they did not include an adequate number of publications. The largest number of RCTs to date was included in the present study, and through subgroup analyses, we also examined the contribution of the site of anastomosis, the number of suture layers in the hand-sewn method, and the year of publication as effect modifiers. A major merit of this study was that we performed the analyses by the pre-specified protocol that closely adhered to the Cochrane Collaboration. Therefore, repeating the meta-analysis might achieve a consensus with statistically greater power and better quality of analysis for surgeons with regard to the method of esophagogastric anastomosis after esophagectomy.

Although all the studies met our inclusion criteria, to some extent, this meta-analysis showed heterogeneity; the suture materials and the surgical techniques varied among the studies. We specifically selected three main factors that were suspected as effective modifiers. First, despite the methods of esophagogastric anastomosis, there was no consensus on whether the site of anastomosis (intrathoracic or cervical) affected the outcome of esophagectomy. Second, it is still controversial whether the stapler method is more effective in preventing anastomotic leakage than either single-layer or double-layer suturing methods. Third, although stapler technology has improved over the past 20 years, and has matured during the current decade, and whether year of publication affects the outcome is unclear. To make these potential problems clear, we performed subgroup analyses that were stratified by such techniques.

Figure 3 Subgroup analyses for anastomotic site, number of suture layers in the hand-sewn method, and year of publication.

Figure 4 Forest plot for 30-d mortality. Fifteen studies were included.
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The primary outcome measures from our meta-analysis demonstrated that there was no significant difference between the two groups for anastomotic leakage. However, in one subgroup analysis, there was a significantly decreased incidence of anastomotic leakage compared with hand-sewn anastomosis in 2003-2013. In another subgroup analysis, stapling was significantly superior to the single-layer hand-sewn method in reducing anastomotic leakage. For secondary outcome measures, the difference identified between the hand-sewn and stapler groups was increased anastomotic stricture in the end-to-side stapling group, while there was decreased anastomotic stricture in the side-to-side stapling group.

CONCLUSION

The results of our meta-analysis suggest that stapler anastomosis should remain the first option, because it can significantly reduce the anastomotic leakage. Furthermore, application of the stapler is usually easy and standardized, such that it should not increase the incidence of technical errors. In contrast, hand-sewn methods require surgical expertise and may not be practicable everywhere. Although in this meta-analysis the end-to-side stapler method was associated with the risk of postoperative anastomotic stricture, several new mechanical anastomosis methods (including side-to-side stapling) have been used to resolve this problem.

COMMENTS

Background

Currently, the standard treatment for esophageal cancer continues to be esophagectomy. Hand-sewn and stapler anastomosis are two major methods for esophagogastrectomy after esophagectomy. The purpose of this meta-analysis was to compare the outcomes from hand-sewn and stapler methods for esophagogastrectomy after esophagectomy by pooling all data from relevant randomized controlled trials (RCTs), to reach a consensus for comparison of anastomotic leakage.

Research frontiers

Several meta-analyses undertaken to compare hand-sewn and stapler anastomosis methods revealed that there was no significant difference in the risk of developing anastomotic leakage, and that stapler anastomosis contributed more frequently to the development of anastomotic strictures.

Innovations and breakthroughs

Previous meta-analyses did not include all published RCTs, and there is clinical heterogeneity among the ones that were included, indicating that several subgroup meta-analyses are needed. The study presented here is believed to be the first meta-analysis to include subgroup analyses, which indicate an association between anastomotic leakage and: (1) the number of layers sutured; (2) year of publication; and (3) the anastomotic site.

Applications

The results suggest that the stapler method reduces the anastomotic leakage rate compared with the single-layer hand-sewn method. In addition, although the end-to-side stapler method increased the risk of anastomotic strictures, the side-to-side stapler was associated with a decreased rate.

Terminology

Hand-sewn anastomosis is the esophagogastrectomy anastomosis performed by hand with interrupted absorbable monofilament sutures. Stapler anastomosis means that the esophagogastrectomy anastomosis is performed using circular or linear staplers.
Peer review
This is a nicely written manuscript and the analyses seem to be well performed. The topic of the esophageagastrectomy anastomosis is not really new, but it is still one of the mainly important problems in esophageal surgery.

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