Comparison of Hand-sewn and Modified Mechanical Anastomosis in Esophageal Cancer Patients Undergoing Transhiatal Esophagectomy: An Iranian Retrospective Cohort Study

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Abstract
Background: There are controversies over the efficacy of mechanical stapler when compared with the hand-sewn (HS) technique in patients who underwent esophagogastric anastomosis in terms of efficacy and post-operative advantages. The purpose of the present study is to compare the clinical outcomes of manual and a modified mechanical stapled (MMS) anastomosis (double stapled technique) during esophagectomy for esophageal cancer.

Methods: A retrospective cohort study was conducted on 409 patient’s medical records who underwent transhiatal esophagectomy for esophageal cancer between March 2010 and March 2016. All patients were operated using HS technique or MMS technique. All cases were visited in two weeks, four, eight and twelve months after surgery and were evaluated in terms of postoperative complications including anastomotic leakage, regurgitation, anastomotic stricture, dysphagia and need for anastomotic dilatation.

Results: 259 (63.3%) patients were operated using HS technique and 150 patients (36.7%) were operated by MMS technique. The mean operative time was 211.45± 82.25 min for the MMS anastomosis group, whereas for the manual group it was 251.42±52.81 min, respectively (P = 0.023). Postoperatively, 38 (14.67%) anastomotic leakage were detected in the HS group compared to 8 (5.33%) the MMS group (P= 0.002). The results showed lesser anastomotic stricture in patients who underwent MMS anastomosis (P= 0.004). However, during the one-year follow-up period, patients with HS anastomosis required more anastomotic dilatation (P= 0.021).

Conclusions: Using a MMS anastomosis may reduce operation time and lead to lower rates of anastomotic leak, decrease anastomotic stricture and anastomotic dilatation.

Background
Esophageal cancer is one of the most prevalent and multifaceted gastrointestinal malignancies and the sixth leading mortality cause among cancers (1, 2). Various methods have been introduced as a mainstay of treatment, including surgical procedures and non-surgical palliative methods. Currently, esophagectomy is considered as a standard method for the management of esophageal cancer (3–5). However, esophagogastric anastomosis using two popular techniques including, HS and mechanical
stapler anastomosis is the most critical part during esophagectomy (6, 7). Regardless of the surgical approach, preventing anastomotic complications is necessary to minimize early morbidity and improve intervention outcomes (6).

Postoperative complications subsequent to esophagogastric anastomosis may lead to life-threatening situations, including anastomotic leakage, anastomotic stricture and other rare complications such as fistula and abscesses. Anastomotic leakage has been reported to occur in more than 10% of the patients undergoing esophagogastric anastomosis with some complications, such as mediastinitis, nourishing discomforts, anastomotic stricture and less common complication, such as cervical osteomyelitis (6, 8, 9). Thus, it is important to choose a more accurate and effective surgical procedure for the prevention and reduction of complications after anastomosis. During the last two decades, stapled techniques have been introduced in order to decrease the risk of anastomotic leakage and strictures (10, 11). In 1998 linear stapling devices were first used by Collared et al to create esophagogastric anastomosis (12) Orringer applied some structural modifications to previous techniques that resulted in better results (13).

Although, some studies including meta-analysis and systematic reviews have been performed to compare the effectiveness of HS and mechanical stapled techniques (linear or circular stapler), the superiority of one technique over the other is still controversial (14, 15).

In current study, we compared the operation time and post-operative outcomes in transhiatal esophagectomy with HS and a MMS (double stapled technique) cervical esophagogastric anastomoses during one-year follow up period, in terms of anastomotic patients’ symptoms, anastomotic leakage, anastomotic stricture and need for anastomotic dilatation.

Methods
All adult patients (> 18 years of age) who underwent esophagectomy (n = 565) for esophageal cancer between March 2010 and March 2016 at department of thoracic surgery, Imam Reza Hospital, Tabriz, Iran (as the referral hospital in northwest of Iran) were eligible for our study. Of these patients 19 cases underwent reconstruction using colon interposition technique and 25 patients using the jejunum. Esophagogastric anastomosis has been done in 68 patients using a circular stapling
technique. The patients who died after operation (11 cases) or did not attend for follow-up period of less than one year (33 cases) were excluded from the analysis. We excluded the mentioned 156 patients and finally enrolled 409 patients in the present study. The study protocol was approved by the Regional Ethics Committee, Vice-Chancellor of Research and Development, Tabriz University of Medical Sciences (Ethical approval number: 91/1-1/4). Written informed consent was obtained from each patient included in the study during administration to permit collection and analysis of any applicable clinical data and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution’s human research committee.

Preoperative evaluations and laboratory tests including, routine blood tests, arterial blood gas (ABG), chest and abdominal computed tomography (CT) scan, endoscopic ultrasound (EUS), echocardiography and spirometry were performed for all patients. Subsequently, demographic information including age, sex, preoperative clinical symptoms and signs such as dysphagia, odynophagia, anorexia, and recent weight loss, distant metastasis and intraoperative surgery-related variables such as operation time, were extracted and recorded in a designed questionnaire. In addition, patients were evaluated postoperatively for anastomotic leakage as the 12-month follow up period.

Surgical Procedure
The cervical esophagogastric anastomosis was performed through one of the two methods of anastomoses, HS or MMS. In the manual method, the end of the cervical esophagus was sutured to the anterior wall of the pulled-up stomach in the neck using interrupted two-layer suturing with 3 – 0 vicryl for inner layer and 3 – 0 prolen for outer layer. In the MMS method, using an Endo GIA™ loaded with 60 blue cartridge (Covidien-Medtronic, Minneapolis, MN, USA) the anastomosis of the posterior wall of the esophagus was performed to the posterior wall of gastric conduit and the entrance of cartridge limb was closed with one other 60-mm linear stapler (Endo-GIA60-3; Covidien) (Fig. 1). All patients were admitted directly to the intensive care unit (ICU) with a nasogastric tube for 4 days. Neck pen rose was placed for all patients and enteral feeding was begun on the third day of surgery.
via a feeding jejunostomy. To assess anastomotic leakage a barium swallow was obtained during the fifth postoperative day. If no leak was present, oral feeding was started with water and a soft diet. In cases of any leakage, wound infection, or a significant amount of secretion from the embedded pen rose, the cervical wound was opened for about 2–3 centimeters to establish drainage.

**Follow-up**

All the patients were visited regularly after two weeks, four, eight and twelve months of operation and all the preoperative, intraoperative and postoperative data were collected from our hospital database retrospectively. Patients presenting digestive symptoms associated with a suspicion of anastomotic stricture underwent diagnostic endoscopy. Anastomotic dilation was performed under general anesthesia in the treatment of symptomatic patients.

**Statistical Analysis**

Continuous variables are expressed as means ± SD. For quantitative data, normality was evaluated by the K-S test and then Mauchly's W test was checked to identify the covariance matrix. Repeated measure with control covariates test was used by Minitab Software version 17. The results include six P-values for comparing groups at different times. The first P-value was for comparison of variations before intervention, the second P-value was for comparison after intervention between the two groups (HS and MMS). The Final P-value Time was used for comparing each variable between before and after the intervention.

The first P-value (Chi-square Test) for comparing two qualitative variables in each time, the second P-value (McNemar Test) for comparing each time with base time and final P-value (Cochran's Q) for comparing dependent variables between different times. A P-value of < 0.05 was considered statistically significant. All results were expressed by frequency (percent) for qualitative variables and Mean ± SD for quantitative variables.

**Results**

The study included 409 patients with esophageal cancer, 259 patients (63.3%) in the HS group and 150 patients (36.7%) in the MMS group. 237 patients (57.9%) were male and 172 (42.1%) were female. Data on patient demographics, clinical findings, operation time and tumor type showed in the Table 1. As mentioned during hospitalization 11 (2.6%) patients died after operation, 7 (2.7%) cases
in HS group and 4 (2.6%) cases in MMS group which were excluded from our analysis.

Table 1

| Patients’ demographic data and preoperative symptoms | HS       | MMS      | P value |
|-----------------------------------------------------|----------|----------|---------|
| Anastomosis type                                    |          |          |         |
| Sex                                                 |          |          |         |
| Female                                              | 78 (19%) | 94 (22.9%) | 0.452   |
| Male                                                | 181 (44.2%) | 56 (13.9%) |        |
| Age                                                 | 65.38 ± 19.07 | 62.54 ± 20.12 | 0.342   |
| Preoperative complaints                              |          |          |         |
| Dysphagia                                           | 259 (100%) | 150 (100%) | 1       |
| Heart burn                                          | 128 (49.4%) | 84 (56%) | 0.119   |
| Weight loss                                         | 100 (38.6%) | 54 (36%) | 0.338   |
| Odynophagia                                         | 71 (27.4%) | 67 (31.3%) | 0.482   |
| Operation time                                      | 251 ± 82.25 | 211.45 ± 52.81 | 0.023   |
| Tumor type                                          | SCC   | Adenocarcinoma | 0.004 |
|                                                     | 243 (58.4%) | 16 (6.1%) |        |
|                                                     | 128 (30.2%) | 22 (5.3%) |        |

Anastomosis leakage in HS group and MMS group was seen in 38 (14.67%) and 8 (5.33%) of cases, respectively. There was a significantly lower rate of anastomotic leakage in patients undergoing MMS technique (PV = 0.002). The mean total operating times in the HS and MMS groups were 251.42 ± 82.25, and 211.45 ± 52.81, respectively, which was significantly lower in the MMS technique compared to the HS counterpart (PV = 0.023).

Postoperative complications including regurgitation, anastomotic stricture, and the need for anastomotic dilatation, were evaluated at 12-month follow-up. All patients underwent serial clinical examinations and appropriate workup during hospital admission, 2nd week, 4th month, 8th month and 12th month after the operation. The prevalence of regurgitation during the follow up period has been shown in Fig. 2. The results revealed that the prevalence of regurgitation was significantly lower in MMS group compared with HS group (PV = 0.001) while had decreasing pattern in both groups at the end of the follow up period. Although the prevalence of regurgitation was higher in HS patients during the first follow up period (PV = 0.004), nevertheless it has significantly resolved in this group during the one-year follow up (PV = 0.02).

Data for anastomotic stricture prevalence during follow up periods are listed in Table 2. The prevalence of anastomotic stenosis has significantly improved in the MMS group during one-year follow up (PV = 0.014). However, upper gastrointestinal barium swallow and subsequent upper gastrointestinal endoscopy were performed to investigate anastomotic stricture in patients with the complaint of dysphagia, odynophagia, and retrosternal pain. Anastomotic strictures prevalence was significantly higher in the HS anastomosis group, with no symptomatic improvement during the
follow-up period (PV = 0.112). Despite HS anastomosis patients, anastomotic stricture symptoms significantly resolved in patients with linear stapled anastomosis (PV = 0.004).

| Table 2 | Prevalence pattern of anastomotic stricture |
|---------|-------------------------------------------|
| Anastomosis stricture | Status | Two weeks | 4 Month | 8 Month | 12 Month | P value * |
| HS technique | Present | 0 (0%) | 28 (10.8%) | 37 (14.2%) | 23 (8.8%) | 0.112 |
| Not present | 0 (0%) | 231 (89.2%) | 222 (85.8%) | 236 (91.2%) | |
| MMS | Present | 0 (0%) | 9 (6%) | 8 (5.3%) | 4 (2.6%) | 0.014 |
| Not present | 0 (0%) | 141 (94%) | 142 (94.7%) | 146 (97.4%) | |
| McNemar | Base | 0.008 | 0.083 | 0.083 | |
| Tests | Chi-Square | 1 | 0.07 | 0.003 | 0.046 |
| Mixed Model | Pv Group = 0.004, Pv Time = 0.235 | |

Prevalence pattern of intervention for anastomotic dilatation showed in Table 3. Patients with severe anastomotic stricture underwent esophageal dilatation under general anesthesia. Patients with HS anastomosis had significantly required dilatation compared with MMS group at the end of the follow up period (PV = 0.04), and also compared with patients underwent MMS technique, the rate of anastomotic stricture dilatation was significantly higher in the patients underwent HS technique during one year of follow up (PV = 0.021).

| Table 3 | Prevalence pattern of intervention for anastomotic dilatation |
|---------|-------------------------------------------------------------|
| Need for dilatation | Status | 4 Month | 8 Month | 12 Month | P value a |
| HS technique | Present | 12 (4.6%) | 13 (5%) | 16 (6.1%) | 0.068 |
| Not present | 247 (95.4%) | 246 (95%) | 243 (93.9%) | |
| McNemar | Base | 0.893 | 0.317 | |
| MMS | Present | 4 (2.6%) | 11 (7.3%) | 3 (2%) | 0.273 |
| Not present | 146 (97.4%) | 139 (92.7%) | 147 (98%) | |
| McNemar | Base | 0.564 | 0.157 | |
| Statistical Tests | Chi-Square | 0.239 | 0.227 | 0.04 |
| Mixed Model | Pv Group = 0.021, Pv Time = 0.785 | |

Discussion

The stomach is a good alternative for patients with esophageal cancer undergoing esophagectomy. Traditionally, the accepted standard treatment for operable esophageal carcinoma is resection of the esophagus and lymph nodes with gastric pull up and constructing cervical or intrathoracic esophagogastric anastomosis (6, 10, 16). The main complications after esophagectomy and esophagogastric anastomosis are anastomotic leakage and stricture that may affect the patients’ quality of life and even threaten their lives (16). However, according to recent studies, the role of
anastomotic leakage and the type of mechanical stapler device used is of great importance in developing anastomotic stricture (17, 18).

Our results showed that the overall rate of postoperative complications following gastroesophageal anastomosis decreased from 18–12.8% in the HS group compared to MMS group which decreased from 20.6–4.6% in over the 12-month follow-up. A retrospective study by Cook et al. Of 1133 patients undergoing esophagectomy followed by esophagogastric anastomosis showed a significant reduction in postoperative complications and the prevalence of problems in the construction of anastomosis using mechanical anastomosis (7).

According to literature, the rate of anastomotic leakage is approximately 3% following stapler anastomosis. (5, 19). However, in the present study, the prevalence of anastomotic leakage in patients undergoing MMS anastomosis was reported to be 4.6%, which may be related to different surgeons. Similarly to our results Mishra et al found that the rate of anastomotic leakage was significantly higher in patients undergoing HS anastomosis compared to patients underwent linear stapled anastomosis (20).

Laterza et al. compared manual and mechanical anastomosis and their results showed that patients with mechanical anastomosis had a high prevalence of anastomotic leakage and benign stricture (21). Further randomized controlled trials revealed higher anastomotic leakage and anastomosis stricture prevalence in the manual group suggesting the use of mechanical anastomosis to construct esophagogastric anastomosis (22–24). Even in intrathoracic esophagogastric anastomosis liner stapled technique significantly decreased anastomosis leakage and anastomosis stricture compared to HS technique (18).

Sugimora et al used a modified Collard technique, a linear stapler was applied to construct the posterior wall of the anastomosis and the anterior wall was closed using the linear stapler twice. The study showed that anastomosis leakage was less frequent in the modified Collard group compared to the HS group but the difference was not significant. Anastomosis stenosis was significantly less in modified Collard group and also the period between esophagectomy and the first time dilatation significantly was shorter in the HS group (25). Similarly to this technique, Ishibahi et al used a triple-
stapled quadrilateral anastomosis for creation of an esophagogastric anastomosis and they reported no significant anastomosis leakage and anastomosis stricture (26).

Some reviews reported no significant difference between HS and mechanical stapled in the prevalence of anastomotic stricture, however, our results showed a decreasing pattern for the rate of anastomotic stricture during follow up period, in modified stapler group compared to the manual anastomosis. Similarly, Cooke et al showed significant decrease in the prevalence of postoperative complications and morbidity in patients using mechanical anastomosis (7). Price et al. Found that although the anastomotic site did not play an important role in predisposing postoperative complications such as anastomotic leakage and stenosis, patients with manual anastomosis experienced higher anastomotic leakage and stricture (24).

The present study was conducted on 409 patients undergoing esophagectomy by two methods of HS and MMS cervical esophagogastric anastomosis. The results of the current study significantly showed higher prevalence of cervical esophagogastric anastomosis leak following transhiatal esophagectomy with manual anastomosis. In addition, this study revealed that the prevalence of benign anastomotic stricture and regurgitation during the 12-month follow-up was significantly higher in the HS group compared to the MMS group. Therefore, we hypothesized that modified mechanical stapler plays an important role in reducing the incidence of postoperative complications.

In the present study, we demonstrated endoscopic interventions such as esophageal dilatation to relieve benign anastomotic stenosis and recurrent dysphagia over a 12-month follow-up. The results of statistical analysis showed that there was no significant difference between patients in both groups who required esophageal dilatation during 12 months follow-up which may reflect the fact that the severity of stenosis was not different in HS and MMS anastomosis patients.

In the study of Hsu, et.al, the operating time was compared between the manual and mechanical anastomosis groups. The results showed that the time of operation in the mechanical group patients was significantly shorter than the manual group (9). However, some studies including meta-analysis showed no significant difference in surgical time between manual and mechanical anastomosis techniques (15, 27). The results of the present study showed that the effective time of using a MMS
technique for cervical esophageal anastomosis was significantly shorter than the manual procedure. Our study has some limitations: first, this study was a retrospective study so we need a clinical trial to achieve acceptable results. Second, the follow-up period was 12 months, however, a longer period of follow-up may have different results. Third, three surgeons included in this study, although the surgical team had sufficient experience in esophageal surgery and all anastomoses were performed in the neck, may still have undesirable bias.

Overly in our study it was revealed that the operative time in the MMS group was significantly shorter and there was a significant decrease in the amount of anastomotic leakage, stenosis, and postoperative regurgitation. Therefore, the MMS technique can be used as a superior method for faster and more efficient esophageal anastomosis than HS procedure after esophagectomy.

Conclusion
Esophagogastric anastomosis using MMS technique reduces operation time, as well as anastomotic leakage and stricture. However, there was no significant difference in the need for esophageal dilatation between HS and MMS anastomosis during the follow-up period.

Abbreviations
HS
Hand-swen
MMS
Modified mechanical stapled

Declarations

Ethics approval and consent to participate:
Written informed consent was obtained from each patient included in the study during administration to permit collection and analysis of any applicable clinical data and the study protocol was approved by the Regional Ethics Committee, Vice-Chancellor of Research and Development, Tabriz University of Medical Sciences (Ethical approval number: 91/1-1/4).

Consent to publish:
Informed consent was obtained from each patient included in the study during administration to permit collection and analysis of any applicable clinical data

Availability of data and materials:
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Competing interests:**
The authors declare that they have no competing interests

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**Authors’ contributions:**
SZR and SB designed the study and carried out coordination and contributed in manuscript editing.
HA and AR contribution in literature search, data collection and analysis and manuscript writing. All authors have read and approved the manuscript.

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Figures
Figure 1

A: The posterior wall of esophagus and the posterior wall of gastric conduit aligned and two stay sutures applied. B: The posterior wall of the anastomosis constructed by using an Endo GIATM loaded with 60 blue cartridge fired vertically. C and D: The lateral sides of anastomosis pulled up by two backups and a 60-mm linear stapler (Endo-GIA60-3; Covidien) fired horizontally to close the anterior wall of the anastomosis
Figure 2

Prevalence pattern of regurgitation in HS and MMS anastomosis groups in over the 12-month follow-up period