Original Article

Clinical analysis of tubular stapler-assisted nested anastomosis in the prevention of postoperative esophageal cancer complications

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Background: Esophageal cancer (EC) is one of the most common malignant tumor types. Surgery is considered the treatment of choice for patients with early- and mid-stage EC. However, because of the traumatic nature of EC surgery and the need for gastrointestinal reconstruction, high rates of postoperative complications such as anastomotic leakage or stenosis, esophageal reflux, and pulmonary infection exist. Its time to explore a novel esophagogastric anastomosis method for McKeown EC surgery to reduce the postoperative complication.

Methods: This study recruited a total of 544 patients who underwent McKeown resection for EC between January 2017 and August 2020. The tubular stapler-assisted nested anastomosis was taken as the time node, including 212 patients in the traditional tubular mechanical anastomosis group and 332 patients in the tubular stapler-assisted nested anastomosis group. The 6-month postoperative incidence of anastomotic fistula and anastomotic stenosis was recorded. Anastomosis in McKeown operation for EC and the influence of different anastomosis methods on clinical efficacy were investigated.

Results: Compared with traditional mechanical anastomosis, tubular stapler-assisted nested anastomosis had a lower incidence of anastomotic fistula (0% *vs.* 5.2%), lung infection (3.3% *vs.* 11.8%), gastroesophageal reflux (6.9% *vs.* 16.0%), anastomotic stenosis (3.0% *vs.* 10.4%), neck incision infection (0.9% *vs.* 7.1%), anastomositis (16.6% *vs.* 23.6%), and a shorter surgical duration (11.02±1.54 *vs.* 18.53±3.20 min). Statistical significance was indicated at $P<0.05$. No significant difference was detected in the incidence of arrhythmia, recurrent laryngeal nerve injury, or chylothorax between the 2 groups. Due to its good effect in McKeown surgery for EC, stapler-assisted nested anastomosis has been widely used in McKeown surgery for EC, and has become a common anastomosis method in our department for McKeown surgery for EC. However, large sample-sized studies and long-term efficacy observation are still needed.

Conclusions: The use of tubular stapler-assisted nested anastomosis can significantly reduce the incidence of complications such as anastomotic fistula, anastomotic stricture, gastroesophageal reflux, and pulmonary infection; therefore, it constitutes the preferred technique for cervical anastomosis in McKeown esophagogastrectomy.

Keywords: Anastomosis; esophageal cancer (EC); complications; McKeown stapler

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Introduction

Esophageal cancer (EC), one of the most common malignant tumor types, ranks 8th in incidence rate and 6th in mortality rate. China has the highest incidence and mortality rates of EC in the world (1-4). Surgery is considered the treatment of choice for patients with early-stage and mid-stage EC (5-8). However, because of the traumatic nature of EC surgery and the need for gastrointestinal reconstruction, high rates of postoperative complications such as anastomotic leakage or stenosis, esophageal reflux, and pulmonary infection exist (9-12). Despite the wide use of mechanical anastomosis in clinical practice and a reduction in the incidence of anastomotic-related complications (13) with advances in science and technology, a high incidence of postoperative anastomotic-related complications persists (14) and presents a challenge to both Chinese and international thoracic surgeons (15,16). The first nested esophagogastric anastomosis assisted by tubular stapler in China was recently performed with a satisfactory clinical result, and the current clinical research results are as follows. In this study, we explored anastomosis techniques in McKeown operation for EC and the influence of different anastomosis methods on clinical efficacy. We present the following article in accordance with the STROBE reporting checklist (available at https://jgo.amegroups.com/article/view/10.21037/jgo-23-166/rc).

Highlight box

Key findings

- We propose a novel tubular stapler-assisted nested esophagogastric anastomosis method for McKeown EC surgery, which effectively reduces anastomose-related complications.

What is known and what is new?

- The traumatic nature of EC surgery and the need for gastrointestinal reconstruction result in high rates of postoperative complications.
- The use of tubular stapler-assisted nested anastomosis can significantly reduce the incidence of complications such as anastomotic fistula, anastomotic stricture, gastroesophageal reflux, and pulmonary infection.

What is the implication, and what should change now?

- In addition to being simple to implement, stapler-assisted nested anastomosis can effectively reduce the incidence of complications with conventional anastomosis and should thus be widely promoted.

Methods

Patients

A total of 544 patients were diagnosed with esophageal squamous cell carcinoma or squamous adenocarcinoma by laparoscopic McKeown surgery in the Thoracic Department of The First Hospital of Lanzhou University between January 2017 and August 2020. All operations were performed by the chief surgeon and his team. According to the method of cervical anastomosis, participants were divided into a tubular stapler-assisted nested anastomosis group or a conventional tubular mechanical anastomosis group. The tubular stapler-assisted nested anastomosis was taken as the time node in this retrospective study. No neoadjuvant therapy was performed before surgery, and no severe cardiopulmonary dysfunction, severe coagulation dysfunction, or metastasis occurred. The inclusion criterion was McKeown operation for EC. Follow-up results and surgical indicators were used as comparison objects to evaluate the clinical efficacy of anastomosis methods in the 2 groups. In order to resolve the problem of deviation of research results, the operation methods were unified, the same person completed the operation, and the postoperative follow-up time was the same; the variables comprised follow-up results, postoperative complications, and surgical indicators. Patients backgrounds between the two groups (*Table 1*).

A total of 332 patients were in the tubular stapler-assisted nested anastomosis group, including 239 men and 93 women, with an average age of 56.58±4.83 years, an average weight of 67.17±7.15 kg, and an average tumor size of 4.78±1.03 cm. Patients with tumors located in the upper, middle, and lower thoracic segments numbered 85, 160, and 87, respectively. A total of 212 patients were in the conventional tubular mechanical anastomosis group, comprising 150 men and 62 women, with an average age of 57.74±7.56 years, an average weight of 65.69±7.56 kg, and an average tumor size of 4.97±1.04 cm. Patients with tumors located in the upper, middle, and lower thoracic segments numbered 47, 84, and 81, respectively. No significant difference in age, sex, body weight, tumor size, or tumor location was noted between the 2 groups (P>0.05). The diagnosis of esophageal squamous cell carcinoma was confirmed in all patients through preoperative pathology. Central venous catheters were placed by peripheral venipuncture prior to surgery. The purpose and specific steps of the catheterization procedure were explained to the patient and their family. The study was conducted in

Table 1 Patients backgrounds between the two groups

Parameter	Tubular stapler-assisted nested anastomosis group	Conventional tubular mechanical anastomosis group
Total number of patients	332	212
Men	239	150
Women	93	62
Average age (years)*	56.58±4.83	57.74±7.56
Average weight (kg)*	67.17±7.15	65.69±7.56
Average tumor size (cm)*	4.78±1.03	4.97±1.04
Tumor location (upper thoracic)	85	47
Tumor location (middle thoracic)	160	84
Tumor location (lower thoracic)	87	81

*, values were expressed as mean ± SD.

accordance with the Declaration of Helsinki (as revised in 2013). Written informed consent was obtained from each participant. The research protocol of this clinical study was approved by the Medical Ethics Committee of The First Hospital of Lanzhou University (No. LDYYLL2022-475).

Surgical procedure

All patients underwent laparoscopic radical surgery for EC through the right thoracic-abdominal-neck 3-incision method. After the dissociation of the thoracic esophagus and the dissection of the thoracic lymph nodes, the patient was placed in a supine position. An incision was made in the anterior edge of the mastoid muscle, the cervical esophagus was separated and removed, and purse-string forceps were introduced into the purse-string suture. The purse-string forceps were then used to dissect the esophagus, and a tubular stapler anvil was placed at the proximal end of the esophagus. After the closure of the distal end and suturing of the traction tube (infusion set tube), laparoscopic dissociation of the stomach was performed. The stomach was lifted out of the abdominal cavity through a small incision under the xiphoid process, In the area superior to the pylorus, the right gastric artery and vein were transected. Utilizing a linear cutting stapler, the stomach was reshaped along the greater curvature from the lesser curvature side superior to the pylorus in an upward direction, creating a narrow tubular shape with a diameter of 3 cm; the gastric fundus was then fixed to the traction tube and the thoracic entrance was enlarged. The stomach fundus was pulled up to the neck by the posterior mediastinum route and a tension-free site on the greater curvature (as close to the right omental vascular arch as possible) was selected to puncture the connecting rod; the bottom nail anvil was finally connected to the anvil and adjusted to the effective stapling range. All patients underwent complete data collection during hospitalization, returned to the hospital according to regular time points after discharge, and completed postoperative follow-up data. All patients underwent a complete examination after admission to evaluate the opportunity for surgery. The clinical data of patients with surgical indications were included in this study. A detailed post-operative visit plan was developed to obtain complete follow-up data to prevent data loss.

Anastomosis method

In the routine anastomosis group, the anastomotic stoma was inspected directly and the esophageal and gastric seromuscular layers were intermittently sutured to embed the anastomosis. A tubular stapler was used to assist in the connection to the bottom nail anvil in the nested anastomosis group. The surgeon made adjustments to the effective stapling range, relied on the support of the stapler to pull the esophagus 3 cm into the stomach, and then intermittently sutured around the esophagus to embed it in the stomach wall. Anastomosis was completed after the suturing of the muscular and gastric seromuscular layers, the verification of stump integrity, and the closure of the gastric stump. The previously inserted gastroenteric feeding tube was removed in all patients. Anastomosis is illustrated

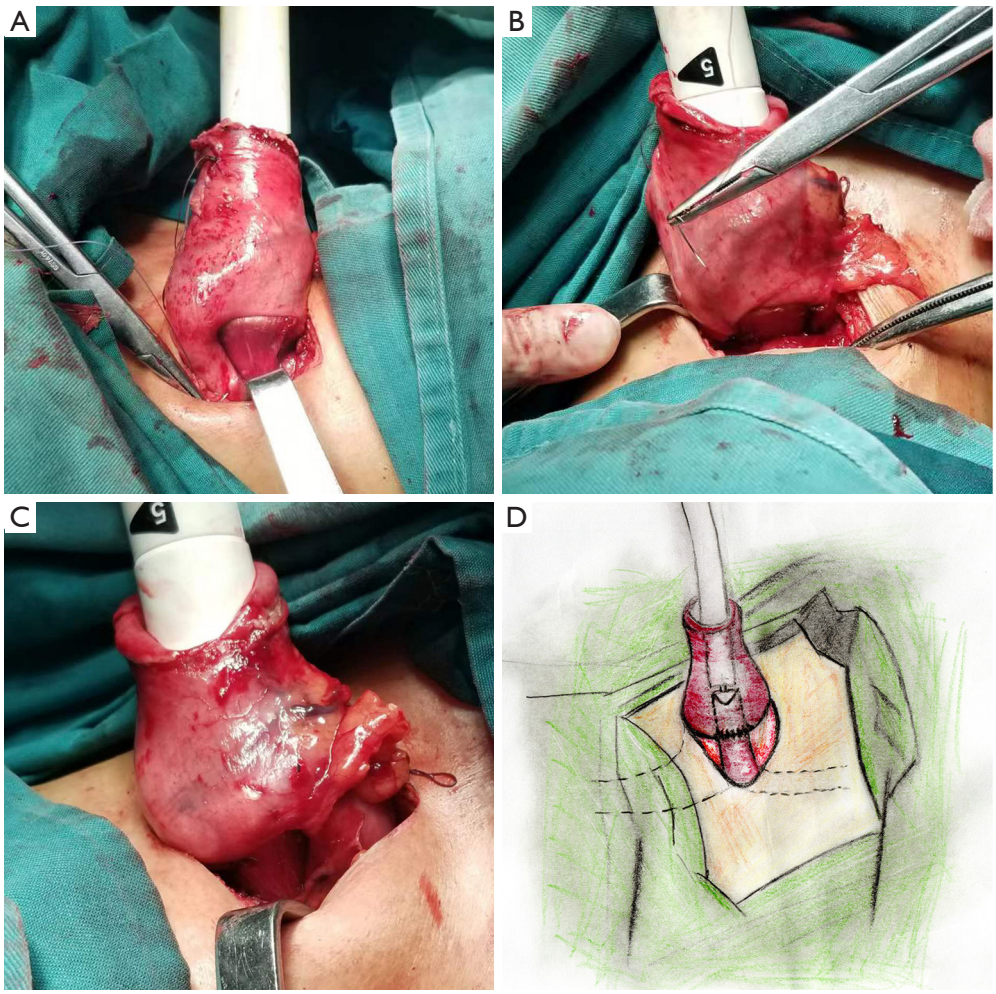

Figure 1 The process of nested anastomosis.

in *Figure 1*. The final state after the gastroesophageal anastomotic site is nested within the gastric cavity in *Figure 2*. Final effect drawing after anastomosis is in *Figure 3*.

Diagnostic criteria for associated complications

The diagnostic criteria for postoperative complications were as follows: (I) anastomotic leakage, as confirmed by a positive methylene blue test or upper gastrointestinal angiography; (II) infection of the neck incision, as confirmed by a positive bacteria culture of the purulent secretion from the catheter placement site; (III) pulmonary infection, as detected by X-ray examination combined with postoperative bloodwork and a positive bacterial sputum culture; and (IV) gastroesophageal reflux, as determined by standard values in the Chinese population as reported in the literature (15)—which were >5 minutes of reflux more than 5 times in 24 hours; abnormal oropharyngeal swab color and pH level <4; and paroxysmal nocturnal dyspnea, asthma, belching, and acid regurgitation—(V) anastomotic inflammation, as confirmed by a 1 month postoperative gastroscopy; (VI) prolonged anastomosis time, defined as the length of time required to complete mechanical anastomosis and anastomotic embedding; (VII) anastomotic stenosis, as indicated by anastomotic stoma <1.0 cm in diameter as measured during a 3-month postoperative gastroscopy and accompanied by dysphagia.

Statistical analysis

The statistical analysis was conducted using SPSS 26.0 (IBM, Armonk, NY, USA). For demographic information,

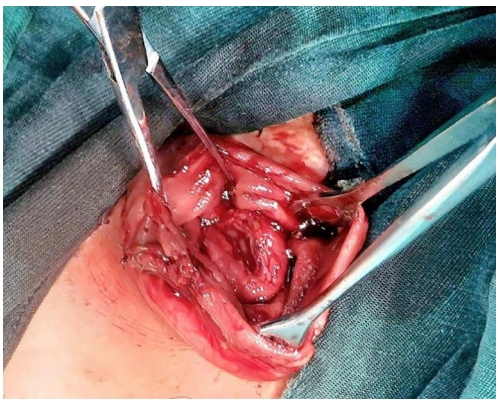

Figure 2 Gastroesophageal anastomotic site is nested within the gastric cavity.

Figure 3 Stapler cutting stitcher.

surgical anastomosis time, and incidence of complications, data were described using frequencies or percentages for categorical variables, and analyzed using the chi-square test or Fisher's exact test. Continuous variables were presented as means ± standard deviation or median (interquartile range), and analyzed using the independent samples *t*-test or Wilcoxon rank-sum test. A P value less than 0.05 was considered statistically significant between the two groups.

Results

All patients underwent successful operations without conversion to thoracotomy or laparotomy. All surgeries involved the use of a linear cutter stapler to reconstruct the stomach into a thin tube shape approximately 3 cm in diameter. A postoperative 6-month follow-up rate of 100% was achieved. No deaths were reported. Compared with the conventional tubular mechanical anastomosis group, the tubular stapler-assisted nested anastomosis group exhibited a lower incidence of the following complications: anastomotic leakage rate [0 (0/332) *vs.* 5.2% (11/212)]; pulmonary infection rate [3.3% (11/332) *vs.* 11.8% (25/212)]; postoperative gastroesophageal reflux rate [6.9% (23/332) *vs.* 16.0% (34/212)]; anastomotic stricture rate [3.0% (10/332) *vs.* 10.4% (22/212)]; neck incision infection rate [0.9% (3/332) *vs.* 7.1% (15/212)]; prolonged surgical anastomosis time (11.02±1.54 *vs.* 18.53±3.20 min). No significant difference was detected in the incidence of the following complications: arrhythmia, recurrent laryngeal nerve injury, chylothorax, and anastomotic stomatitis (*Table 2*). In the conventional tubular mechanical anastomosis group, 4 patients with anastomotic leakage were successfully treated with a combination of unobstructed drainage and parenteral nutrition support and 9 patients with anastomotic stenosis experienced significant symptom alleviation after gastroscopic balloon dilation (3 patients) and radial anastomotic incision (6 patients).

Discussion

China has the highest global incidence of EC, of which most cases are located in the middle segment of the esophagus, followed by the lower segment and upper segment (16). Surgery is the preferred treatment method for early-stage and mid-stage EC. EC's longitudinal infiltration pattern and sequence of growth along the esophageal submucosa necessitates adherence to strict surgical margins. The resection margin is generally located at least 5 cm away from the tumor, and some ECs present with multifocal lesions in clinical practice. Total thoracic esophagectomy with cervical anastomosis is widely regarded as the standard treatment for middle and upper EC (17,18). Clinician and patient expectations of and demand for minimally invasive EC surgery have grown with the continual development of video-assisted thoracoscopy, laparoscopic technology, and related surgical instruments. The advantages of laparoscopic minimally invasive surgery for EC include fewer complications, quicker postoperative recovery (19), and a lower level of pain and trauma, assets that have attracted growing attention and favor from thoracic surgeons (20-26). However, the incidence of anastomotic leakage and related postsurgical complications of cervical anastomosis is significantly higher than in intrathoracic anastomosis,

Table 2 Comparison of complications between the two groups

Complications	Tubular stapler-assisted nested anastomosis group (n=97)	Conventional tubular mechanical anastomosis group (n=85)	P value
Incidence of anastomotic fistula	0% (0/332)	5.2% (11/212)	0.000
Lung infection	3.3% (11/332)	11.8% (25/212)	0.000
Gastroesophageal reflux	6.9% (23/332)	16.0% (34/212)	0.001
Anastomotic stenosis	3.0% (10/332)	10.4% (22/212)	0.000
Neck incision infection rate	0.9% (3/332)	7.1% (15/212)	0.000
Operative anastomosis time*	(11.02±1.54) min	(18.53±3.20) min	0.001
Arrhythmia	6.3% (21/332)	7.1% (15/212)	0.731
Recurrent laryngeal nerve injury	0.9% (3/332)	2.4% (5/212)	0.169
Chylothorax	1.2% (4/332)	1.4% (3/212)	0.832
Anastomositis	16.6% (55/332)	23.6% (50/212)	0.043

*, values were expressed as mean ± SD.

which considerably limits the clinical application of total thoracic esophagectomy and cervical anastomosis. Therefore, the research of thoracic surgeons has long focused on reducing the incidence of oral leakage in cervical anastomosis. Promisingly, the incidence of anastomotic-related complications, including anastomotic leakage, stenosis, and regurgitation, has decreased due to the continual advancement of anastomotic technology and the application of staplers. Nevertheless, complications cannot be completely avoided (27,28). Studies from China and worldwide have reported an anastomotic leakage incidence of 3–26% (18,29-31) and an even higher incidence of stenosis and reflux (32,33), resulting in significantly prolonged hospitalization, increased hospitalization costs, and decreased postoperative quality of life. Therefore, the advancement of anastomosis techniques and reduction of surgery-related complications remain crucial research topics in EC surgery and constitute the focal points of our study. Appropriate anastomosis technology and anastomosis instruments can reduce the incidence of postoperative complications, reduce the physiological and psychological burden of patients, and accelerate the postoperative rehabilitation of patients, reflecting the concept of accelerated surgical rehabilitation.

This study observed a significantly lower incidence of complications in the stapler-assisted insertion anastomosis group than in the conventional anastomosis group, including anastomotic leakage, anastomotic stenosis, reflux, and postoperative pneumonia. Neck anastomotic leakage is a frequent complication of cervical anastomosis in EC. The common causes include excessive anastomotic tension, impaired blood circulation near the anastomotic stoma, local tissue contamination, infection, malnutrition, and inappropriate anastomotic methods. Alverdy *et al.* (34) noted that anastomotic fistulas may be bacteria-related pathophysiological processes. Bacteria easily migrate to the anastomotic stoma of patients who have large tumors; these patients experience difficult surgical separation and excessive blood loss; the local tissue collagenase activity then grows and eventually develops into anastomotic fistulas. The formation of an anastomotic fistula leads to delayed or non-healing of anastomosis, which is not conducive to the recovery of postoperative digestive tract reconstruction, affects the postoperative quality of patients, aggravates the burden, is not conducive to recovery, and may even result in death. Therefore, it is very important to reduce the occurrence of postoperative complications.

The incidence of anastomotic leakage in the experimental group was significantly lower than that in the conventional anastomosis group. We attribute this difference to the following. First, the embedding of the gastroesophageal anastomosis in the gastric cavity produces no postsurgical tension in the anastomotic stoma and acts as one of the key factors for anastomotic healing. Second, because the mechanical anastomosis was not completed during the first embedding, no risk of pulling or tearing the anastomotic stoma during embedding and suturing was present. Complete gastroesophageal end-to-side anastomosis in an

entirely tension-free state constitutes a crucial measure of anastomotic leakage prevention. Third, the anastomosis can be evenly and deeply nested into the gastric cavity with the support force of the stapler. If a small fistula occurs, it can be drained to the gastric cavity without spreading the infection. Fourth, visible or invisible wounds are caused by unavoidable pulling and rotation of the anastomotic stoma during conventional anastomotic embedding due to the poor exposure of the operating field, especially when the posterior wall is embedded. The aforementioned characteristics of the conventional anastomosis group may contribute to the incidence of anastomotic leakage. The use of a stapler and anastomotic nesting can greatly reduce the difficulties encountered during anastomotic embedding, improve the quality and safety of anastomosis, and lower the incidence of postoperative coughing and expectoration (35-37). This anastomosis not only reduces the tear risk caused by the anastomotic tension, but also reduces the irritation to the respiratory tract, which is conducive to reducing the occurrence of postoperative complications and speeding up the recovery of patients.

Additional crucial measures for preventing anastomotic leakage during anastomosis include the following. The first is ensuring adequate blood supply to the stomach, maintaining the integrity of the right omental vascular arch, preserving the main trunk of the right gastric artery, and selecting an anastomotic site near the greater curvature of the vascular arch. The second is ensuring sufficient tubular stomach length, which is essential for tension-free anastomosis and anastomotic nesting. We endeavored to mould the stomach into a tubular shape approximately 3 cm in diameter and parallel to the greater curvature of the vascular arch. An excessively wide diameter would affect the length of the tubular stomach. The third is ensuring the correct reshaping of the tubular stomach. The shape of the stomach also plays a crucial role in the successful nesting of the stapler. The proximal diameter must be wider than the middle and lower parts to accommodate the nesting of the gastroesophageal anastomosis and part of the esophagus into the tubular stomach. Ensuring the smooth nesting of the anastomosis helps prevent tension on the esophageal lumen over the anastomosis, which could impair the esophageal blood supply and lead to postoperative dysphagia.

The incidence of postoperative anastomotic stenosis in the stapler-assisted nested anastomosis group was significantly lower than in the conventional anastomosis group. In the conventional anastomosis group, 4 patients exhibited anastomotic leakage, which acted as an independent factor in the formation of anastomotic stenosis (38-41). Inflammatory hyperplasia occurs during the recovery process of anastomotic leakage, and excessive scarring leads to anastomotic stenosis after healing. Although a study has indicated that anastomotic stenosis is related to gastroesophageal reflux, the reason for this relationship remains undetermined (42). Anastomotic edematous or cicatricial strictures may originate from chronic acidic or alkaline stimulation (43). Therefore, the reduction or prevention of anastomotic stenosis and gastroesophageal reflux are of critical concern.

The incidence of regurgitation in the stapler-assisted nested anastomosis group was significantly lower than in the conventional anastomosis group. This finding may have been due to the possibility that a structure similar to the gastric fundus formed around the anastomosis post surgically. The concurrent increased pressure over the esophageal anastomosis during reflux closes the esophageal cavity and prevents the reflux material from entering the esophagus (44), thereby reducing aspiration, reducing the incidence of aspiration pneumonia, and improving the quality of life of patients after surgery. Furthermore, a significantly lower incidence of postoperative pneumonia was observed in the nested anastomosis group than in the conventional anastomosis group, which also exhibited the antireflux characteristic that is characteristic of nested anastomosis. Our experiment adopted a tubular stomach diameter of 3 cm, which is similar to the artificial nipple insertion method (45). An overly long measurement affects the thoroughness of the resection, whereas an overly short measurement cannot achieve anastomotic decompression and antireflux effects. A significant difference in the incidence of stomatitis was not present in the data; although this indicates the anti-esophageal reflux characteristic of nested anastomosis, it also suggests an inability to reduce the erosion damage of the reflux fluid to the gastroesophageal anastomosis. The optimized design of the nested anastomosis process entails a simpler operation and a significantly shorter procedure relative to conventional anastomosis. The results of this study are roughly consistent with the expected results of our hypothesis, which verifies our hypothesis and further illustrates the advantages of this anastomosis method, which is suitable for application and promotion in the surgical treatment of EC.

Conclusions

In conclusion, in addition to being simple to implement,

stapler-assisted nested anastomosis can effectively reduce the incidence of complications such as anastomotic leakage, anastomotic stenosis, reflux, and aspiration pneumonia compared with conventional anastomosis, and should thus be widely promoted.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jgo.amegroups.com/article/view/10.21037/jgo-23-166/rc

Data Sharing Statement: Available at https://jgo.amegroups.com/article/view/10.21037/jgo-23-166/dss

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The research protocol of this clinical study was approved by the Medical Ethics Committee of The First Hospital of Lanzhou University (No. LDYYLL2022-475). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). All patients provided written informed consent.

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