Purse-indigitation mechanical anastomosis *vs.* traditional mechanical anastomosis undergoing McKeown esophagectomy: a retrospective comparative cohort study

Peiyuan Wang[1,2,3#], Derong Zhang[1#], Xiaozhou Lin[4#], Yujie Chen[1], Hao He[1], Peng Chen[1], Weijie Chen[1], Hang Zhou[1], Suyu Chen[5], Zhen Chen[6], Raja M. Flores[7], Connor J. Wakefield[8], Inderpal S. Sarkaria[9], Shuoyan Liu[1], Feng Wang[1]

[1]Department of Thoracic Oncology Surgery, Clinical Oncology School of Fujian Medical University, Fujian Cancer Hospital, Fuzhou, China; [2]Fujian Key Laboratory of Translational Cancer Medicine, Fuzhou, China; [3]Fujian Provincial Key Laboratory of Tumor Biotherapy, Fuzhou, China; [4]Department of Second Surgery, Zhangpu County Hospital, Zhangzhou, China; [5]Department of Digestive Endoscopy, Clinical Oncology School of Fujian Medical University, Fujian Cancer Hospital, Fuzhou, China; [6]Operation Room of Surgery Center, Clinical Oncology School of Fujian Medical University, Fujian Cancer Hospital, Fuzhou, China; [7]Department of Thoracic Surgery, Icahn School of Medicine at Mount Sinai, Mount Sinai Health System, New York, NY, USA; [8]Department of Internal Medicine, Brooke Army Medical Center, Fort Sam Houston, TX, USA; [9]Department of Cardiothoracic Surgery, The University of Pittsburgh School of Medicine and the University of Pittsburgh Medical Center, Pittsburgh, PA, USA

Contributions: (I) Conception and design: P Wang, D Zhang, F Wang; (II) Administrative support: S Liu, X Lin; (III) Provision of study materials or patients: Y Chen, H He, P Chen; (IV) Collection and assembly of data: W Chen, H Zhou, S Chen, Z Chen; (V) Data analysis and interpretation: P Wang, RM Flores, CJ Wakefield, IS Sarkaria; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Shuoyan Liu; Feng Wang. Department of Thoracic Oncology Surgery, Clinical Oncology School of Fujian Medical University, Fujian Cancer Hospital, Fuzhou, China. Email: shuoyanliu2010@163.com; wfmd120@163.com.

Background: Postoperative anastomosis-related complication rates remain high in patients undergoing McKeown esophagectomy with cervical anastomosis, and the optimal anastomotic technique remains under debate. We describe a new method of anastomosis, referred to as purse-indigitation mechanical anastomosis (PIMA) by reinforcing esophagogastric anastomosis, which can be performed after minimally invasive surgery. This study was designed to compare its feasibility, efficacy, and safety with those of traditional mechanical anastomosis (TMA).

Methods: Between September 2020 and January 2022, 264 patients undergoing McKeown esophagectomy at a single center were included. Demographic data, including patient age, sex, diagnosis, neoadjuvant chemotherapy/radiation therapy in cases of malignancy, comorbidities, and operation time, anastomotic time, estimated blood loss, post-operative complications were collected. Their medical records were retrospectively reviewed, analyzed and compared between the PIMA and TMA cohorts.

Results: The baseline comparability of the PIMA and TMA before the comparisons is no statistical difference. Univariable analysis revealed significantly decreased anastomotic leak rate with PIMA compared to TMA (4.10% *vs.* 11.59%, P=0.04). No significant difference was demonstrated in total operation time, estimated blood loss, postoperative hospital stay, or pulmonary complications between PIMA and TMA (243.94±21.98 *vs.* 238.70±28.45 min; 201.10±67.83 *vs.* 197.39±65.13 mL; 8.83±2.77 *vs.* 9.35±3.78 days; 8.21% *vs.* 11.59%; all P>0.05). The incidence of postoperative pulmonary complications (3.44% *vs.* 50%) was significantly associated with an increased rate of anastomotic leak [odds ratio (OR): 15.50; 95% confidence interval (CI): 4.81–43.71; P<0.01].

Conclusions: PIMA is feasible, safe to perform, and demonstrated a leak rate less than half that of TMA in this study. PIMA may represent a superior alternative to standard esophagogastric cervical anastomosis techniques. Larger sample size and long-term survival are required to fully evaluate PIMA.

Keywords: Purse-indigitation mechanical anastomosis (PIMA); anastomosis; anastomotic leak; esophagectomy; esophageal cancer

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Introduction

In esophageal cancer, resection with immediate reconstruction—usually with the stomach—is currently considered the standard surgical treatment for curative or palliative measures. Unfortunately, leakage of the esophagogastric anastomosis after esophagectomy, with an average incidence rate of 10%, remains the most challenging complication. Leakage from an esophagogastric anastomosis can have serious implications for patient morbidity, as it prolongs fasting time and hospital stay, worsens financial burden, and increases the risk of reoperation and mortality (1,2).

The esophagogastric anastomosis can typically be performed in the chest or neck and several reports have described various anastomotic techniques including hand sewn, circular stapled, linear stapled and the modified Collard approach (combined linear and transverse stapled anastomosis) (3). There are certain notable factors associated with anastomotic leak including the absence of serosa layer, longitudinal orientation of the muscle fibers, the segmental blood supply, and tension of anastomosis. It has been demonstrated that wrapping the pedicled omental flap for esophagogastric anastomosis and using fibrin glue may help to promote sealing and decrease the leak rate (4,5). Stapling techniques during esophagectomy have often been employed. However, an esophagogastric anastomosis can be performed using a variety of techniques (6,7). Further investigation of esophagogastric anastomosis should be discussed and shared among experts in order to identify those incremental changes that may further improve outcomes (8,9).

Minimally invasive esophagectomy (MIE) has become a viable option in the surgical treatment of esophageal cancer. In our center, we adopted a circular stapled anastomotic technique because it has the advantage of a short learning curve and is more popular in McKeown esophagectomy worldwide. Since 2020, our purpose has been to investigate if improved treatment of the esophageal stump could decrease the occurrence of anastomotic leak. We made a minor modification based on traditional mechanical anastomosis (TMA). In the present study, we introduce an improved method of cervical esophagogastric anastomosis, referred to as purse-indigitation mechanical anastomosis (PIMA), and compare its feasibility, efficacy, and safety with those of TMA. We hypothesize that novel methods, like PIMA, can improve upon TMA by reducing postoperative anastomosis-related complications. We present the following article in accordance with the STROBE reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-3865/rc).

Methods

Study design and participants

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Committee of Fujian Cancer Hospital (No. SQ2021-072-01), and informed consent was taken from all the patients. A total of 318 patients with esophageal cancer, hospitalized between September 2020 to January 2022 in the Fujian Cancer Hospital, were preoperatively evaluated for eligibility for surgical resection. The inclusion criteria included patients who underwent esophageal cancer surgery for thoracic esophageal cancer for pathologic cT1–4aN0–2M0 [American Joint Committee on Cancer (AJCC) eighth edition]. The exclusion criteria for participation in this study were the following: (I) extended total gastrectomy; (II) colonic interposition or small bowel jejunal interposition reconstructions; (III) emergency resections; (IV) 2-stage Sweet and Ivor Lewis esophagectomy; (V) resections for benign disease; (VI) mediastinoscopy-assisted esophagectomy; (VII) completely hand-sewn anastomosis; and (VIII) open esophagectomy. Of the 318 patients, 264 met the criteria and were enrolled into the study. Resections were carried out by 2 different surgical teams (PIMA by S. Liu, F. Wang and P. Wang and TMA by D. Zhang, Y. Chen and H. Zhou). PIMA or TMA was performed after thoracoscopic and laparoscopic

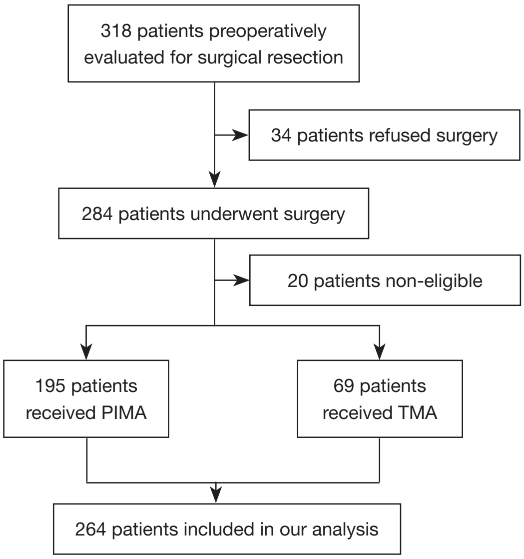

Figure 1 Flow diagram of the study population. PIMA, purse-indigitation mechanical anastomosis; TMA, traditional mechanical anastomosis.

esophagectomy of esophageal cancer and cervical esophagogastrostomy in these patients, with 195 receiving PIMA and the other 69 receiving TMA (*Figure 1*). Three grades of anastomotic leak were defined (10). Demographic data including patient age, sex, diagnosis, neoadjuvant chemotherapy/radiation therapy in cases of malignancy, and comorbidities were collected (available at https://cdn.amegroups.cn/static/public/atm-22-3865-1.xlsx).

Surgical approaches

The operations were performed using thoracoscopy and laparoscopy, consisting of 3 stages: the thoracic, abdominal, and cervical stages. The thoracic stage and abdominal stage were performed in a manner previously described (7,11,12). No pyloroplasty was performed during the operation. Feeding tubes were inserted during the abdominal stage. The gastric conduit (3-cm wide) was achieved in the routine manner.

Cervical esophageal mobilization and esophagogastric anastomosis were performed during the cervical stage. The formed gastric tube was drawn up to the left neck through the posterior mediastinal route. For the TMA group, after an appropriate size of anvil (size of stapler: no. 21 or no. 25; Johnson & Johnson) was inserted and well placed, an incision was made at the lesser curvature side on the esophagogastric junction for the entrance of the stapler shaft. A circular end-to-end stapled anastomosis within 5-cm distal to the right gastroepiploic artery was then completed with the anastomotic site on the posterior wall of the gastric conduit and close to the greater curvature to ensure better blood flow (*Figure 2A-2D*). The remnant gastric conduit was transected about 1–2 cm from the anastomotic line, ensuring an adequate blood supply (*Figure 2E*).

For the PIMA group, the esophageal stump was sutured by interrupted horizontal mattress suture, while the anastomotic line near to the ischemic point was sutured by the purse-string technique. It is worth noting that the string at the proximal end of the esophagus should be 1 cm away from the anastomosis line and about 1–1.5 cm from the distal end of the slender gastric conduit to ensure coverage of the ischemic point, from which leakage can easily occur (*Figure 2F-2H*). The purpose of this suture method is to strengthen the anastomosis and the serous membrane of the anastomosis, such that if anastomotic fistula occurs, it remains an internal one. The scheme of PIMA is illustrated in *Figure 3*.

Postoperative treatment and follow-up

Anti-infection, nutritional support, and other treatments were routinely administered postoperatively. The cervical drainage tube was removed after 72 hours' observation of no postoperative bleeding. Enteral nutrition was initiated after 24 hours of surgery. Esophageal radiography using diatrizoate meglumine was performed to confirm the integrity of the esophagogastric anastomosis postoperatively. An oral soft-food diet was initiated at the third postoperative week. Patients were followed for up to 3 months after discharge, and all patients underwent upper gastrointestinal examination to test the integrity of the anastomosis. The primary outcome was the incidence of anastomotic leak within 3 months after surgery to evaluate the safety and efficacy of the new technique.

Variables and statistical analysis

The basic demographic data of patients were recorded including sex, age, tumor location, neoadjuvant therapy, pathological type, pathological stage, nerve involvement, vascular invasion, total operation time, time of anastomosis, estimated blood loss, and type of postoperative complication (anastomotic leakage, anastomotic stricture, pulmonary

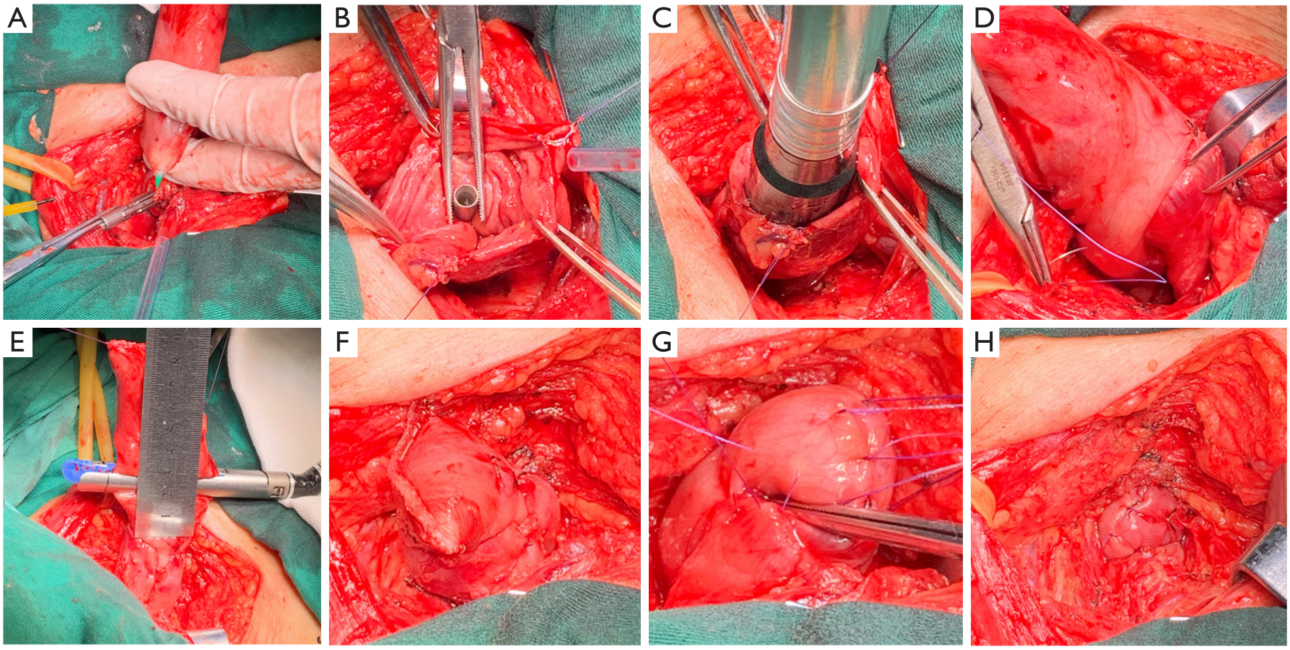

Figure 2 Anastomosis procedure. (A) The anvil and position device are placed. (B) The device is adjusted. (C) The circular stapler is applied to attach the anvil. (D) The right and left lateral walls of the esophagogastric anastomosis are reinforced by horizontal mattress suture. (E) The gastric conduit is removed at least 1–2 cm from the anastomotic line by the linear cutter. (F) The gastric conduit stump. (G) The inside of the ischemic point is covered by purse-string suture, and the anterior and posterior walls of the esophagogastric anastomosis are reinforced by interrupted horizontal mattress suture. (H) The esophagogastric anastomosis is placed in the esophageal bed at the cervicothoracic junction.

complication). The quantitative data are expressed as the mean ± standard deviation (SD). Statistical analyses to evaluate variables included Pearson χ^2 test, Fisher exact test, and univariate logistic regression. Baseline demographic and treatment date were compared between patients who underwent PIMA and those who underwent TMA. The statistical significance (alpha value) threshold was fixed at 0.05. Odds ratios (ORs) were estimated from logistic regression models. All P values were two-sided, and 95% confidence intervals (CIs) are provided. All data were analyzed with GraphPad Prism version 5.0 (GraphPad Software, San Diego, CA, USA).

Results

Patient characteristics

Characteristics of the patients, including sex, age, tumor location, neoadjuvant therapy, pathological type, T stage, N stage, pathologic stage, nerve involvement, and vascular invasion are shown in *Table 1*. In all, 264 patients with thoracic esophageal cancer were enrolled and underwent thoracoscopic and laparoscopic esophagectomy of esophageal cancer, followed by cervical esophagogastrostomy. No statistical differences were found among the abovementioned characteristics (*Table 1*, all P values >0.05).

Operative and postoperative outcomes

All patients received the McKeown procedure with a variety of anastomotic techniques. *Table 2* presents the operative and short-term postoperative outcomes, showing that the overall incidence of postoperative anastomotic leak in the PIMA group was lower than that in the TMA group (4.10% *vs.* 11.59%, P=0.04). No significant difference was found between the PIMA and TMA group for the following measures: total operation time (243.94 ±21.98 *vs.* 238.70±28.45 min, P=0.13), estimated blood loss (201.10±67.83 *vs.* 197.39±65.13 mL, P=0.68), postoperative hospital stay (8.83±2.77 *vs.* 9.35±3.78 days, P=0.22),

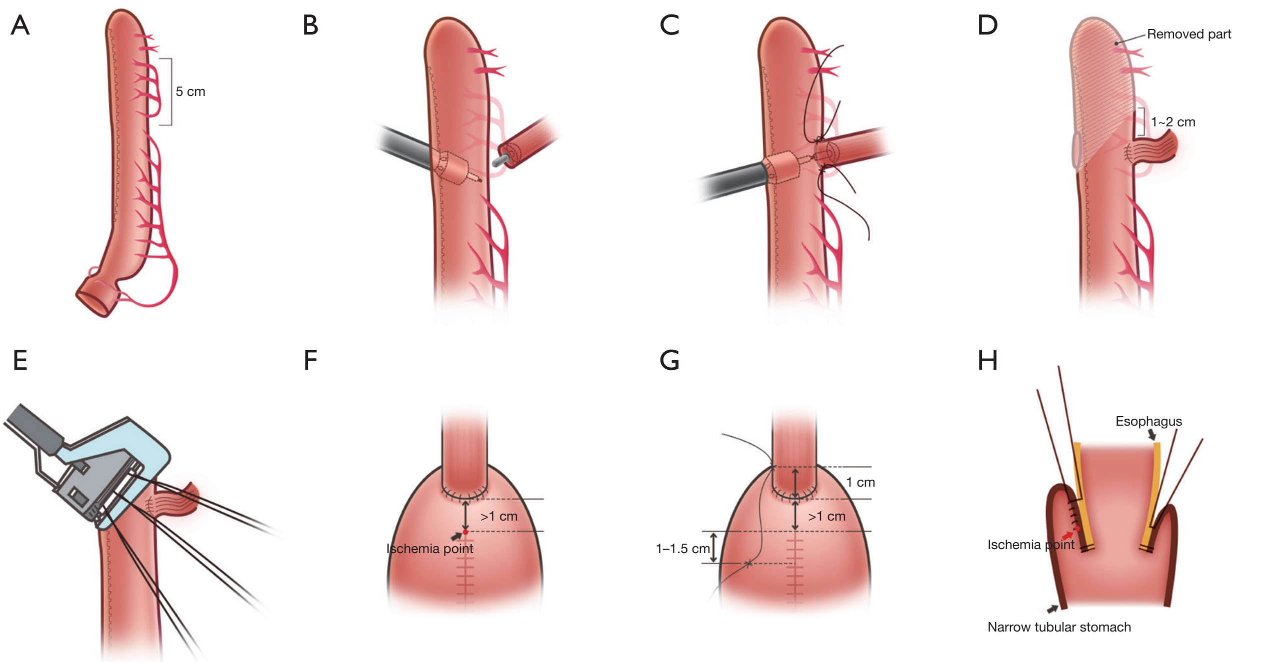

Figure 3 Scheme of PIMA. (A) The gastric conduit is drawn to the neck. The position of the esophagogastric anastomosis is selected 5 cm distal to the right gastro-omental artery, as indicated. (B) The anvil is inserted into the remnant esophagus, the proximal gastric conduit is cut open, and the circular stapler is applied to attach the anvil. (C) The right and left lateral walls of esophagogastric anastomosis are reinforced by horizontal mattress suture. (D) The dashed area is transected at least 1–2 cm from the anastomotic line. (E) The gastric conduit is removed by a linear cutter. (F) The arrow indicates the ischemic point at which the anastomotic stoma fistula typically occurs. (G) The ischemic point is covered inside the anastomosis by purse-string suture. (H) The anterior and posterior walls of the esophagogastric anastomosis are reinforced by interrupted horizontal mattress suture. PIMA, purse-indigitation mechanical anastomosis.

pulmonary complications (8.21% *vs.* 11.59%, P=0.47), or anastomotic stricture (1.03% *vs.* 1.45%, P=1.00). Surprisingly, 3 patients in the PIMA group who only had subcutaneous emphysema after discharge had leak grade I, while the others had leak grade II; meanwhile, in the TMA group, 8 patients had leak grade II (P=0.20). One patient in the PIMA group died after the operation because of severe pulmonary complications, while in the TMA group no 90-day mortalities occurred (P=1.00).

Factors associated with anastomotic leak

Overall, 16 patients (6.06%) experienced an anastomotic leak. Among the patients in the TMA group, those who underwent TMA had higher leak rates (n=8; 11.59%) compared with those who underwent PIMA (n=8; 4.10%; P=0.04). We also found that the incidence of postoperative pulmonary complications (3.44% *vs.* 50%) was significantly associated with an increased rate of anastomotic leak (OR: 15.50; 95% CI: 4.81–43.71; P<0.01). In the patients who underwent neoadjuvant chemoradiotherapy, there tended to be an increased rate of anastomotic leak compared with those who underwent esophagectomy alone (OR: 3.60; 95% CI: 0.98–13.22; P=0.06). However, there was no significant difference in the incidence of anastomotic leak in patients with neoadjuvant chemotherapy compared with those who underwent surgery alone (OR: 1.48; 95% CI: 0.45–4.82; P=0.53; *Table 3*).

Discussion

Anastomotic leak is a common complication after McKeown esophagectomy and cervical anastomosis. Over the past decades, a variety of anastomotic techniques have been used, among which a uniform technique has not been agreed upon (7,13,14). Recent studies have demonstrated that MIE promotes postoperative recovery by decreasing complications (15,16). In this study, our data revealed a

Table 1 Clinical characteristics of the study population (n=264)

Variables	PIMA (n=195)	TMA (n=69)	P value
Sex			0.32
Male	154	50	
Female	41	19	
Age (years)			0.76
<60	61	20	
≥60	134	49	
Tumor location			0.65
Upper	22	8	
Middle	96	38	
Lower	77	23	
Neoadjuvant therapy			0.54
NCRT	23	5	
NCT	58	20	
No[a]	114	44	
Pathological type			0.43
Squamous cell carcinomas	190	66	
Non-squamous cell carcinomas[b]	5	3	
Pathological T stage			0.2
Tis/T0/T1/T2	91	26	
T3/T4	104	43	
Pathological N stage			0.31
N0/N1	153	50	
N2/N3	42	19	
Pathologic stage			0.89
0–II	93	34	
III–IV	102	35	
Nerve involvement			0.61
Yes	64	25	
No	131	44	
Vascular invasion			0.588
Yes	100	38	
No	95	31	

[a], no treatment before surgery; [b], adenocarcinoma, small-cell carcinoma, melanoma, spindle cell carcinoma. NCRT, neoadjuvant chemoradiotherapy; NCT, neoadjuvant chemotherapy; PIMA, purse-indigitation mechanical anastomosis; TMA, traditional mechanical anastomosis.

Table 2 Operative and postoperative outcome variables (n=264)

Parameters	PIMA (n=195)	TMA (n=69)	P value
Total operation time (min), mean ± SD	243.94±21.98	238.70±28.45	0.13
Estimated blood loss (mL), mean ± SD	201.10±67.83	197.39±65.13	0.68
Postoperative hospital stay (days), mean ± SD	8.83±2.77	9.35±3.78	0.22
Pulmonary complications, n (%)	16 (8.21)	8 (11.59)	0.47
Anastomotic leak, n (%)	8 (4.10)	8 (11.59)	0.04
Anastomotic stricture, n (%)	2 (1.03)	1 (1.45)	1.00
In-hospital and 90-day mortality, n (%)	1 (0.50)	0 (0.00)	1.00

SD, standard deviation; PIMA, purse-indigitation mechanical anastomosis; TMA, traditional mechanical anastomosis.

significantly decreased anastomotic leak rate when the cervical anastomosis employed the novel PIMA as compared with TMA.

Risk factors for anastomotic leak after radical McKeown esophagectomy include tension or ischemia at the anastomosis, extent of the mobilization of esophagus, lack of surgical experience, surgical technique, the compression of the conduit at the thoracic inlet, malnutrition, tumor stage, involvement at the anastomotic margin, neoadjuvant therapy, and patient comorbidities, among others (17,18). Previous studies have reported that a 3-cm wide gastric conduit is superior in providing blood supply and tube length compared to a 5-cm wide gastric conduit. Moreover, one multivariable analysis found a wider gastric conduit to involve a higher risk of developing anastomotic leakage (17,19). In the present study, PIMA and TMA were all performed with a 3-cm wide gastric conduit.

There are several requirements for the application of PIMA: (I) to ensure better blood supply, the anastomotic site should be within 5 cm from the top of the right gastroepiploic artery; (II) a longer gastric conduit in PIMA compared with TMA is needed, and the width of the gastric conduit should be approximately 3 cm and (III) the ischemic point between the right gastroepiploic artery and anastomosis should be covered by purse-string suture, as the greater the distance is from the distal end of the right gastroepiploic artery, the more likely anastomotic leak is to occur. The cardinal principle of the PIMA is to re-embed the ischemic area. If an anastomotic leak does occur, the

Table 3 Univariable analysis of factors associated with anastomotic leak in patients with esophageal cancer who underwent esophagectomy (n=264)

Variables	No leak (n=248)	Leak (n=16)	OR	95% CI	P value
Sex					1.00
Male	191	13	1.00		
Female	57	3	1.29	0.36–4.70	
Age (years)					0.78
<60	77	4	1.00		
≥60	171	12	1.35	0.42–4.32	
Tumor location					0.19
Upper	30	0	–		
Middle	122	11	–	–	
Lower	96	5	–	–	
Neoadjuvant therapy					
No[a]	151	7	1.00		
NCRT	24	4	3.60	0.98–13.22	0.06
NCT	73	5	1.48	0.45–4.82	0.53
Pathological T stage					0.31
Tis/T0/T1/T2	112	5	1.00		
T3/T4	136	11	1.81	0.61–5.37	
Pathological N stage					0.77
N0/N1	191	12	1.00		
N2/N3	57	4	1.12	0.35–3.60	
Pathologic stage					0.45
0–II	121	6	1.00		
III–IV	127	10	1.59	0.56–4.50	
Nerve involvement					0.42
No	166	9	1.00		
Yes	82	7	1.58	0.57–4.38	
Vascular invasion					0.8
No	129	9	1.00		
Yes	119	7	0.84	0.30–2.33	
Pulmonary complication					<0.01
No	232	8	1.00		
Yes	16	8	15.50	4.81–43.71	
Anastomotic type					0.04
PIMA	187	8	1.00		
TMA	61	8	3.07	1.10–8.52	

[a], no treatment before surgery. NCRT, neoadjuvant chemoradiotherapy; NCT, neoadjuvant chemotherapy; OR, odds ratio; CI, confidence interval; PIMA, purse-indigitation mechanical anastomosis; TMA, traditional mechanical anastomosis.

digestive fluid can be restricted within an internally closed space, preventing leakage beyond this stage. Indeed, in the PIMA group of our study, 3 patients with grade I leak had delayed leakage and no abnormalities present in the upper gastrointestinal examination.

Anastomotic stenosis and esophageal reflux are frequent complications after McKeown esophagectomy (20). Anastomotic stenosis presents as dysphagia needing one or more endoscopic dilatations. Perhaps due to the short follow-up period in our study, only 1 patient experienced anastomotic stenosis. PIMA did not increase the rate of anastomotic stenosis. Clinically, we found that this novel technique might decrease the occurrence of postoperative reflux although we cannot explain these findings given limited data and low incidence of postoperative reflux in our study.

It should be noted that the addition of chemoradiation may increase the chance for toxicity, including anastomotic leak after surgery. Our findings are consistent with those in previously published studies (21-23). In our study, neoadjuvant chemoradiotherapy tended to be associated with a higher rate of anastomotic leak compared with surgery alone. Moreover, neoadjuvant chemotherapy did not increase the rate of anastomotic leak. It thus seems that radiotherapy has a greater contribution to the occurrence of anastomotic leak than does chemotherapy.

Owing to the application of pleural flaps in covering the upper mediastinum, leak related to cervical anastomosis mainly presents as a local infection, subcutaneous emphysema, and abscess (24). In our study, when a leak did occur, there was no leakage into the pleural cavity leading to potential subsequent pulmonary complications. Pulmonary complications are frequent postoperative complications of McKeown esophagectomy. We found that when pulmonary complications did occur, the incidence of anastomotic leak significantly increased (P<0.01).

Several limitations to this study should be noted. First, our design was restricted to being a retrospective analysis, which cannot account for all the potential factors that could help explain some of our findings. Second, the sample size of our study was relatively small and there were not an equal number of patients between groups with this being particularly subject to selection bias; because we adopted PIMA recently and the review only went back to 2020. Third, we only included patients who underwent cervical anastomosis via McKeown esophagectomy, and other surgical approaches were not considered. Finally, due to the short follow-up period and limited data obtained, we lack sufficient evidence to evaluate the long-term survival between techniques.

In conclusion, we believe that our novel anastomotic method is a feasible, safe, and viable alternative procedure for esophagogastric anastomosis, as it may significantly reduce the incidence of postoperative anastomosis leak in patients undergoing McKeown MIE for cancer.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-3865/rc

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-3865/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-3865/coif). Dr. ISS has received honoraria for education/speaking and/or consulting from Intuitive Surgical, CMR, Stryker, and AMSI. The other authors have no conflicts of interest to declare.

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. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Committee of Fujian Cancer Hospital (No. SQ2021-072-01), and informed consent was taken from all the patients.

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