Original Article

Efficacy and analysis of modified "three-tube method" in the treatment of intrathoracic anastomotic leakage after esophagectomy

Qinghui Zeng[1,2#], Lu Liu[3#], Fangbiao Zhang[2], Chun Zhao[2], Zhijun Wu[2], Xia Lin[2], Chunhui Zheng[2], Yingming Xiang[2], Shaosong Tu[2], Xiangyan Zhang[2], Zhengfu He[1]

[1]Department of Thoracic Surgery, Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, Hangzhou, China; [2]Department of Cardiothoracic Surgery, Lishui Municipal Central Hospital, Lishui, China; [3]Department of Interventional Radiology, Lishui Municipal Central Hospital, Lishui, China

Contributions: (I) Conception and design: Z He; (II) Administrative support: Z He; (III) Provision of study materials or patients: Z He; (IV) Collection and assembly of data: Q Zeng; (V) Data analysis and interpretation: L Liu; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Zhengfu He. Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, 3 East Qingchun Road, Hangzhou 310016, China. Email: hezhengfu123@hotmail.com.

Background: This study aimed to retrospectively evaluate the clinical efficacy of the modified "three-tube method" for the treatment of intrathoracic anastomotic leakage (IAL) after esophagectomy, and to analyze the independent risk factors for prolonging the treatment time of the modified "three-tube method".

Methods: From January 2013 to December 2018, IAL was reported in 22 patients with esophageal cancer who underwent esophagectomy with intrathoracic anastomosis. By reviewing and analyzing the clinical data of the 22 patients, the efficacy of the modified "three-tube method" treatment and the independent risk factors associated with a longer treatment duration of the modified "three-tube method" were evaluated.

Results: Of the 22 patients, 19 were male (86.4%). The average age was 65.2 years old. A total of 4 patients (18.2%) underwent preoperative neoadjuvant chemotherapy; 6 patients (27.3%) had a Charlson comorbidity index (CCI) score of 1–3; the average diagnosis time of IAL was 9.5 days; the median intervention time was 4 days; and the average fistula length was 1.5 cm. The average albumin level after surgery was 30.5 g/L, and the average C-reactive protein (CRP) level was 139.4 mg/L. The modified "three-tube method" average treatment time was 19.5 days. One patient (4.5%) died of respiratory failure during treatment. Univariate analysis and multivariate analysis by establishing multiple linear regression model found that the date of intervention and the fistula size were significantly associated with a longer treatment duration of the modified "three-tube method".

Conclusions: The modified "three-tube method" is a safe and effective means for non-surgical treatment of IAL after esophagectomy. The intervention time and the fistula size are independent risk factors for prolonging the treatment time of the modified "three-tube method".

Keywords: Modified "three-tube method"; esophageal cancer; esophagectomy; intrathoracic anastomotic leakage (IAL)

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Introduction

Radical esophagectomy is still the most effective treatment for early and locally advanced esophageal cancer (1,2). However, the surgery is traumatic and has many postoperative complications. Postoperative anastomotic leakage is one of the most serious complications after esophagectomy (3-5), and despite reduction with the improvement of surgical techniques and optimization of postoperative patient management, it is reported that the morbidity of anastomotic leakage is still 10–20%, and the mortality is still as high as 4–50% (6). Previously, re-surgical intervention was the main treatment for anastomotic leakage, but patients often have a poor general condition after esophagectomy, and reoperation frequently poses great risks to such patients (7). Guo *et al.* (8) reported that there was no statistical difference in time to closure of leak was noted between patients who were managed conservatively and those who were managed surgically and there was a higher rate of operative mortality in patients who underwent surgical intervention as compared with patients who underwent conservative treatment. Therefore, endoscopic treatment has become the preferred treatment for postoperative anastomotic leakage in recent years, including the insertion of a fully covered self-expanding metal stent (SEMS), endoscopic vacuum-assisted closure (EVAC), endoscopic naso-leakage drainage (ENLD), the traditional "three-tube method" (including chest tube, gastrointestinal decompression tube, enteral nutrition tube), and the modified "three-tube method", which has been improved by the traditional "three-tube method" (including chest tube, naso-leakage tube, and three-chamber jejunal feeding tube). In this study, we reviewed the experience of our modified "three-tube method" in the treatment of postoperative intrathoracic esophageal anastomotic leakage in esophageal cancer to evaluate the therapeutic effect and identify risk factors associated with the treatment duration with modified "three-tube method". We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/apm-21-2583).

Methods

Patients

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics committee of Sir Run Run Shaw Hospital (20190829-1). Informed consent of participants in this study was waived due to its retrospective nature. From January 2013 to December 2018, 24 patients who had an esophageal anastomotic leak following esophagectomy for cancer in Sir Run Run Shaw Hospital were identified, including 2 patients who experienced cervical leakage and 22 patients who experienced intrathoracic anastomotic leakage (IAL). The 2 participants with cervical leakage were cured after treatment with debridement, intravenous antibiotics, and parenteral nutrition support. The remaining 22 participants with intrathoracic leakage were treated with the modified "three-tube method" and included in the study. All cases of IAL were diagnosed by gastroscope and chest computed tomography (CT) scan.

Data collection and definitions

Demographic and clinical data were collected from the medical records, including age, gender, smoking history, drinking history, comorbidities, laboratory results, surgical methods, fistula size, diagnosis time, intervention time, duration of modified "three-tube" treatment, and prognosis (*Table 1*). We defined anastomotic leakage as that which included not only gastroesophageal junction leakage but also thoracic stomach leakage. All cases of IAL were confirmed by gastroscope, and mediastinal infection was assessed by chest CT scan. The Charlson comorbidity index (CCI) was used to quantify comorbidities. Postoperative albumin value and postoperative C-reactive protein (CRP) value referred to the lowest and highest value, respectively, detected between the date of surgery and the date of diagnosis of IAL. Duration of the modified "three-tube" treatment was defined as the time between placement and removal of the naso-leakage tube and the three-chamber feeding tube. We defined treatment failure when placement of the tubes failed or when the anastomotic leakage did not improve despite the modified "three-tube method" treatment and required an alternate treatment, or the patient died due to the fistula.

Modified "three-tube method" implementation steps

(I) GIF-Q260J gastroscope (Olympus, Tokyo, Japan) was used to diagnose IAL and measure the length of the fistula (longest diameter). If the gastroscope could enter the fistula, the abscess was flushed as quickly as possible. (II) Under the direct vision of the gastroscope, the Freka stomach tube (Huarui Pharmaceutical Co., Ltd., Wuxi, China) was placed into the fistula through 1 side of the nasal cavity

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Table 1 Clinical characteristics

Variables	n=22
Gender, n (%)	
Male	19 (86.4)
Female	3 (13.6)
Age (years)	65.2±9.5
Drinking, n (%)	
No	11 (50.0)
Yes	11 (50.0)
Smoking index, n (%)	
None	10 (45.5)
<400	3 (13.6)
≥400	9 (40.9)
CCI score, n (%)	
0	16 (72.7)
1–3	6 (27.3)
Neoadjuvant chemotherapy, n (%)	
No	18 (81.8)
Yes	4 (18.2)
Surgical procedure, n (%)	
Ivor-Lewis	18 (81.8)
Sweet	4 (18.2)
Time to diagnosis (days)	9.5±3.4
Time to intervention (days)	3.4 (0–18)
Fistula size (cm)	1.5±0.7
Albumin (g/L)	30.5±3.3
CRP (mg/L)	139.4±75.3
Duration of treatment (days)	19.5±4.2
Hospital stay (days)	23.6±4.2
Mortality, n (%)	1 (4.5)

Data are shown as a number with percentage (%) or mean ± standard deviation ($\bar{x}$±s) or median and range. CCI, Charlson comorbidity index; CRP, C-reactive protein.

of the patient as the naso-leakage tube, X-ray fluoroscopy (Siemens, Munich, Germany) was used to assist the insertion of the naso-leakage tube; the lavage and drainage were performed. (III) Through the other side of the patient's nasal cavity, a Freka three-chamber jejunal feeding tube (Huarui Pharmaceutical Co., Ltd., China) was placed under the gastroscope to the jejunum, and the position of the jejunal feeding tube was verified by X-ray fluoroscopy; the gastrointestinal decompression and enteral nutrition were exerted. (IV) The naso-leakage tube was continuously suctioned with negative pressure and intermittently flushed; the gastric tube end of the three-chamber jejunal feeding tube was routinely suctioned with negative pressure; postoperative enteral nutrition was performed through the jejunal nutrition tube end of the three-chamber feeding tube according to the patient's specific condition. (V) The naso-leakage tube was washed with saline 3 times a day to observe the traits of the drainage fluid. At the same time, every 2–3 days, according to the iodine oil contrast examination of esophagus to observe if the vomica diminished, it was decided whether to pull out 1–2 cm of the naso-leakage tube. Finally, when it was observed that the abscess had almost disappeared under the iodine oil contrast examination of esophagus, the naso-leakage tube was removed. After 3 days of observation, healing of the leakage was confirmed endoscopically, and the patient could resume oral feeding. If there was no discomfort, the three-chamber feeding tube could be removed. (VI) The chest tube was placed routinely after surgery, and the removal time depended on the volume and the traits of the drainage fluid. During the treatment, the physician was required to fully communicate with the nurse to ensure that the irrigation tube was unobstructed, and the negative pressure ball was replaced in time (*Figure 1*).

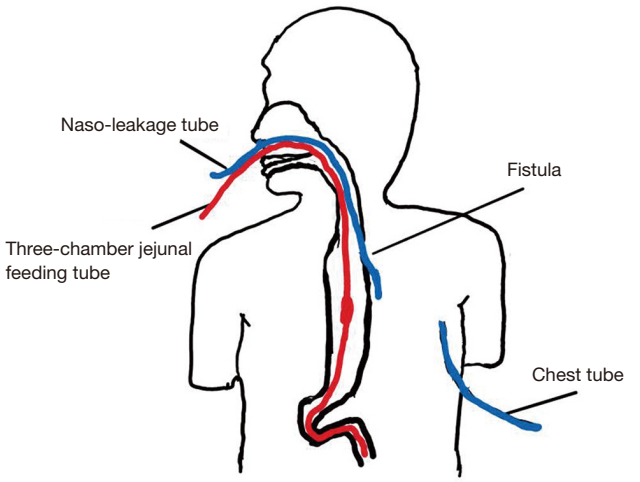

Figure 1 Graphical illustration of the "modified three-tube method".

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Statistical analysis

The categorical variables were presented as a number with percentage, and the continuous variables were presented as mean ± standard deviation ($\bar{x}$±s) or median and range. Differences between groups were analyzed using the Mann-Whitney U test or the Kruskal-Wallis test. Univariate analysis was performed using Pearson correlation analysis or Spearman correlation analysis. Multivariate analysis was performed by establishing multiple linear regression models. Statistical significance was considered when $P<0.05$. Statistical analysis was performed using SPSS version 22 (IBM Corp., Armonk, NY, USA).

Results

Clinical analysis

A total of 22 patients underwent esophageal resection of the esophageal squamous cell carcinoma, thoracic gastric replacement of the esophagus, gastro-esophageal intrathoracic anastomosis, and chest and abdomen 2-field lymph node dissection. All anastomoses were anastomosed with Endo-GIA staples (Medtronic, Minneapolis, MN, USA). There were 19 males (86.4%) with an average age of 65.2±9.5 years. A total of 18 participants (81.8%) were treated with Ivor Lewis procedure (laparoscopic combined with right transthoracic approach), and 4 participants (18.2%) underwent Sweet procedure (left transthoracic approach). There were 4 participants (18.2%) who underwent preoperative neoadjuvant chemotherapy. In terms of CCI scoring, 16 participants (72.7%) scored 0 and 6 (27.3%) scored 1–3 points. A total of 10 participants (45.5%) denied smoking, 3 (13.6%) had a smoking index <400, and the remaining 9 participants (40.9%) had a smoking index ≥400. There were 11 participants (50%) with a drinking history. The mean time to diagnosis of IAL was 9.5±3.4 days, and the median intervention time was 4 (0–18) days. The average length of fistula measured by the gastroscope was 1.5±0.7 cm. The mean postoperative albumin level was 30.5±3.3 g/L, and the average postoperative CRP level was 139.4±75.3 mg/L. All 22 participants received successful placement of the naso-leakage tube and the three-chamber jejunal feeding tube. All participants had no obvious dyspnea, chest pain, nasal bleeding, or other discomfort after catheterization. The average duration of the modified "three-tube method" was 19.5±4.2 days. A solitary participant (4.5%) died of respiratory failure during the course of treatment, and the remaining 21 participants (95.5%) were discharged from the hospital. The average postoperative hospital stay was 23.6±4.2 days.

Analysis of related factors for prolonging treatment effect

No significant differences were detected in the duration of treatment for the modified "three-tube method" between gender, surgical procedure, smoking index, and history of drinking. However, there was a statistically significant difference between the groups of receiving preoperative neoadjuvant chemotherapy and CCI score ($P=0.03$ and $P=0.03$, respectively) (*Figure 2*). Univariate analysis found that longer treatment time with the modified "three-tube method" was not related to age, diagnosis time, postoperative albumin level, and postoperative CRP level, but the time to intervention (correlation coefficient $R=0.77$, $P=0.00$) and the fistula size (correlation coefficient $R=0.96$, $P=0.00$) were related to the duration of modified "three-tube method" treatment (*Figure 3*). Finally, preoperative neoadjuvant chemotherapy, CCI score, time to intervention, and the fistula size were included in the multiple linear regression model. Multivariate analysis found that the time to intervention [non-standardized coefficient $B=0.36$, 95% confidence interval (CI): 0.21 to 0.51, $P=0.00$] and the fistula size (non-standardized coefficient $B=4.27$, 95% CI: 3.31 to 5.22, $P=0.00$) were significantly associated with longer modified "three-tube method" treatment (*Table 2*).

Discussion

Anastomotic leakage is a serious complication of postoperative esophageal cancer, and IAL is the most dangerous type. In the past few decades, despite the improvement of surgical techniques and the optimization of postoperative patient management, and reduction in both morbidity and mortality of IAL, IAL is still one of the main causes of postoperative death in esophageal cancer. In the past, re-surgical intervention was the main treatment, but patients with IAL after esophagectomy were often accompanied by a poor general condition, and reoperation frequently presented great risks to such patients (7). Guo *et al.* (8) reported that there was no statistical difference in time to closure of leak was noted between patients who were managed conservatively and those who were managed surgically and there was a higher rate of operative mortality in patients who underwent surgical intervention as compared with patients who underwent conservative

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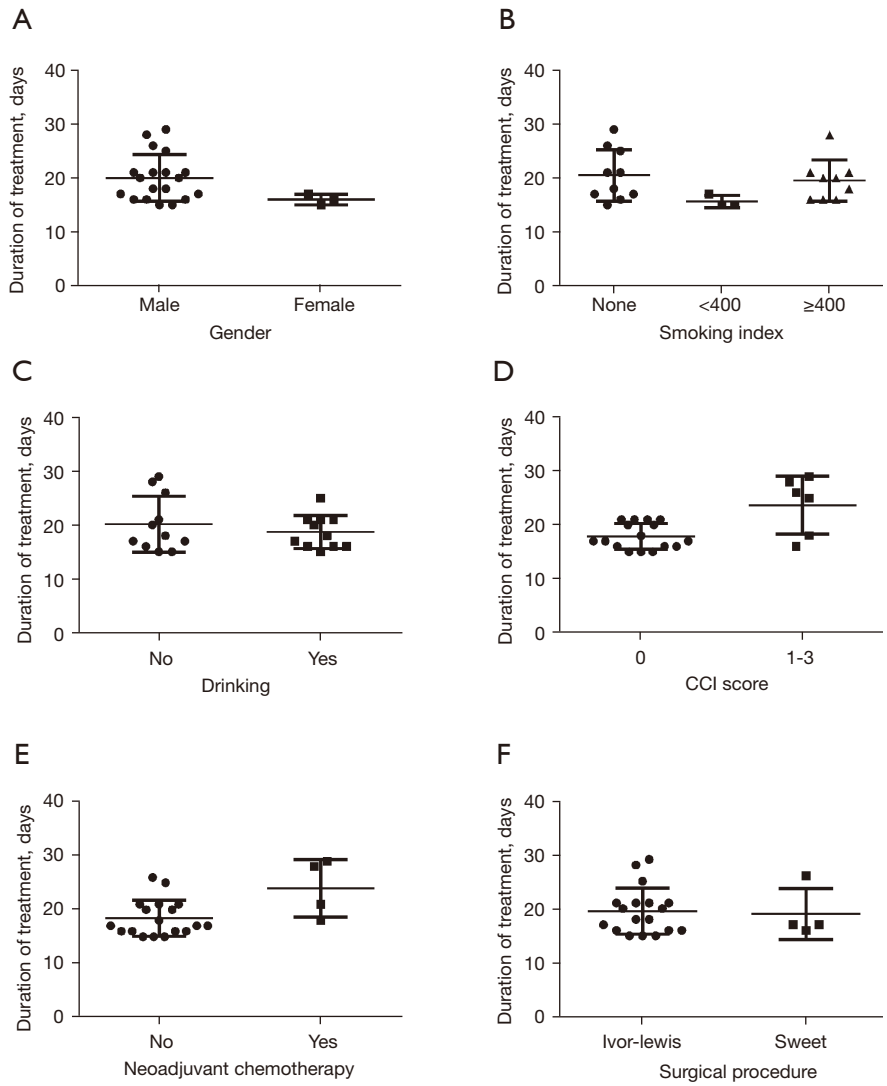

Figure 2 Differences between groups were tested using the Mann-Whitney U test or the Kruskal-Wallis test. There was no significant difference in duration of treatment between gender (A), smoking index (B), drinking (C), and surgical procedure (F) (all P>0.05), but there was a significant difference between the CCI score (D) and the neoadjuvant chemotherapy (E) group (all P<0.05). CCI, Charlson comorbidity index.

treatment. Therefore, endoscopic treatment has become the preferred treatment for IAL after esophagectomy in recent years, including SEMS, EVAC, ENLD, the traditional "three-tube method", and the modified "three-tube method" introduced in this study.

When IAL occurs, gastric fluid with a certain corrosiveness enters the mediastinum through the fistula, resulting in the formation of a mediastinal lumen, abscess, and even esophageal-thoracic fistula. At the same time, due to the difficulty of oral feeding, the lack of nutrition further affects the healing of the fistula. Continued infection and nutrient consumption will eventually lead to the death of the patient (7). Therefore, the keys to the cure of IAL are adequate drainage of the mediastinum or thoracic cavity (when esophageal-thoracic fistula occurs) (7,9), gastrointestinal decompression, and nutritional support.

The traditional "three-tube method" uses the chest tube, gastrointestinal decompression tube, and enteral nutrition tube to achieve the purpose of gastrointestinal decompression and enteral nutrition support. However,

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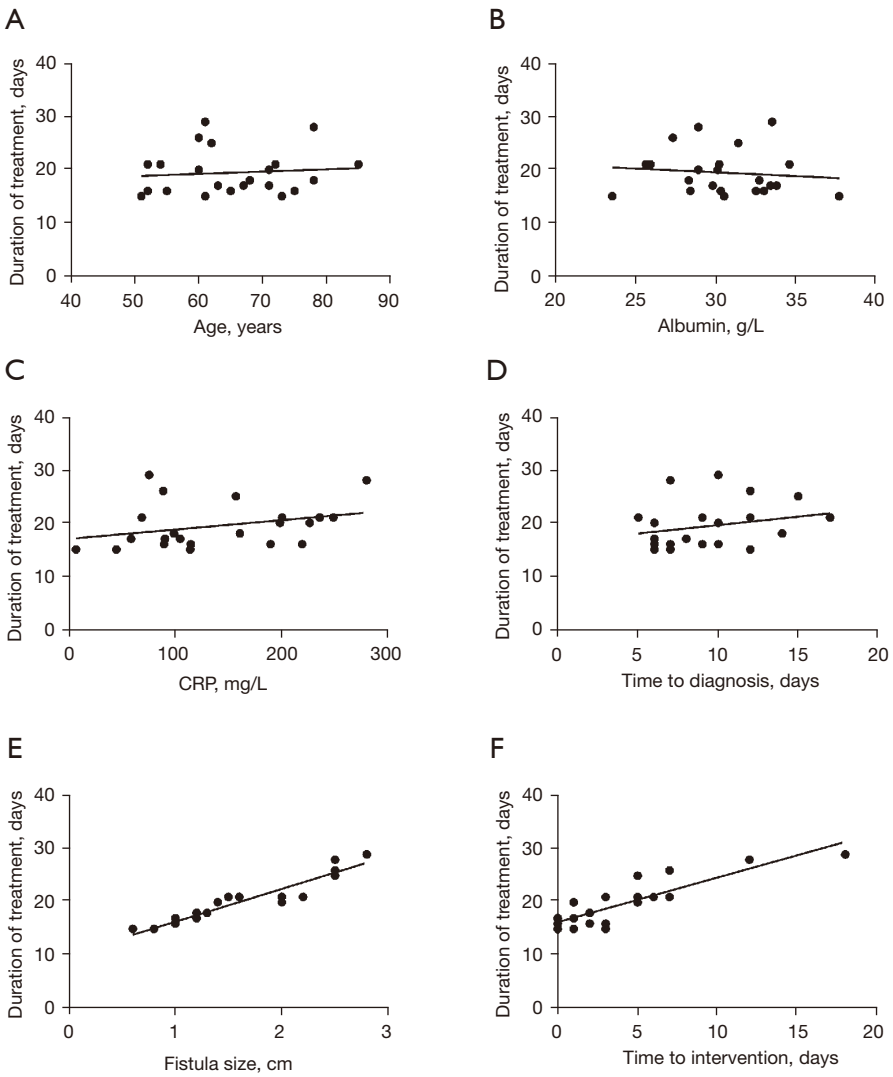

Figure 3 Univariate analysis was performed using Pearson correlation analysis or Spearman correlation analysis. The correlation coefficient R and P values between duration of treatment and age (A), albumin (B), CRP (C), and time to diagnosis (D) were: R=0.10 P=0.67, R=–0.11 P=0.62, R=0.31 P=0.16, R=0.25 P=0.26, and the correlation coefficient R and P between the fistula size (E) and the time to intervention (F) are: R=0.96 P=0.00, R=0.77 P=0.00. CRP, C-reactive protein.

Table 2 Multivariate analysis of factors associated with longer modified "three-tube method" treatment

Factors	Non-standardized coefficient (B)	95% CI	P value
Neoadjuvant chemotherapy	–1.22	–2.51 to 0.07	0.06
CCI score	1.06	0 to 2.13	0.05
Fistula size (cm)	4.27	3.31 to 5.22	0.00
Duration of treatment (days)	0.36	0.21 to 0.51	0.00

Multiple linear regression model R^2=0.969. CCI Charlson comorbidity index; CI, confidence interval.

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because the IAL often leads to the formation of the mediastinal abscess, the intraoperative chest tube is often fixed between the 6th or 7th intercostal space of the midaxillary line or posterior axillary line, which makes it difficult for the chest tube to reach the position of the fistula, leading to poor drainage (10,11). In the modified "three-tube method", in addition to the traditional chest tube drainage, naso-leakage tube for mediastinal abscess drainage, and in the process of placing the naso-leakage tube, the abscess suction and irrigation under the endoscope for the removal pus and necrotic tissue are very helpful and can significantly reduce systemic inflammatory response (10). In addition, the healing of the fistula can also be shortened by daily irrigation through the naso-leakage tube.

In recent years, the use of SEMS for the treatment of IAL has shown a certain therapeutic effect. Its main advantage is that by placing a stent to isolate the fistula, the passage of the gastric juice cannot continue into the vomica and early oral feeding is achieved (9). However, it does not solve the purpose of mediastinal drainage, and the pus and necrotic tissue in the mediastinum vomica will continue to inhibit the healing of the fistula. In contrast, the modified "three-tube method" not only provides continuous drainage but also has the ability to flush to clear the necrotic material. In addition, serious complications related to SEMS have also been reported (9,10,12). Schweigert *et al.* (13,14) reported that 29 patients underwent SEMS after being diagnosed with anastomotic leakage, and the results showed a high incidence of stent-related complications. Among the 29 patients, 3 (10.3%) had aortic erosion, 1 (3.4%) had intestinal bleeding due to stent displacement, and 1 (3.4%) had airway obstruction. All of these complications are fatal for patients with anastomotic leakage. In our study, 22 patients were treated with the modified "three-tube method", only 1 patient (4.5%) eventually died of respiratory failure, and their death may not have been directly caused by the modified "three-tube method". Therefore, the modified "three-tube method" may be a safer intervention than SEMS, but this requires a larger sample size study to further verify.

The EVAC method is also used for the treatment of IAL after esophagectomy, whereby the purpose of drainage is mainly achieved by placing a vacuum suction sponge in the mediastinum abscess under endoscope. At the same time, the sponge can stimulate the proliferation of granulation tissue in the abscess and promote the healing of the abscess and the fistula (15,16). The main drawback of EVAC is that it is necessary to replace the drainage sponge once every 2–3 days, which increases the patient's financial burden and discomfort. In addition, for a smaller leakage opening (less than 0.9 cm), the sponge does not enter the fistula and the conventional EVAC cannot be used (16). There have been reports of adhesions between the sponge and the fistula, resulting in bleeding when replacing the sponge, and even leading to fatal bleeding when large vessels are involved (17,18). Compared with EVAC, the modified "three-tube method" only requires iodine oil contrast examination of the esophagus every 2–3 days to evaluate the reduction of the abscess, thus avoiding the discomfort caused by repeated endoscopy, with good economic benefits. Moreover, for the smaller leakage opening (the smallest leakage opening in this study was 0.6 cm), the modified "three-tube method" still applies.

Some researchers believe that in the treatment of IAL, only the use of naso-leakage tube drainage and enteral nutrition tube can achieve the desired effect, while the gastrointestinal decompression tube and chest tube are redundant (4). However, we believe that the chest tube can maximally drain the pleural effusion to prevent adhesion and separation of the pleural cavity. If there is esophageal-thoracic fistula, the separated pleural cavity will bring difficulties to pleural drainage, which will lead to prolonged treatment duration. In addition, adequate pleural drainage can promote lung recruitment and reduce the occurrence of pulmonary-related complications (5). As mentioned above, due to the corrosive nature of gastric juice, when there is continuous gastric juice around the fistula, it may cause a delay in the healing of the fistula, which reinforces the need for the gastrointestinal decompression tube. In addition, skillful application of the three-chamber jejunal feeding tube can assume the role of gastrointestinal decompression tube and jejunal feeding tube at the same time, thus avoiding the increase of the tube and any associated patient discomfort. In our study, the mean time to treatment was 19.5 days, which was less than the 31.2 days of simple naso-leakage drainage (4), and less than the 21 days of naso-leakage tube combined with gastrointestinal decompression tube (10), which may be derived from the synergy between the naso-leakage tube, the chest tube, and the three-chamber jejunal feeding tube in our modified "three-tube method". A larger sample of research is required to further verify these findings. Some academics believe that drainage of the naso-leakage tube is not applicable in larger leakage openings (greater than 1 cm) (5); but in our study, the largest leakage opening was 2.8 cm, which still achieved good results. In the multivariate analysis, we also found that the length of

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the fistula was indeed one of the risk factors associated with a longer treatment duration of the modified "three-tube method".

According to our experience, the modified "three-tube method" can be safely and effectively used for IAL after esophagectomy. Although we observed 1 patient death in our study, the patient eventually died of respiratory failure, possibly not related to the modified "three-tube method". The intervention time and the fistula size are the independent risk factors for prolonging the treatment time of the modified "three-tube method", which suggests that it is necessary to intervene as soon as possible after the diagnosis of IAL. Previous studies have also shown that after the diagnosis of IAL, delaying the intervention time is likely to lead to higher mortality in patients (19,20). For patients with a larger size of fistula, due to the extension of the modified "three-tube" treatment time, we may need to assess the patient's condition more comprehensively to adopt a more appropriate treatment.

According to our understanding, this study was the first study to evaluate and analyze the effect of the modified "three-tube method" on IAL after esophagectomy. However, since this was a single-center, retrospective, and small-sample study, the appropriate population, and complications for modified "three-tube method" were not detailed. Larger sample size and prospective cohort studies are required to validate the advantages of this method over other treatment methods.

Conclusions

In short, considering the therapeutic effect, safety, economy, and ease of operation of the modified "three-tube method", based on our experience, we believe that the modified "three-tube method" is a safe and effective non-surgical treatment of IAL after esophagectomy. The intervention time and the fistula size are the independent risk factors for prolonging the treatment time of the modified "three-tube method". Further prospective, large-sample studies are needed to determine its clinical value.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/apm-21-2583). The 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. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics committee of Sir Run Run Shaw Hospital (20190829-1). Informed consent of participants in this study was waived due to its retrospective nature.

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