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Original article

Leak grading and percutaneous transanastomotic drainage for the treatment of cervical anastomotic leakage after esophagectomy

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SUMMARY. **Anastomotic leakage, a major complication of esophagectomy, can be fatal. However, there is no consensus on treatment strategy for this critical complication. Percutaneous trans-anastomotic drainage (PTD) refers to intraluminal trans-fistula vacuum drainage for cervical anastomotic leakage. This study aims to evaluate the efficacy of this form of treatment according to leak grade. The severity of leakage in the 117 of 647 consecutive postesophagectomy patients with cervical anastomosis leaks was graded according to esophagogram findings as follows: Grade I, linear extravasation; Grade II, localized obvious cavity; and Grade III, large cavity extending into the mediastinum or thoracic cavity. Treatment tended to be allocated according to grading, PTD being performed in most patients with Grades II and III. Three cases with conduit necrosis requiring immediate surgical intervention were excluded. Leakage was detected by radiologic evaluation in 117 (18.2%) of the remaining 644 patients, over half being Grade II (51%). Patients with Grade II leaks who underwent PTD required significantly shorter treatment (PTD: 16.8 days/non-PTD: 22.3 days; $P = 0.02$). Moreover, patients who underwent PTD within 3 days of diagnosis ($n = 29$) required significantly shorter treatment than those who underwent it 4+ days after diagnosis ($n = 14$) (early-PTD: 14.9 days/late-PTD: 20.6 days; $P = 0.01$). It is useful to assign treatment strategy according to leak grading. Additionally, PTD promotes early healing and is considered a valuable treatment option for cervical anastomotic leakage.**

KEY WORDS: **anastomotic leakage, esophagectomy, treatment.**

INTRODUCTION

Developments in perioperative management and surgical techniques for esophagectomy have resulted in decreases in postoperative morbidity and mortality and an increase in long-term survival.[1] Anastomotic leakage, one of the most serious postoperative complications of esophagectomy, has a substantial impact on postoperative length of hospital stay, overall morbidity, mortality, stricture formation, and dysphagia.[2,3]

In patients with cervical anastomotic leakage, an abscess may extend into the mediastinum or thoracic space and cause life-threatening mediastinitis and pyothorax, as can occur with intrathoracic anastomosis.

In this study, we describe grading of leaks according to esophagogram findings and a beneficial treatment, namely percutaneous trans-anastomotic drainage (PTD) under fluoroscopic guidance, for managing cervical anastomotic leakage. PTD utilizes the anatomical advantages of anastomoses and abscesses being located immediately under the cervical wound. This study aims to evaluate the efficacy of PTD according to grade of leaks, with particular attention to duration of treatment.

MATERIAL AND METHODS

Patients

A total of 647 patients who had undergone thoracic esophagectomy for carcinoma of the thoracic esophagus from January 2011 through August 2015

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were identified from the database of the Division of Esophageal Surgery, National Cancer Center Hospital East. The study protocol was approved by the Institutional Review Board of the National Cancer Centre (approval code: 2015-166).

Surgical techniques

In all cases, surgical procedures were performed via either a transthoracic (including a minimally invasive approach) or transhiatal approach. Subtotal esophagectomy was performed with a two- or three-field regional lymph node dissection irrespective of the tumor stage. Patients with stage II and III disease generally received preoperative systemic chemotherapy. Most patients older than 80 years underwent transhiatal esophagectomy. Salvage esophagectomy was performed after definitive chemoradiotherapy in cases with residual tumor.

From January 2011 through December 2013, reconstruction of the resected esophagus was usually performed via a posterior mediastinal route using a gastric tube. A retrosternal route was chosen in patients at risk (e.g. cases with cardiovascular disease, liver cirrhosis, and chemoradiotherapy) or who were undergoing pedicled right colon grafts. Since diaphragmatic herniation or gastric outlet obstruction developed in some cases in which a posterior mediastinum route had been used, from the beginning of 2014 a retrosternal route was mainly chosen. As for the anastomotic procedure, a gastric tube with 4–5 cm in width and 25–30 cm in length ('half-sized gastric tube') was pulled up to the neck, after which end-to-side esophagogastric anastomosis was performed using a circular staple. In patients at risk, anastomoses were performed in an end-to-end manner using a hand-sewing technique.

Perioperative management

All patients received the same perioperative management. In brief, the endotracheal tube was removed in the operating room. On POD 1, enteral feeding through a nasogastric tube was initiated. The right thoracic drain was removed on POD 1 and the cervical drain on POD 2 (with each drain output of <100 mL/day). A radiographic contrast swallowing examination was routinely performed on POD 6–8. In critically-ill patients such as those receiving ventilation, the contrast agent was passed into the anastomotic site through a nasogastric tube. The examination comprised three steps: first, small amounts of water were drunk to evaluate swallowing; second, a water-soluble contrast agent (Gastrografin; Bayer, Berlin, Germany) was swallowed to examine passage through the anastomosis or pylorus and identify any major leakage; and third, a mixture of equal amounts of water-soluble agent and 200% wt/vol barium sulfate suspension (Barytester A240 Powder; Fushimi Pharmaceutical, Kagawa, Japan) was swallowed to allow detailed assessment of minor leakage. If this examination revealed no leakage or obstruction, oral intake started and the patient was discharged on approximately POD 14.

As for postoperative complications, development of anastomotic stricture was defined as clinically relevant when dysphagia required endoscopic intervention. Recurrent nerve palsy was defined as vocal cord dysfunction confirmed by scheduled laryngoscopic examination, including transient injury requiring no therapy.

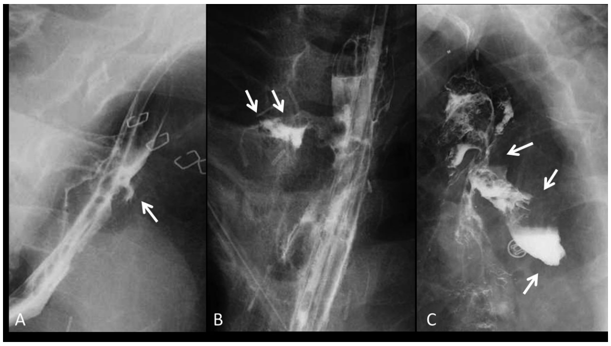

Fig. 1 Leak-grading according to esophagram findings. (A) Grade I: linear extravasation. (B) Grade II: obvious localized cavity. (C) Grade III: large cavity extending into the mediastinum or thoracic space.

Leak grading and treatment strategy

If leakage was confirmed by esophagogram, the extravasation of contrast agent around the anastomotic site was evaluated and graded as follows (Fig. 1): Grade I, small leak with linear extravasation; Grade II, localized obvious cavity close to anastomosis; and Grade III, large cavity extending into the mediastinum or thoracic space. Patients with Grade I leaks were treated by fasting and nasal decompression only. Those with Grade II or III leaks attempted to undergo PTD (but some cases failed to perform despite several trials). Additionally in Grade III, a percutaneous transcervical mediastinal tube or transthoracic chest tube was inserted.

We also divided, for reference, patients with leakages according to the definitions of the Esophageal Complications Working Group (ECCG),[4,5] to make comparisons with other articles. The ECCG classification is composed of Type I: local defect requiring no change in therapy or treated medically or with dietary modification, Type II: localized defect requiring interventional but not surgical therapy, for example, interventional radiology drain, stent or bedside opening, and packing of incision, and Type III: localized defect requiring surgical therapy.

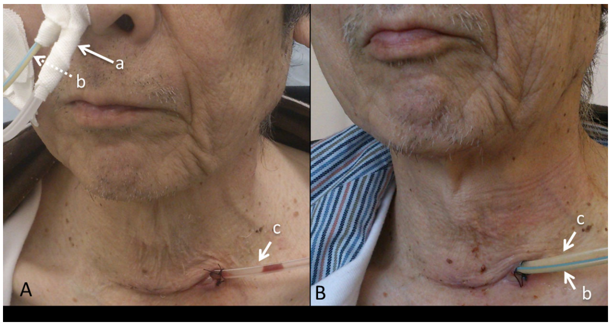

Fig. 2 Management of leakage with three tubes. (A) Management of leakage started with (a) nasogastric decompression tube, (b) intestinal feeding tube, (c) percutaneous trans-anastomotic drainage (PTD) tube. (B) When the cavity and fistula had decreased in size, the nasogastric tube was removed and the nasointestinal feeding tube was replaced by a transcervical tube for patient comfort.

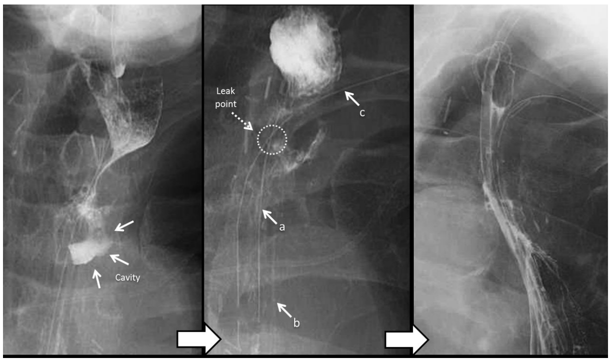

Fig. 3 (A) Components of percutaneous trans-anastomotic drainage (PTD). (a) Nasogastric decompression tube (b) Nasointestinal feeding tube (c) PTD tube. (B) Schematic representation of PTD. PTD tube is placed into the conduit via the leak point. The resultant decompression of the cavity and conduit leads to rapid integration of the cavity and leak point.

PTD technique

The management of leakage included a nasogastric decompression tube, nasointestinal feeding tube, PTD tube (Fig. 2), and appropriate antibiotics. All three tubes were placed accurately under radiological guidance. All patients tolerated having two tubes in their nasal cavities well.

A PTD tube (14Fr Salem Sump Tube, Nippon Covidien, Shizuoka, Japan) was introduced through the cervical wound and inserted into the conduit through the leak point (Fig. 3). The tube was positioned so that the side holes in its distal part straddled the leakage point, allowing drainage of both the conduit and abscess cavity. Intermittent suction with negative pressure of −99 cm H_2O (cyclically suctioned for 10 seconds and paused for 2 seconds) was applied to achieve effective drainage and prevent the abscess spreading into the mediastinum or thoracic space. PTD aimed to facilitate rapid integration of the cavity and leak point into a firm linear fistula. When the cavity and fistula had decreased in size (about a week later), the nasogastric tube was removed and the feeding tube replaced by a cervical tube for patient comfort (Fig. 2). After termination of therapy, another esophagogram was performed to confirm closure of the leak (Fig. 3), and the PTD tube could be removed. Patients were allowed to start oral intake on the same day.

Statistical analysis

Statistical differences between the two groups were analyzed with the χ^2 test and the Mann–Whitney U test. P-value < 0.05 was considered to indicate significance. All analyses were performed with SPSS for Windows (SPSS, Tokyo, Japan).

RESULTS

From January 2011 to August 2015, 647 patients with thoracic esophageal carcinoma underwent esophagectomy with cervical anastomosis in the National Cancer Center Hospital East. Three patients with conduit necrosis who underwent immediate surgical intervention were excluded from the analysis. Anastomotic leakage was detected by radiologic evaluation in 117 of the 644 remaining cases (18.2%), including some patients with no clinical symptoms. The study subjects' relevant clinical characteristics according to presence or absence of anastomotic leakage are shown in Table 1. There were no statistically significant differences between the two groups, except for the rate of retrosternal route and hand-sewn anastomosis.

In the 117 patients with leakage, the mean interval from surgery to diagnosis was 8.4 days (range: 1–22 days) (Table 2). The leakages were identified on the first contrast examination in 84 patients (71.8%), and in the remaining patients by repeated examinations. According to esophagogram findings, over half the leaks were Grade II (51%) and most of the leak points were in the left wall (59%). Unfortunately, there were three in-hospital deaths among those with Grade III leaks. Including patients who had died after hospital discharge, 90-day mortality was five patients (all with Grade III leaks). Incidentally, of three patients with conduit necrosis performed immediate conduit resection with diversion, one patient was dead of postoperative sepsis.

Clinical outcomes according to leak grading are shown in Table 3. The interval from diagnosis to performing PTD tended to be longer for patients with Grade III leaks than for those with grade II leaks (2.8 days/1.8 days, respectively; $P = 0.41$). Exceptionally, two cases with Grade I leaks performed PTD due to failure to improve. Although the duration of treatment (from diagnosis to starting oral intake) and hospital stay were significantly longer for patients with Grade III leaks than for those with grade II leaks, they did not differ significantly between those with Grade I and Grade II leaks. Of the 117 patients with leakage,

Table 1 Clinical characteristics of the 644 study patients according to presence or absence of leakage

Variable	With leakage ($n = 117$)	Without leakage ($n = 527$)	P -value
Sex male/female	106/11	483/44	0.88
Age median(range)	68.5 (33–89)	70.1 (34–88)	0.44
ASA grade			
Grade 1	63 (53.8)	280 (53.1)	0.88
Grade 2	54 (46.2)	247(46.9)	
Location of tumors, *n* (%)			
Upper thorax	21 (17.9)	64 (12.1)	0.45
Middle thorax	47 (40.2)	222 (42.2)	
Lower thorax	49 (41.9)	241 (45.8)	
Preoperative treatment, *n* (%)			
Chemotherapy	40 (34.2)	196 (37.1)	0.54
Chemoradiotherapy	14 (12.0)	37 (7.1)	0.07
Type of surgery, *n* (%)			
Minimally invasive	71 (60.7)	335 (63.5)	0.56
Transthoracic	41 (35.0)	180 (34.2)	
Transhiatal	5 (4.2)	12 (2.3)	
Type of conduit, *n* (%)			
Gastric tube	105 (89.7)	491 (93.2)	0.20
Colon	12 (10.3)	36 (6.8)	
Route of reconstruction, *n* (%)			
Posterior mediastinal	51 (46.4)	284 (53.9)	0.04
Retrosternal	66 (51.8)	243 (46.1)	
Type of anastomosis, *n* (%)			
Hand sewn	76 (69.1)	161 (30.6)	0.001
Circular staple	33 (30.0)	261 (49.5)	
Linear staple	8 (0.9)	105 (19.9)	
Operation time (min), mean (range)	361 (140–601)	340 (170–780)	0.56
Blood loss (mL) mean (range)	366 (20–1380)	29 (10–4820)	0.22
Histologic type, *n* (%)			
Adenocarcinoma	4 (3.6)	22 (4.2)	0.80
Squamous cell carcinoma	108 (91.8)	490 (93.0)	
Other	5 (4.5)	15 (2.8)	
Pathological stage of disease†, *n* (%)			
0‡	6 (5.5)	18 (3.5)	0.73
I	40 (34.5)	136 (25.9)	
II	26 (21,8)	159 (30.1)	
III	40 (34.5)	189 (35.7)	
IV	5 (3.6)	25 (4.7)	

†International Union Against Cancer TNM Classification of Malignant Tumors, 7th edition; ‡after neoadjuvant therapy.
ASA, American Society of Anesthesiologists.

Table 2 Details of 117 patients with anastomotic leakage.

	Value
Time of diagnosis (POD), mean (range)	8.4 (1–22)
Grade of leak, *n* (%)	
I	39 (35)
II	58 (51)
III	20 (15)
Location of leak point, *n* (%)	
Right wall	19 (16)
Left wall	69 (59)
Anterior wall	14 (12)
Posterior wall	10 (9)
Stump (circular)	5 (5)
Mortality, *n* (%)	3 (2.6)†

†All cases had grade III leaks.
POD, postoperative day.

according to the definitions of the ECCG, Type I was almost consistent with Grade I leaks (37 patients). Type II, performing PTD or chest drainage, was 80 patients, while Type III, requiring surgical therapy, was none.

To assess the effectiveness of PTD, we retrospectively compared the duration of treatment between patients with Grade II leaks managed with ($n = 43$) and without PTD ($n = 15$) (Table 4) (the reasons why we excluded patients with Grade III were the duration of treatment would be profoundly affected by the degree of mediastinal or thoracic abscess, and fewness of non-PTD group in Grade III). There were no statistically significant differences in background factors between the two groups. Those who underwent PTD had significantly shorter mean durations of treatment (PTD, 16.8 days/non-PTD, 22.3 days; $P = 0.02$). Moreover, we compared an 'Early-PTD group,' in which PTD had been successfully performed within 3 days of diagnosis ($n = 29$) and a 'Late-PTD group,' in which performed from 4 days onwards ($n = 14$). The early-PTD group had a significantly shorter duration of treatment (early-PTD, 14.9 days/late-PTD, 20.6 days; $P = 0.01$) (Table 5). However, hospital stay did not differ significantly between the PTD and non-PTD group (37.5 days/38.9 days, respectively;

Table 3 Clinical results according to grade of leak.

	Grade I ($n = 39$)	Grade II ($n = 58$)	Grade III ($n = 20$)	P-value
PTD ratio, n (%)	2 (5)	43 (74)	17 (85)	
Interval from diagnosis to PTD, days, mean (range)	7 (6–8)	1.8 (0–9)	2.8 (0–18)	0.41 (II/III)
Duration of treatment, days, mean (range)	14.5 (1–49)	18.2 (7–39)	43.3 (14–130)†	0.09 (I/II) 0.02 (II/III)
Hospitalization after surgery, days, mean (range)	33.3 (20–67)	37.9 (20–93)	52.4 (27–151)†	0.12 (I/II) 0.01 (II/III)

†excluding the three deaths.
PTD, percutaneous trans-anastomotic drainage.

Table 4 Clinical results of PTD in patients with Grade II leaks

	PTD group ($n = 43$)	Non-PTD group ($n = 15$)	P -value
Sex male/female	38/5	14/1	0.38
Age median(range)	68.6 (33–89)	68.1 (57–79)	0.85
BMI (kg/m^2) median(range)	22.0 (18.1–28.5)	21.8 (17.9–27.7)	0.77
ASA Grade I/II	28/15	9 /6	0.81
Route of reconstruction, n (%)			
Posterior mediastinal	32	9	0.58
Retrosternal	11	6	
Duration of treatment, days, mean (range)	16.8 (5–35)	22.3 (8–39)	0.02
Anastomotic stricture, present, n (%)	13 (30.2)	1 (6.7)	0.07
Recurrent nerve palsy, present, n (%)	13 (30.2)	1 (6.7)	0.07
Hospital stay, days, mean (range)	37.5 (20–93)	38.9 (23–65)	0.70

ASA, American Society of Anesthesiologists; BMI, body mass index.

Table 5 Duration of treatment after PTD according to timing of procedure in patients with Grade II leaks

	Early-PTD group (within 3 days of diagnosis) ($n = 29$)	Late-PTD group (4+ days after diagnosis) ($n = 14$)	P-value
Duration of treatment, days, mean (range)	14.9 (5–29)	20.6 (13–35)	0.01

$P = 0.70$) (Table 4) nor between the early-PTD group and late-PTD group (38.3 days/35.6 days, respectively; $P = 0.46$). No complications associated with performing PTD were identified and no patient was diagnosed with leak recurrence.

DISCUSSION

According to the National Clinical Database in Japan, the leakage rate was about 13.3%, and the 30-day mortality was 2.8% in 5354 patients undergoing esophagectomies.[6] According to the Society of Thoracic Surgeons database in the USA, anastomotic leakage is significantly associated with postoperative arrhythmia, pneumonia, acute respiratory distress syndrome, and sepsis; consequently, the 30-day mortality was 7.2% for patients with leakage and 3.1% without leakage.[7] Preventing the sequelae of leakage would dramatically reduce the cost and morbidity of esophagectomy. Therefore, early and accurate diagnosis is essential. However, few authors have reported grading severity of leaks to determine the optimal treatment strategy.

In our cohort, leakage was allocated to one of three grades according to esophagogram findings and each treatment was tailored accordingly. As a rule, PTD was performed in patients with Grade II and III leaks. Almost all Grade I leaks ($n = 37$) healed completely in 2 weeks with only fasting and nasal decompression and without open drainage nor PTD. Grading of leaks contributed to determining the therapeutic strategy; in particular, whether to perform PTD and other interventions.

Recently, several studies have reported the feasibility of endoscopic evaluation of anastomotic integrity after esophagectomy.[8–10] However, routine contrast radiography is still performed by many surgical centers before reintroducing oral intake.[11] Although contrast swallowing carries a risk of aspiration, it can simultaneously assess swallowing skill, anastomotic integrity, and gastric emptying. In addition, prompt placement of PTD tube can be performed under radiographic guidance when Grade II or III leaks are identified. Endoscopic evaluation lacks these advantages. Additionally, the findings of endoscopic mucosal changes are so subjective that correctly recognizing leakage or conduit ischemia can be difficult in some cases. It seemed that further evaluations are needed to establish diagnostic criteria for leakage in endoscopy.

Several studies have reported the efficacy of intraluminal suction drainage for intrathoracic anastomotic leakage, such as nose-fistula drainage (NFD) under radiographic guidance[12–15] and endoscopic vacuum-assisted closure.[16–18] However, PTD has several advantages over a transnasal approach for managing cervical leakage. First, PTD tubes surely suction pus from the space adjacent to the leak point. The side holes of the tube are under unequal negative pressure, that is, the more proximal holes are under higher negative pressure than the more distal ones. Consequently, PTD tube that are correctly placed such that the proximal side holes are located in the abscess can be relied on to reduce the cavity size, thus facilitating healing of leakage and preventing development of a mediastinal or thoracic abscess. In this study, the mean duration of treatment of Grade II leakage with PTD was 16.8 days; previous studies have reported 21 days[12] and 31.2 days[14] for NFD treatment of intrathoracic leakage. Second, PTD tubes are rarely displaced from the abscess cavity, whereas NFD tubes are at risk of tube dislodgement from the cavity by swallowing. Thus, the drainage may be inadequate, especially when the leakage hole is large and it is therefore difficult to apply constant negative pressure to the cavity and the distal tip of NFD tube tends to migrate into conduit. Indeed, Hu *et al*. concluded that only intrathoracic leaks in which the entrance size is less than 1 cm can be treated by NFD.[15] Third, PTD treatment reduces discomfort in the nasopharyngeal space. As previously mentioned, although PTD treatment starts with one cervical tube and two nasal tubes, about a week later, the nasal tubes are removed for patient comfort. Potential benefits of a transcervical approach include prevention of aspiration and nasopharyngeal complications, enhanced patient mobilization, and improved pulmonary hygiene.[19]

In this study, although the size of leak holes and abscess cavities is larger in Grade II than in Grade I leaks, the duration of treatment did not differ significantly between them. Given the fact that PTD was successfully performed in 74% of patients with Grade II leaks in contrast to 5% of those with Grade I leaks, PTD clearly contributed to reducing the treatment duration.

In patients with Grade III leaks, the interval from diagnosis to performing PTD tended to be longer than in those with Grade II leaks (2.8 days/1.8 days; $P = 0.41$). In some patients with Grade III leaks, even though the first esophagogram revealed Grade II leaks, the failure of first trial of PTD would be involved in deterioration into Grade III leaks in the next esophagram. Additionally, in those with Grade II leaks, the early-PTD group required a significantly shorter duration of treatment than the late-PTD group. Therefore, early success of PTD achieves significant benefits in terms of early healing and preventing spread of the abscess.

With regard to hospital stay, this did not differ significantly between patients with Grade II leaks who did and did not undergo PTD (Table 4). This lack of difference may be attributable to a nonsignificant tendency to a higher incidence of anastomotic stricture and recurrent nerve palsy in the former group (Table 4). It is generally recognized that most anastomotic strictures result from anastomotic leaks[20] (In the patients with Grade II and III leaks, the incidence of stricture was 24.1% and 29.5%, respectively ($P = 0.30$)). The leak holes were probably larger in patients who underwent PTD successfully than in those who did not, making the former more prone to developing strictures during healing. Needless to say, recurrent nerve palsy has a negative impact on recovery of the swallowing function.

The present study had several limitations due to retrospective cohort design. Over a 4-year study period, surgical technique (route of reconstruction or type of anastomosis) differed significantly. Furthermore, because of the small number of PTD group in Grade I leaks and non-PTD group in Grade III leaks, rigorous statistical evaluation was not possible in those grades concerning the efficacy of PTD.

In conclusion, the selection of treatment strategy according to grade of leak according to esophagogram findings is helpful. Additionally, PTD contributes to early healing of leakage, which means that the sooner it is performed, the better. PTD is an effective alternative therapeutic option for patients with cervical anastomotic leakage after esophagectomy.

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