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Author(s)	Shichinohe, Toshiaki; Ebihara, Yuma; Murakami, Soichi et al.
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Title: Intraluminal continuous decompression and drainage using a vacuum pump for controlling cervical anastomotic leakage after a three-field esophagectomy with a gastric pull-up

Authors: Toshiaki Shichinohe, Yuma Ebihara, Soichi Murakami, Yo Kurashima, Naoya Fukuda, Saseem Poudel, Dai Miyazaki, Takahiro Tsuchikawa, and Satoshi Hirano

Affiliation of the authors: Department of Gastroenterological Surgery II, Hokkaido University Graduate School of Medicine.

Corresponding author: Toshiaki Shichinohe

Postal address, e-mail address, telephone and fax numbers of the corresponding author:

Department of Gastroenterological Surgery II, Hokkaido University Graduate School of Medicine, West-7, North-15, Kitaku, Sapporo, Hokkaido, 060-8638, Japan

shichino@med.hokudai.ac.jp,

Tel: +81-11-706-7714, FAX: +81-11-706-7158

Abstract

Background: Anastomotic leakage is one of the major complications that can occur after an esophagectomy. We report on the advantages of a computer-controlled portable vacuum pump system, Thopaz®, for intraluminal continuous decompression and drainage in the non-surgical management of cervical anastomotic leakage.

Method: Continuous decompression with negative pressure of 20 cmH₂O was set at the anastomotic leakage point by a naso-gastric tube or a trans-gastric decompression tube. The drainage effect was confirmed by swallowing contrast media under fluoroscopy.

Results: Three successive cases with postoperative anastomotic leakage received this treatment. The treatments were successful without complication and the leakages were healed 7, 15, and 17 days after the treatments respectively.

Conclusion: The management of anastomotic leakage using the portable pump system was beneficial in bringing about a prompt healing with minimum intervention. To further demonstrate the advantage of this procedure over conventional treatments, a larger data set and clinical trials are required.

Key words

Anastomotic leakage, Decompression, Drainage, Vacuum pump

Introduction

Anastomotic leakage is one of the life-threatening complications that can occur after esophagectomy (1). Although leakage after cervical anastomosis is usually less serious compared to intra-thoracic anastomosis, the abscess may descend to the mediastinum and may cause postoperative mortality. Therefore preemptive surgical intervention with prompt open drainage by cervical incision is the first-choice for treatment. Although cervical open drainage is a simple minor operation, it may induce frustrating symptoms in patients with persistent discharge of saliva and dermatitis around the open fistula.

Meanwhile, intraluminal trans-fistula vacuum drainages are reported to be potent non-invasive treatments for intra-thoracic anastomotic leakage after an Ivor-Lewis esophagectomy (2-4). Unlike to the intra-thoracic anastomotic leakage, intraluminal drainage has not been considered an option for cervical anastomotic leakage.

In this report, we propose non-surgical management of anastomotic leakage by intraluminal continuous decompression and drainage with a computer-controlled portable vacuum pump system, Thopaz® (Covidien Japan. Tokyo Japan. Fig1). We demonstrate favorable results of three clinical cases involving three different reconstruction routes.

Patients and Methods

To control anastomotic leakage by intraluminal continuous decompression and drainage, we used a computer-controlled portable vacuum pump system (Thopaz®).

The merits of the system are as follows: since the negative pressure applied to the cavity is monitored based on the actual pressure within the drainage tube, we obtain a more accurate and real-time computer-controlled suction compared to a conventional continuous low pressure suction unit consisting of water-sealed reservoirs and pump.

Although the main purpose of the Thopaz ® system is to treat thoracic drainage (5), the regulations of the Pharmaceuticals and Medical Devices Agency of Japan allows intracorporeal drainage for all other organs.

The goal of the procedure was to obtain sufficient intraluminal decompression and drainage. A decompression tube which had been inserted during the operation to the antrum of the gastric conduit was relocated, or a naso-gastric (NG)-tube was inserted under fluoroscopy. To obtain an effective drainage, the anastomotic leakage point was adjusted to locate it between the tip and side holes of the tube. The drainage effect was confirmed by swallowing contrast media under fluoroscopy. Continuous decompression with the setting of negative pressure of 20 cmH₂O was maintained until the leakage was dissolved.

Three esophageal cancer patients with postoperative cervical anastomotic leakage received the treatment. In each case, informed consents were obtained prior to using the device.

Case report

Case1

72 year-old male patient with stage I thoracic esophageal cancer suffered cervical anastomotic leakage after a video-assisted three-field esophagectomy. The physical status of the patient was low due to a postoperative condition for tumorectomy and upper lobectomy of the left lung for the treatment of chest wall mesothelioma three months before. Therefore subcutaneous gastric pull-up was chosen for a reconstruction to avoid the risk of anastomotic leakage. Anastomotic leakage developed one week after the operation, and required open drainage under general anesthesia. Although intraluminal decompression had been continued using a decompression tube relocated to the leakage point under fluoroscopically with a conventional reservoir type suction unit under a negative pressure of 20cmH₂O, discharge from the fistula continued and the leakage did not respond to the treatment for two months. In order to obtain effective decompression, we used the Thopaz® system (Fig2A). After applying the system,

although the negative pressure setting was same with the conventional reservoir type suction units, discharge from the fistula became minimal. The absence of mucosal injury caused by the procedure was confirmed using an upper gastrointestinal scope (Fig2B). 17 days after applying the Thopaz® system the fistula was closed.

Case2

68 year-old male patient with stage I thoracic esophageal cancer received video-assisted three-field esophagectomy with gastric conduit reconstruction via posterior mediastinal route. Since the patient has no risk-factor for the operation, the posterior mediastinal route was chosen. From postoperative day (POD) 5, the patient developed a fever and a CT scan revealed air collection around the anastomosis (Fig3A). Anastomotic leakage was not apparent using fluoroscopy examination by contrast media at that point, thus non per oral (NPO) and administration of antibiotics was ordered. On POD 12, repeated fluoroscopy examination revealed anastomotic leakage spreading to the upper mediastinum (Fig3B). For intraluminal decompression and drainage, a 14Fr. NG-tube was placed on the leakage point under fluoroscopy (Fig3B) and drainage was started using the Thopaz® system with a negative pressure of 20cmH₂O. 7 days after starting the drainage the leakage was dissolved and decompression was discontinued.

Case3

64 year-old male patient with stage IIIa esophageal cancer received neo-adjuvant chemotherapy followed by video-assisted esophagectomy. Taking into consideration risks related to the neo-adjuvant chemotherapy he had received, reconstruction by gastric conduit via the retrosternal route and both a decompression tube and an enteral diet tube were concurrently inserted into the gastric conduit. At POD 8, the patient had a fever and a CT scan revealed air collection around the anastomosis (Fig4A). NPO and administration of antibiotics were ordered as a non-surgical therapy. On the next day, a fluoroscopy examination by contrast media revealed anastomotic leakage spreading to the upper mediastinum (Fig4B). For initial drainage, a 14Fr. NG-tube was placed to the leakage point under fluoroscopy to obtain sufficient drainage effect. Continuous intraluminal decompression and drainage was started using the Thopaz® system with a negative pressure of 20cmH₂O. The decompression tube of the gastric conduit was also connected to the other pump for decompression with the same pressure. 5 days after starting the drainage, the physical conditions and laboratory data of the patient had normalized and a fluoroscopy examination confirmed the reduction of the fistulous space. Therefore, the NG-tube was removed and the decompression tube was relocated

to the leakage point for drainage (Fig4C). 15 days after starting the intraluminal drainage, the leakage was dissolved and decompression was discontinued.

Discussion

Gastroesophageal anastomotic leakage is one of the major complications after esophagectomy. The percentage of anastomotic leakage for last 15 years was 15% (19/127) in our hospital; 11% (14cases) of “minor” leakage defined as Grade I and II by the Clavien-Dindo classification (6), and 4% (5 cases) of “major” leakage defined as Grade III or higher. The leakage rate from accumulated data were about 13.3 % according to the National Clinical Database in Japan (7) and 10.2% according to the result of a large European multicenter study (8). According to the report from the STS General Thoracic Surgery Database in the US, the overall leak rate was 10.6%, and mortality after anastomotic leakage was 11.6% (1). In the case of three-field esophagectomy and cervical anastomosis, the contamination due to anastomotic leakage descends to the mediastinum and may cause life-threatening mediastinitis and pyothorax. Therefore prompt open drainage by cervical incision is the most reliable treatment. In contrast, a conservative treatment is also chosen for “minor leakages.” It consists of NPO and administration of antibiotics. However, predicting the seriousness of leakages

is difficult, making it hard to choose the right treatment, including open drainage.

Intraluminal drainage could be a promising option to develop a non-surgical management of this frequent adverse event. Recently, the efficacies of intraluminal trans-fistula vacuum drainage of abscess for intra-thoracic anastomosis leakage after Ivor-Lewis esophagectomy were reported to have achieved a high success rate. Yin et al. reported fluoroscopically-guided three-tube insertion, consisting of drainage tube to the abscess cavity with 8-10mmHg negative pressure, NG-tube, and feeding tube (2). Liu et al. reported simple endoscopic trans-fistula tube placement and drainage with 25mmHg negative pressure (3). Brangewitz et al. reported the superiority of endoscopic intracavitary vacuum therapy (EVAC) using a sponge-sutured tube by 125mmHg negative pressure compared to the conventional stent therapy (4). The overall closure rate was significantly higher in the EVAC group (84.4 %) compared with the covered self-expanding metal or plastic stents group (53.8 %) (4).

In the present cases, the intraluminal negative pressure we set on the Thopaz® system was 20cmH₂O, which is equal to 14.7mmHg. The setting of the pressure was based on the following reasoning: both negative pressure of the thoracic cavity by respiration, and positive pressure of the alimentary tract by swallowing are factors which cause the spreading of contamination; the negative respiratory pressure is within -10cmH₂O and

internal pressure of the gastric conduit was reported at 6 to 20cmH₂O (9), thus we set -20cmH₂O pressure for continuous decompression. Mucosal injury by continuous negative pressure was a concern, but no apparent mucosal injury was observed using endoscopy (Fig2B).

Although the efficacy of the continuous decompression and drainage by the pump system could be demonstrated, the number of patients with anastomotic leakage in a single institution may not be large enough to undertake research with a statistically significant number of cases. In fact, only 5 open drainage cases of cervical anastomotic leakages with salivary discharge were experienced out of 53 evaluable cases of esophagectomy with esophago-gastric anastomosis in the past 5 years of in our institution; the lengths of treatment by conventional open drainage were 10, 14, 23, 35, and 77 days respectively. Therefore, to prove the usefulness of the treatment, a large multicenter study is required.

Based on the experience of our cases and the results reported in the literature (2-4), our proposed management for cervical anastomotic leakage is as follows: If an anastomotic leakage is suspected, fluoroscopic examination by contrast media should be done at the earliest opportunity. If anastomotic leakage is diagnosed, place an NG-tube or an intraluminal decompression tube adjacent to the fistula and confirm that sufficient

drainage is obtained by withdrawing the media through the tube with a syringe. If the drainage is insufficient, intra-cavity drainage should be attempted using either fluoroscopy or endoscopy. We recommend to start continuous decompression and drainage using the Thopaz® system with 20cmH₂O negative pressure while giving the patient NPO and antibiotics. Continuous negative pressure is continued under careful observation to insure the right timing for surgical intervention. The decision to stop the treatment is based on the confirmation of the healing of the fistula. The status of leakage should be checked using fluoroscopic examination with contrast media every 5 days to one week until fistulous closure.”

In conclusion, intraluminal continuous decompression and drainage treatment for cervical anastomotic leakage with the Thopaz® system brought about better results to deal with this complication. To further demonstrate the advantage of this procedure over conventional treatments, we would require a larger data set and clinical trials.

Conflict of interest

The authors declare that they have no conflict of interest.

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Figure legends

Figure 1. Portable drainage pump system, Thopaz®

The Thopaz® system was used for intraluminal continuous decompression and drainage of cervical anastomotic leakage with the negative pressure of 20 cmH₂O.

Figure 2. Case1. Cervical anastomotic leakage after subcutaneous reconstruction

Continuous intraluminal decompression was performed for 17 days. The decompression tube which had been inserted during operation to the antrum of the gastric conduit was placed at the anastomotic leakage point (pointed by forceps) using fluoroscopy (A). Upper gastrointestinal scope findings on 11 days after applying continuous decompression; no mucosal injury caused by the treatment was observed (B).

Figure 3. Case2. Cervical anastomotic leakage after posterior mediastinal reconstruction

Continuous intraluminal decompression was performed for 7 days. (A): POD5; CT scan revealed collection of air around the anastomotic site. (B): POD12; Esophagography revealed anastomotic leakage spreading to the posterior mediastinum. An NG-tube was

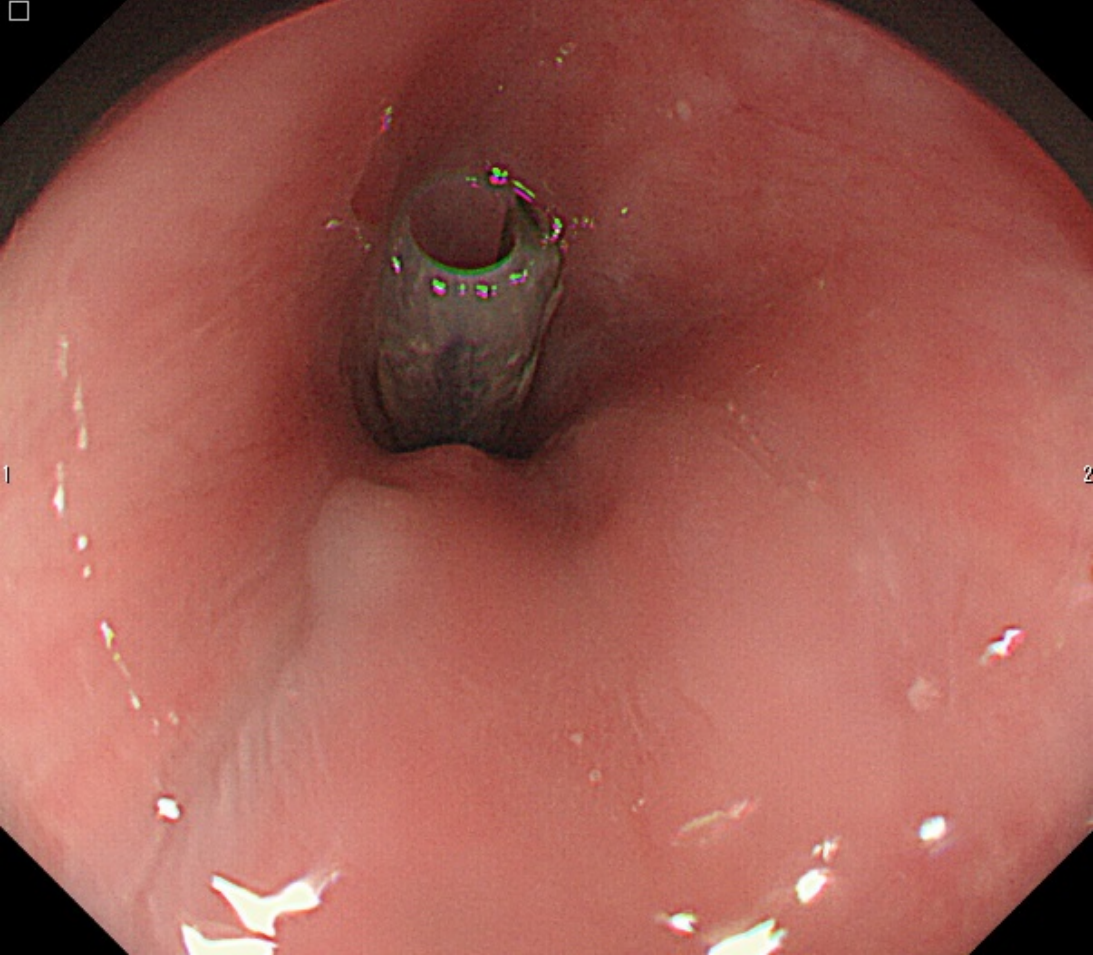
placed on the leakage point and continuous decompression was applied.

Figure 4. Case3. Cervical anastomotic leakage after retrosternal reconstruction

Continuous intraluminal decompression was performed for 15 days. (A): POD8; a CT scan revealed a collection of air around the anastomotic site. (B): POD9; Esophagography revealed anastomotic leakage spreading to the posterior mediastinum. An NG-tube was placed to the leakage point and continuous decompression was started. (C): POD14; Fluoroscopy examination confirmed the reduction of the fistulous space. The NG-tube was removed and the decompression tube was relocated to the leakage point for drainage.







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