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# An Endoscopic Vacuum-Assisted Closure Technique Modified Through the Overtube for Patients with Esophageal Anastomotic Leaks

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## Abstract

Endoscopic Vacuum-Assisted Closure (E-VAC) therapy is safe and effective for esophageal anastomotic leaks. However, the repetitive exchange of sponge tubes is technically demanding. We designed an E-VAC technique, modified through the use of overtube, to make E-VAC therapy safer and more comfortable for both endoscopists and patients. Intraluminal E-VAC therapies were used for the treatment of post-operative thoracic esophageal leaks in five cases of esophageal cancer. After overtube insertion, sponge tube was inserted through the overtube, while keeping biopsy forceps inside the Nasogastric Tube (NGT), and was positioned at intraluminal leakage site under endoscopic guidance. NGT was repositioned from the mouth to the nostrils using carrier tube and a controlled negative pressure was applied. Sponge tube was regularly changed twice a week until the complete closure of leaks. Technical and clinical success rates were analyzed to evaluate the safety and efficacy of this technique. The modified E-VAC therapy was applied in five selected cases for a mean of 13.8 days (range, 7 to 28 days) with a mean of 3.2 sponge tube changes (2 to 6 changes) for anastomotic leaks that were, on average, 1.0 cm (0.5 cm to 2 cm). The mean procedural time was 14.9 min (12 to 30 min) and no E-VAC therapy-related complications occurred. All patients were discharged, on average, after 44.4 days (range, 14 to 95 days) of hospitalization and two cases were treated with additional esophageal metal stents after six and two sponge tube changes, respectively. Our E-VAC therapy technique, modified via inserting sponge tubes through the overtube, is effective and safe for patients with thoracic esophageal anastomotic leaks.

**Keywords: Vacuum-assisted; Esophageal; Leakage; Overtube**

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## Introduction

Thoracic esophageal anastomotic leaks occur in 1% to 14% of patients after esophageal surgery [1] and is associated with shorter survival post-surgery [2,3]. They range from minimally symptomatic to life threatening [3]. Management strategies should be selected based on the time of detection, size of the leak, extent of the abscess, and condition of the patient [4]. Surgery is recommended for early abundant leaks associated with sepsis [3]. However, it is often difficult to do surgery on debilitated patients and reoperations increase morbidity [5]. Endoscopic management is widely used to correct post-operative anastomotic leaks for small leaks or as an alternative to surgery [3,6]. Endoscopic Vacuum-Assisted Closure (E-VAC) therapy has been introduced as a novel treatment for post-operative anastomotic leaks [7]. An open-pored polyurethane foam, attached to a portable vacuum pump *via* a flexible tube, is introduced into the lumen or intra-cavity of anastomotic leaks. Controlled suction is applied to drain the secretion from the leaks accumulated in the cavity, thereby decreasing bacterial contamination and local edemas [8]. At the same time, vacuum therapy promotes the formation of granulation tissue, which accelerates the healing of defects [9]. Utilized as either a primary or rescue therapy, E-VAC therapy is beneficial to the management of esophageal perforations or leaks [10]. The conventional techniques of E-VAC consist of two processes [7]. Firstly, a sponge is attached, by suturing, to the end of a Nasogastric Tube (NGT), which passes

through the nose and out the mouth. Secondly, the sponge is inserted into the esophagus with an endoscope by gasping silk loop of NGT using endoscopic biopsy forceps. As patients may have debilitating septic conditions, E-VAC therapy should be completed in a short time for increased safety. Making sponge tubes during procedures takes several minutes. In addition, the direct insertion of large sponge tubes via the upper esophageal sphincter is difficult and has the risk of aspiration. In some institutions, E-VAC therapy was done in intensive care units or operation rooms under general anesthesia at the tracheal intubation state [10]. We modified the E-VAC technique through the use of overtube for patients with esophageal anastomotic leaks. Overtube has been widely used as a conduit for larger tubes or repetitive passage into the digestive tract in procedures, such as variceal ligation, foreign body removal or enteroscopy [11]. Sponge tubes can be easily positioned in anastomotic leaks *via* overtube. This overtube technique protects cricopharyngeal area and upper esophageal mucosa from the traumatic insertion of sponge tubes and reduces the risk of aspiration. Repositioning sponge tubes from the mouth to the nose can be done using carrier tubes, which are widely used in endoscopic nasobiliary drainage [12]. Our 'through the overtube' technique is easily conducted in endoscopic units under conscious sedation. In this study, we introduced this modified E-VAC technique to patients with thoracic esophageal anastomotic leaks and analyzed the safety and the efficacy of this technique.

## Materials and Methods

### Patients and methods

We conducted a retrospective study of E-VAC therapies performed between June 2015 and January 2018 at a single hospital (Chungbuk National University Hospital, Cheongju, Republic of Korea). All patients received anastomotic leaks after esophagectomy and intrathoracic esophago-gastric anastomosis for the treatment of esophageal cancer. Intraluminal E-VAC was applied in five cases of post-operative esophageal leaks. We collected data on diagnoses, operation methods, and the duration from operation to leak diagnosis, the size of leaks, location of leaks, accompanying complications, and the overall days from leak diagnosis to final outcome. To evaluate the effectiveness of the modified E-VAC procedure, we analyzed the procedural time, number of sponge tube exchanges, and final outcomes. Final outcomes were evaluated as complete healing by E-VAC therapy, complete healing by additional methods, such as esophageal stents, histoacryl injections, and reoperation, or failure. Esophageal defect closure following E-VAC therapy was defined as no evidence of continued leaks under direct endoscopic visualization or a negative esophagography following the discontinuation of E-VAC therapy. This study was conducted in accordance with the Declaration of Helsinki (1964) and was approved by the Institutional Review Board of Chungbuk University Hospital and informed consent was obtained from all patients before the procedure.

### Preparation of equipment

We constructed endo-sponge tubes using 16-Fr silastic NGT (Covidien, Medtronic, Dublin, Ireland) and open-pored polyurethane sponges (V.A.C 10 cm × 7.5 cm, Granufoam small Dressing Kit, KCI Manufacturing, Ireland) before the E-VAC therapy. The sizes of endo-sponges could be customized to span the length of a luminal defect. Once cut to the appropriate size, a tunnel was created from each endo-sponge's center to its distal end without exiting the other end. NGTs were placed inside these holes. Once in place, NGTs were fixed to endo-sponges with four interrupted 0 silk transfixion sutures (Ethicon, Somerville, NJ, USA). The width of the endo-sponge tubes were to be no greater than 20 mm to pass through the overtube. A Biopsy forcep was inserted into the NGT to give force to descend through the overtube to the lesion. Carrier tubes made of 14-Fr nelaton catheter tubes (Latex suction catheter, Sewoon Medical Co., Ltd., Cheonan, Republic of Korea) and overtubes (Bard Interventional Products, Tewksbury, Mass, inner diameter 45F, 15 mm; outer diameter 60F, 20 mm) were prepared (Figure 1A, 1B).

### Modified E-VAC technique

The modified E-VAC procedure was performed under conscious sedation, using propofol, at an endoscopic unit. The adequate lubrication of all the surfaces of the overtube, prior to assembly and being back-loaded onto endoscopes, was done. In this procedure, an overtube was placed inside a patient's esophagus, as the usual method of overtube insertion. A biopsy forceps-reinforced endo-sponge tube was then inserted into the overtube. After the endo-sponge tube made it through the overtube, it was positioned at the esophageal defect *via* endoscopy guidance (GIF-H260, Olympus, Tokyo, Japan). After the endoscope was withdrawn, the NGT exiting from the mouth remained. The nasal positioning of the NGT was done using carrier tubes. O-ring made using guidewire was inserted into oropharynx. A carrier tube was then inserted through the nose and into the oropharynx. The distal end of the carrier tube was trapped by the preloaded O-ring guidewire at the patient's oropharynx and pulled out of the patient's mouth [12]. The end of the NGT was then connected to the carrier tube and both tubes were pulled out of the patient's nostrils (Figure 1). After the oral-nasal conversion of the NGT, it was fixed at the patient's nose and connected to - 125 mmHg of suction pressure using an electronic vacuum pump system (V.A.C. by KCI®, Wiesbaden). After three to four days, when the amount of suction decreased, we changed the sponge tubes. Patients were treated with broad-spectrum antibiotics and total parenteral nutrition. The removal of sponge tubes was done by pulling them out of the esophagus and through the mouth using grasping forceps. Afterwards, we examined the esophagus using an endoscope with a transparent capin order to examine the size of leaks. Any pus and residual fluid were thoroughly suctioned. Sponge tube replacement occurred until the defect was covered by granulating tissue (Figure 2). This procedure was repeated at 3- to 4-day intervals to change out sponge tubes, and evaluate the healing process and was terminated when the cavity was walled off, or esophageal continuity was restored. This procedure was performed by either one of two endoscopists (KBK and SMP).

## Results

### Patient characteristics

Patient demographics and perforation characteristics are shown in Table 1. All patients were male with a mean age of 68 years (range, 64 to 72 days). All leaks occurred at the sites of gastroesophageal anastomosis after esophagectomy and Ivor-Lewis anastomosis. Anastomotic leaks were detected, on average, after 8.4 days (range, 2 to 13 days) post-operation by both chest CT and esophagography (Figure 3). Anastomotic leaks were located at an average of 25.6 cm (range, 22 cm to 30 cm) below from dental arch. The mean defect size was 1.0 cm (range, 0.5 cm to 2 cm). All patients underwent E-VAC as a first-line treatment with indwelling thoracostomy tubes for accumulated fluid removal.

### E-VAC procedures

All patients received the modified intraluminal E-VAC therapy.

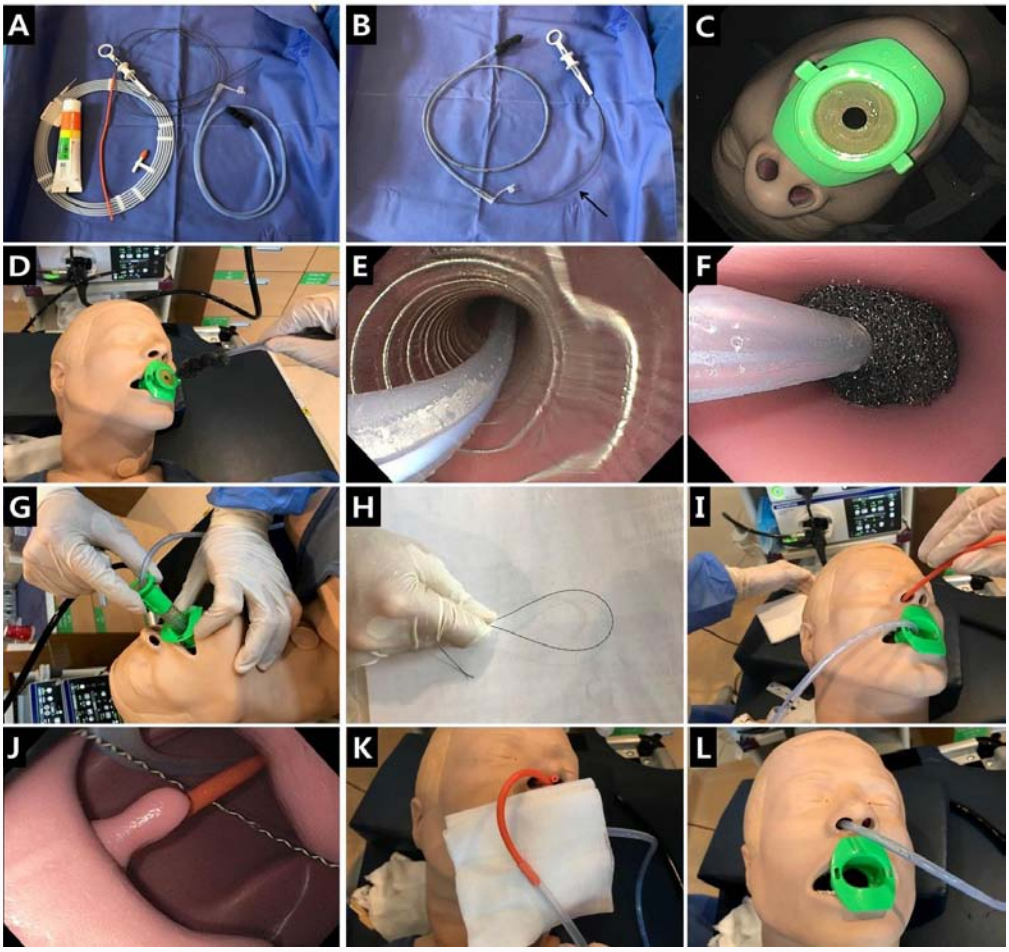


**Figure 1:** Modified endoscopic vacuum-assisted closure technique through the overtube. (A) Preparing devices before endoscopic procedure. (B) Endosponge device encircling NGT keeping with biopsy force p (arrow) inside. (C) Insertion of overtube. (D) Insertion of endosponge device through the overtube. (E) Advancement of endosponge device inside the overtube. (F) Intraluminal placement of endosponge device under direct vision of endoscopy. (G) Withdrawal of overtube. (H) O-loop by guidewire. (I) insertion of carrying tube through nose. (J) Carrying tube inside the O-ring guidewire. (K) Fitting NGT inside the carrying tube. (L) Endosponge device through the nose. NGT: Nasogastric Tube.

**Table 1:** Patient demographics and characteristics of esophageal anastomotic leaks.

| Demographics | Total (N=5) |
|---|---|
| Age (years), mean ± SD | 68 ± 3 |
| Male, N(%) | 5 (100%) |
| Body Mass Index, kg/m$^2$ | 24.3 (21.3-29.4) |
| Mean defect size (range), cm | 1.0 (0.5-2) |
| Interval from operation to anastomotic leak diagnosis, days | 8.4 (2-13) |
| Method of diagnosis, N(%) | |
| Chest CT | 5 (100) |
| Esophagogram | 5 (100) |
| Location of esophageal leak | |
| Distance from dental arch, mean (range), cm | 25.6 (22-30) |
| Other treatment | |
| Tube thoracostomy drainage | 5 |

CT: Computed Tomography; EGD: Esophagogastroduodenoscopy; PSS: Perforation Severity Score; BMI: Body Mass Index; E-VAC: Endoluminal Vacuum Assisted Closure

The mean endoscopic procedural time from overtube insertion to the NGT's fixation to nose was 14.9 min (range, 12 min to 30 min).

**Table 2:** E-VAC procedures.

| E-VAC parameters | Mean (range) |
|---|---|
| Duration E-VAC therapy, days | 13.8 (7-28) |
| Number of E-VAC changes | 3.2 (2-8) |
| Interval between E-VAC changes, days | 3.5 (3-5) |
| Procedure time, min | 14.9 (12-30) |
| E-VAC-specific complications | 0* |

**Table 3:** Outcomes of E-VAC therapy.

| Parameters | N (%) or days |
|---|---|
| Successful closure | 5 (100%) |
| Mean hospital days (range) | 44.4 (14-95) |
| 30-day mortality | 0 (0%) |

LOS: Length of Stay; E-VAC: Endoluminal Vacuum Assisted Closure

The mean duration of the modified E-VAC therapy was 13.8 days (range, 7 to 28 days). A mean of 3.4 sponge exchanges (range, 2 to 6 exchanges) were done for the five cases. There was a mean of 3.5 days (range, 2 to 5 days) between each E-VAC therapy session. There were no procedure-related or sedative endoscopy-related complications (Table 2).

**Table 4:** Characteristics and outcomes of five patients treated with E-VAC therapy.

| Patients | Age/Sex | Perforation size, cm | Distance of leak from incisor, cm | Sponge Exchanges (n) | E-VAC duration, days | Combined therapy | E-VAC results | Clinical outcome | Complications |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 69/M | 2 | 22 | 5 | 28 | None | Closure | Improved | None |
| 2 | 66/M | 1 | 30 | 2 | 7 | Stent | Closure | Improved | None |
| 3 | 64/M | 0.5 | 24 | 6 | 20 | Stent | Closure | Improved | None |
| 4 | 68/M | 1 | 27 | 2 | 7 | None | Closure | Improved | None |
| 5 | 72/M | 0.6 | 25 | 2 | 7 | None | Closure | Improved | None |

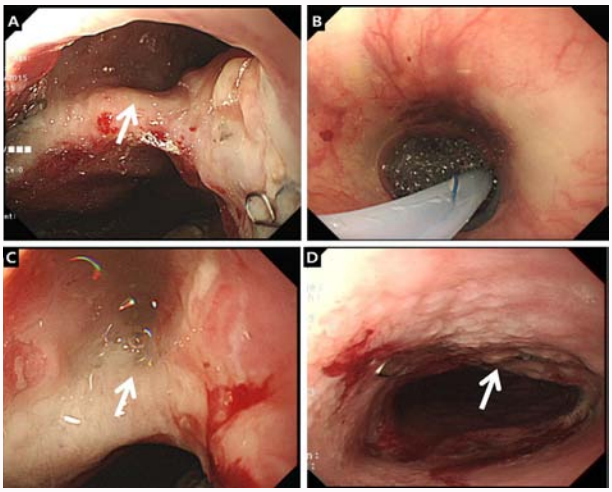


**Figure 2:** Endoscopic images of esophageal anastomotic leak treated by endoscopic vacuum-assisted closure. (A) Anastomotic leakage at thoracic esophagus (arrow). (B) Application of endosponge device through the overtube at the anastomotic gap. (C) After the application of the endosponge device, the cavity appears reduced in size and covered by healthy, granulation tissue (arrow). (D) Complete healing of the anastomotic gap at esophagoscopy (arrow).

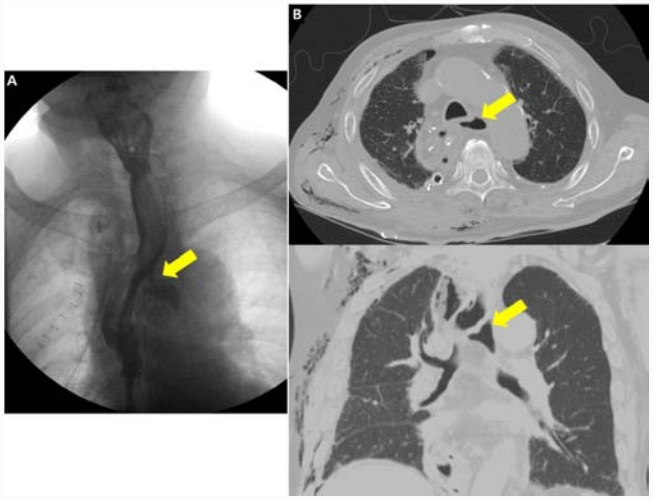


**Figure 3:** Radiologic images of esophageal anastomotic leak. (A) Water-soluble contrast esophagography confirming the presence of an anastomotic leak after an esophagectomy and sleeve esophago-gastric anastomosis. (B) Axial chest CT scan showing extraluminal air (arrow) near thoracic esophagus. (C) Coronal chest CT scan showing perforation of esophagus and cavitary lesion showing air-fluid level.

### Outcomes

Leaks were completely healed in all patients. The mean length of hospitalization was 44.4 days (range, 14 to 95 days) (Table 3). Two patients were combined treated with esophageal stents after two and six sponge tube changes, respectively, for the early oral intake of nutrition and to reduce the length of hospitalization (Table 4). No post-interventional strictures or functionally relevant scar formations were observed during a follow-up period of 56 to 380 days after the termination of E-VAC therapy.

## Discussion

Our study demonstrates that E-VAC therapy, modified 'through the overtube', is effective and safe. Technical and clinical success was achieved in all included patients for the treatment of thoracic esophageal anastomotic leaks. In addition, this technique can be done in a short time without complications. Endoscopic vacuum therapy is applicable for a wide range of esophageal defects in both post-operative esophageal leakages and esophageal traumatic perforations. A recent systemic review about endo-luminal topical negative pressure included 180 patients in 11 studies [13]. They reported that the closure of perforations occurred in 91.1% of patients and the overall rate of mortality was 12.8%, which was superior to previous treatments for esophageal perforations, such as surgery, stents, or clips. Initially, E-VAC therapy was applied when other conventional treatments failed or were deemed impossible. However, due to the accumulated evidence of its safety and efficacy, it was widely applied for upper gastrointestinal perforations and anastomotic leaks as a primary or rescue therapy [10]. Our observation was that once the extra-luminal cavity related to the leak was lined with healthy granulation tissue, sepsis control and E-VAC therapy can be safely discontinued. In our results, the mean total duration was 13.8 days with sponge tube changes performed for about every 3.5 days for an average of 3.4 sponge tube changes per case. This is compatible with previous data in which the duration of E-VAC therapy ranged from 11 to 27 days with sponge tube changes occurring around every 4.8 days for 2.75 to 6 sponge tube changes per case [9]. The success rates of E-VAC therapy for perforation and anastomotic leaks have been reported to be 70% to 100% of patients, as study does [14]. The placement of self-expanding esophageal metal stents has been reported for severely infected foregut wall defects in patients where E-VAC has failed, and is a first-line treatment when combined with endo-sponges (stent-over-sponge) [15]. We applied full-covered metal stents in conjunction with E-VAC therapy to early oral intake and to reduce the length of hospitalization in two cases. The 'through the overtube' technique combined with the deployment of the sponges directly into leak sites would greatly simplify its application, thereby avoiding the need for general anesthesia and allowing the standardization of the technique. This allows for easier sponge placement and exchange compared to the traditional E-VAC technique. We experienced that endo-sponge placement in esophageal leaks could be done within 15 min, and it became shorter in later cases. To reduce the procedural time, adjusting the sponges' diameter to more easily pass through the overtube is important. Since the inner diameter of the overtube

used was 15 mm, we trimmed endo-sponges to readily pass through the overtube. To reduce serious injury to the pharynx and proximal esophagus, the lubrication of overtube before insertion is also important. Overtube-related complications, such as transient vocal cord paralysis, cricopharyngeal perforation, proximal esophageal laceration, varix rupture, bleeding and free esophageal perforation, have been reported [16,17]. In addition, E-VAC therapy has been reported in the literature to cause complications, such as bleeding, anastomotic strictures, mucosal tears caused by sponge removal, sponge dislocations, and bronchoesophageal fistulae [16,18]. There were no procedure-related complications in this study. Recently, commercial tubes, such as Endosponge® (B. Braun, Melsungen, Germany) [19] and Eso-sponge®tube (B. Braun Surgical, S.A., Rubí, Spain) [20], for E-VAC therapy using overtube have been produced. However, these tubes were not available in our country. Therefore, we made sponge tubes by ourselves, under patient permission, using black polyurethane sponges. Black polyurethane ester (V.A.C. VeraFlow, KCI) and white polyvinyl alcohol (V.A.C. WhiteFoam, KCI) were used in other reports [8]. The limitations of this study include the small number of patients included, as well as the study being retrospective. Since esophageal anastomotic leaks are rare events, patients undergoing E-VAC therapy as a first-line treatment were few in a single institution. In spite of the retrospective study, data related to E-VAC therapy could be obtained from electronic medical records and image data from previous endoscopic procedures. In addition, our patients were treated with parenteral nutritional support during E-VAC therapy. Several modified techniques to enable simultaneous enteral feeding; using a Sengstaken-Blakemore [21] or a triluminal tube [22], and vacuum drainage have been employed. Due to the debilitated state of our patients and the lack of evidence regarding the efficacy of multiple lumen tubes, we used a single lumen tube and parenteral nutrition in our procedure. Finally, the "through the overtube" method cannot be applied to cervical esophageal leaks [23].

## Conclusion

In conclusion, E-VAC therapy modified through the overtube was applicable for thoracic esophageal anastomotic leaks. It was easily applicable in ordinary endoscopy under conscious sedation and had short procedural times. The preparation of all equipment before implementing E-VAC and gentle maneuvering were necessary for technical success. For clinical success, the close observation of patients' conditions and proper changing of sponge tubes were needed.

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