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**Research** Paper

# Endoscopic vacuum therapy for anastomotic leakage after esophagectomy: a retrospective analysis at a tertiary university center



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# ABSTRACT

*Introduction:* Anastomotic leakage after esophagectomy with gastric-pullup is the most feared postoperative complication associated with high morbidity and mortality rates. Management of anastomotic leakage underwent an evolution in the last decade from surgical and conservative to an endoscopic management. However, to date there is no clear consensus on management and if endoluminal vacuum therapy (EVT) is the most superior therapy.

*Material and methods:* Between 2012 and 2022 all patients that underwent Ivor-Lewis esophagectomy for an underlying malignancy were included in this study. Patients that developed an anastomotic leakage and received endoscopic vacuum therapy were further analysed.

*Results*: A total of 17 patients were treated with EVT following AL after esophagectomy. The median duration of EVT was 23 days with a median number of 5,5 vacuum sponge changes per patient. EVT-systems were placed 12 times intraluminal and 5 times extraluminal. Successful closure of the defect was achieved in 14 patients.

*Conclusion:* Endoscopic vacuum therapy can be successfully applied in the treatment of anastomotic leakage after esophagectomy even in septic patients with an extraluminal cavity. Event-related complications are present but rare.

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#### Introduction

Esophagectomy is a complicated surgery that carries a high risk of mortality compared with other surgically treated malignancies. In house mortality range between 7 and 9% [1] with complications rate being reported as high as 50% and often increase in the presence of an anastomotic leakage (AL) [2,3]. The incidence of AL varies highly and is reported to up to 60%, however, the Esophagus Complications Consensus Group (ECCG) reported an incidence of 19% across 14 high-volume centres [4]. Consequences of AL are high morbidity and morality rates, a prolonged intensive care unit (ICU) and hospital stay, increased hospital costs and negative long-term outcomes such as long-time survival and quality of life [5–7].

Over the last two decades treatment of AL after esophagectomy has undergone an evolution. Historically, AL was mostly treated by conservative and surgical management. However, as soon as a redo-surgery is performed, mortality rates increase and can be over 60% [8]. Nowadays, most AL after esophagectomy are treated by endoscopic options such as endoclips, stents and endoscopic vacuum therapy (EVT). EVT was first described by Weidenhagen for controlling AL in rectal surgery [9]. The

\* Corresponding author. *E-mail address:* nader.el-sourani@uol.de (N. El-Sourani). same procedure was adopted for defects of the upper gastrointestinal tract in 2006 [10]. In our department, endoscopic management with self-expanding metal stents (SEMS) has been the standard treatment in the early days of endoscopic management, however, with the introduction of EVT our management has changed. Up to date, the treatment of AL after esophagectomy remains controversial as the indications remain unstandardised and the lack of available randomised controlled studies. In addition, the currently available EVT data is too heterogenous as crucial factors such as intraluminal or extraluminal placement, numbers of sponges used and use of negative pressure are insufficiently described.

The aim of this study was to evaluate EVT for postoperative AL after esophagectomy and evaluating its use as a standardised approach for the future.

## Material and methods

**Study population.** Between 2012 and 2022 all patients that underwent esophagectomy for underlying malignancy were included in this study. All patients that developed a postoperative AL and received EVT were further analysed. This led to a total of 17 patients who were treated with EVT for AL at our university department. In addition, the following parameters were analysed: postoperative day of detection of an AL,

CAES Classification, median combined intensive care unit and intermediate care stay, median hospital stay, tumor histology, tumor grading, tumor location, neoadjuvant therapy, number of lymph nodes harvested, R-Status, operation method, operation time, morbidity and mortality. Regarding endoscopic treatment, following parameters were analysed: location of the defect, size of the defect, number of vacuum sponges used, event-related complications, length of treatment and treatment outcome. Approval by the Ethics Committee of the University of Oldenburg was obtained (2022-117).

Diagnosing and classifying anastomotic insufficiency. AL was defined by a communication between the intra - and extraluminal compartment through a defect in the integrity of the intestinal wall of the anastomosis. A routine examination of the anastomotic integrity was not performed. If AL was suspected an upper endoscopy (UE) and computed tomography (CT) was carried out. AL was classified according to the classification suggested by the Surgical Working Group of Endoscopy and Ultrasound (CAES) and Esophagectomy Complications Consensus Group (ECCG) and divided into three types. Type II leaks were treated endoscopically. Subsequently, patients suffering by macroscopic visible mediastinal leakage cavity (called "extraluminal cavity") were always treated by endoluminal vacuum therapy. In contrast to this group, patients with smaller anastomotic defects and none or small leakage cavity (called "intraluminal cavity") were treated with EVT or stent therapy. In addition, endoscopic vacuum therapy has become more and more established as the standard therapy over the past few years.

**Endoscopic vacuum therapy.** UE was performed in sedated and/or intubated patient (GIF-H180, GIF-H190, Olympus Corporation, Tokyo, Japan). During the initial endoscopy, the cavity was cleaned and measured to determine the required length and diameter of the sponge, which then was reshaped accordingly. Open-pore polyurethane sponges, Eso-SPONGE® (B. Braun Melsungen AG, Melsungen, Germany) with a primary diameter of  $24 \times 55$  mm and a 12 CH Redon drain or an individually adapted sponge (V.A.C. VERAFLO<sup>TM</sup> Dressing Kit, KCI, St. Paul, USA) fixed to a drain (Argyle<sup>TM</sup> Edlich Gastric Lavage Tube, 16 CH, Medsitis, USA), were used.

In general, it could be differentiated between the intraluminal placement of the sponge in the case of small anastomotic defects, usually less than 10 mm, or residual cavities with no infection and the intracavitary placement of the sponge where it is introduced through the wall defect into an extraluminal, i.e. mediastinal, cavity. The intracavitary version of EVT was preferred. For placement of the sponge two endoscopic methods were used, the "push" technique or the "piggyback" technique. Using the push technique, the sponge was advanced to the correct location along an overtube with a pusher or the endoscope, usually used a specially approved device (Eso-SPONGE®, B. Braun Melsungen AG, Melsungen, Germany). Using the piggyback technique, the sponge was placed in the leakage cavity under direct endoscopic vision while a suture loop placed at the tip of the sponge was grasped by endoscopic forceps and the sponge was pulled close to the endoscope. The drainage tube was placed transnasally and connected to a variable speed medical vacuum pump (V.A.C. ULTA®, KCI, San Antonio, Texas, USA). Suction was applied at a negative pressure 100 mmHg. In addition, a transnasal gastric or duodenal tube was inserted for enteral nutrition. After 3 to 5 days a re-endoscopy was done to remove the sponge, document the success of the treatment and to re-insert a sponge. Endoluminal vacuum therapy was continued until the cavity has been reduced to less than one cm. During each endoscopy, the CAES/ECCG classification of anastomotic leakage was used.

**Statistical analysis.** The statistical analysis was performed with IBM SPSS Statistics Version 64-Bit Version for Mac OS. Continuous variables were expressed as medians.

# Results

**Patient demographics.** Fig. 1 shows the inclusion and exclusion of patients. A total of 33 AL were detected after esophagectomy. Excluded from the study were a total of 16 patients. A total of 17 patients were treated with EVT for postoperative AL. All patients characteristics are shown in Table 1. There were 15 male (88%) and 2 female (12%) patients, with a median age of 60 years (range: 32–83). The median body mass index (BMI) was 26 (range: 17–35). 10 patients (59%) were classified as ASAII while 7 patients (41%) were classified as ASA III. The reason for esophagectomy was Adenocarcinoma (AC) in all patients. All tumors were located in the distal third of the esophages. 5 patients (29%) received a hybrid minimal invasive esophagectomy while 12 (71%) patients received an open esophagectomy. The median lymph node harvest was 23 (range: 11–37). The median time to diagnose an AL was 8 days (range: 3–30).

**Outcomes of endoscopic vacuum therapy.** Findings of UE and outcomes of EVT are shown in Table 2. A total of 17 patients were treated with EVT for postoperative AL. The median time from surgery to diagnosis was 8 days (range: 3–30). The median distance from the upper incisor to the defect was 27 cm (range: 20–36), with a median defect size of 15 mm (range: 3–32). In 5 patients the defect developed into a macroscopic visible extraluminal cavity. The median hospital stay was 74 days (range: 4–193) with a median ICU/IMC stay of 38 days (range: 4–193). Complete closure of the defect was achieved in 14 patients (82%).

**Adverse events, failure and mortality.** 1 out of 17 patients (6%) developed a bronchial-fistula after initiating EVT and died in the postoperative period. In 2 patients (12%) AL caused a sepsis with multi-organ failure despite initiating EVT. 2 patients were successfully treated with EVT, however, in one case a stent placement after EVT was the cause of a bronchial-fistula and in another case, the placement of a feeding tube was the cause of an intestinal perforation. In both instances, the patients died.

## Discussion

This study reports our experience and results with EVT for AL secondary to esophagectomy at a tertiary university centre. AL after esophagectomy is the most serious complication associated with high morbidity and mortality rates, increased hospital stay and costs, and a decreased overall survival and quality of life [11]. Historically, AL was controlled through a combination of surgery and conservative management, however, in the last decade endoscopic management, specifically EVT, has been used to successfully manage AL. The ECCG and CAES proposed a classification and treatment algorithm for AL after esophagectomy [4,12]. Here, surgical revision was only suggested in cases of graft necrosis or in patients with sepsis (type III). While type I can always be treated conservatively through a nasogastric-tube, nil per mouth and antibiotics, type II should be treated endoscopically through clipping the defect, stenting or EVT.

A systematic review of three available studies showed that 37 out of 40 patients (93%) were successfully treated with EVT without the presence of EVT-related complications [13–15]. In addition, a recent meta-analysis comparing stenting versus EVT confirms that EVT has a significantly higher success rate and faster healing of esophageal leaks without an elevated treatment related complication rate, but fails to show a clear superiority [16]. This is also reflected in our results. 14 out of 17 patients were successfully treated with EVT. However, 2 out of 5 patients died due to complications that could not be attributed to EVT. The reasons were a stent placement following successful closure after EVT that led to a stent-migration and development of a bronchial-fistula, and a perforation caused by a placement of a feeding-tube. The overall mortality within this cohort was 24%. Therefore, EVT can be regarded as a life-saving tool, as mortality



Fig. 1. Flow chart showing inclusion of patient.

increased up to 60% once redo-surgery for AL is introduced [11]. Our results show that the median duration of EVT was 23 days with a median of 5,5 vacuum sponge changes per patient. However, in patients with large defects and extraluminary cavities the treatment duration is longer. Similar results have been reported by other studies [17,18].

Previous studies reporting the use of EVT might have had a slightly higher sample size, however, their data was too heterogenous as it included patients with AL after esophagectomy and patients with esophageal perforations. However, those two groups cannot be put into the same treatment basket, as the blood supply and perfusion of the gastric conduit cannot be compared to that of an intact esophagus.

This study has some limitations. First, this study is a retrospective and non-randomised study. Second, the sample size is relatively small. However, although those limitations are present, it is to our knowledge one of the only available studies mentioning defect size and analysing

#### Table 1

Patient characteristics.

Variables	
Age	60 (32-83)
Sex	
Male	15 (88%)
Female	2 (12%)
BMI	26 (17-34)
ASA I	0
ASA II	10 (59%)
ASA III	7 (41%)
ASA IV	0
Neoadjuvant Therapy	
None	5 (29%)
Chemotherapy	9 (53%)
Radiochemotherapy	3 (18%)
Tumor localisation	
Proximal	0
Middle	0
Distal	17 (100%)
Histological type	
Adenocarcinoma	17 (100%)
Squamous cell carcinoma	0
Surgical procedure	
Open	12 (71%)
Hybrid	5 (29%)
Time between surgery and diagnosis of AL, days	8 (3-30)
Clavien-Dindo calssification	
3	12 (71%)
4	0
5	5 (29%)
Lymph nord harvest	23 (11-37)

Data are presented as number (%) or median (range). ASA, American Society of Anaesthesiologists; AL, anastomotic leakage.

its potential outcome on the treatment option that should be chosen. In addition, the data is more homogenous and includes more endoscopic variables compared to published data.

In conclusion, our experience and results suggest that EVT is a safe treatment option for patients with small and large defect sizes and presence of an extraluminal cavity. Future studies involving a larger sample size and randomised controlled studies are needed to evaluate the true value of EVT for AL.

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#### **Ethical approval**

The ethics committee of the University of Oldenburg approved the study (2022–117).

#### **CRediT** authorship contribution statement

NES: collected the data, performed the analysis and wrote the manuscript.

SM: collected data and reviewed the manuscript.

MB: reviewed manuscript and supervised it.

#### **Declaration of competing interest**

Nor do the authors have to disclose any conflict of interest.

Table 2

Findings of upper endoscopy and outcomes of endoscopic vacuum therapy.

Variables	
Defect size, mm	15 (3-32)
Defect location, cm	27 (20-36)
Intraluminal	12 (71%)
Extraluminal cavity	5 (29%)
Duration of EVT	23 (10-80)
Number of sponges	5,5 (4-18)
Complete closure	14 (82%)
Adverse event related to EVT	
Bronchial fistula	(12%)
Intestinal perforation	1 (6%)
Combined ICU/IMC stay, days	38 (4-193)
Hospital stay, days	74 (4-193)
Mortality	5 (29%)

Data are presented as number (%) or median (range). EVT, endoscopic vacuum therapy; ICU, intensive care unit; IMC, intermediate care.

#### N. El-Sourani, S. Miftode and M. Bockhorn

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