Endoluminal vacuum therapy using a new “fistula sponge” in treating defects of the upper gastrointestinal tract – a comparative, retrospective cohort study.

Florian Richter  
University Medical Center Schleswig-Holstein (UKSH)

Claudio Conrad  
University Medical Center Schleswig-Holstein (UKSH)

Julia Hoffmann  
University Medical Center Schleswig-Holstein (UKSH)

Benedikt Reichert  
University Medical Center Schleswig-Holstein (UKSH)

Witigo von Schönfels  
University Medical Center Schleswig-Holstein (UKSH)

Clemens Schafmayer  
University Hospital Rostock

Jan-Hendrik Ergberts  
Israelitisches Krankenhaus

Thomas Becker  
University Medical Center Schleswig-Holstein (UKSH)

Mark Ellrichmann  
mark.ellrichmann@uksh.de

University Medical Center Schleswig-Holstein (UKSH)

Research Article

Keywords: Fistula sponge, Endoluminal vacuum therapy, Anastomotic insufficiencies, Esophageal perforation, Endoscopic treatment

Posted Date: February 19th, 2024

DOI: https://doi.org/10.21203/rs.3.rs-3948295/v1
License: ☕️ Ⓥ This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.
Abstract

**Background:** Anastomotic insufficiencies (AI) and perforations of the upper gastrointestinal tract (uGIT) result in high morbidity and mortality. As treatment options surgical revision, endoscopic stent placement as well as endoluminal vacuum therapy (EVT) have been established. The Eso-Sponge® is the only licensed EVT system with limitations in treating small defects (<10mm). Therefore, a fistula sponge (FS) was established for the treatment of such defects as a new therapeutic approach.

**Methods:** The aim of the study was to compare indications, technical/clinical success rates, and complications in a retrospective, comparative study of both EVT approaches. Between 01/2018 and 01/2021 clinical data of patients undergoing FS-EVT or conventional EVT (cEVT; Eso-Sponge®, Braun Melsungen, Germany) due to AI/perforation of the uGIT were recorded. Indication, diameter of leakage, therapeutic success, and complications during the procedure were assessed. FSs were prepared using a nasogastric tube and a porous drainage film (Suprasorb® CNP, Lohmann & Rauscher, Germany) sutured to the distal tip.

**Results:** A total of 72 patients was included (20 FS-EVT; 52 cEVT). FS-EVT was performed in 60% suffering from AI (cEVT = 68%) and 40% from perforation (cEVT = 32%; p > 0.05). FS-EVT's duration was significantly shorter than cEVT (7.6±12.0d vs. 15.1±14.3d; p = 0.014). The mean diameter of the defect was 9 mm in the FS-EVT group compared to 24 mm in cEVT (p < 0.001). Therapeutic success was achieved in 90% (FS-EVT) and 91% (cEVT; p > 0.05).

**Conclusions:** EVT comprises an efficient treatment option for transmural defects of the uGIT. In daily clinical practice, fistulas <10 mm with large abscess formations poses a special challenge since intraluminal cEVT usually is ineffective. In these cases, the concept of extraluminal FS placement is safe and effective.

**Background**

Perforations and anastomotic insufficiencies (AI) of the esophagus pose a therapeutic challenge since the rate of serious complications such as mediastinitis or sepsis is high and leads to a mortality rate of 5–50%. (1–6) Esophageal perforations can occur in the context of ulceration, circulatory disorders, carcinoma, violent vomiting, or medical intervention. (7) Iatrogenic perforation is the most common cause of esophageal perforation, accounting for 59–63% of cases. (1, 2) The mortality rate of esophageal perforations depends on the height of the perforation, and thus the varying distance to the mediastinum. Accordingly, thoracic perforations lead to slightly higher mortality rates of 5.4–36% compared to cervical perforations with 6–20% and abdominal perforations with 3–22% mortality rates. (8–12)

Operations conducted within the upper gastrointestinal tract (uGIT) encounter a significant risk of AI in 2–25% of cases with spillage of fluids or food particles into an extraluminal cavity resulting in inflammation of the surrounding area. In this regard, the surgical technique, the height of the
anastomosis and potential neoadjuvant treatment play a decisive role. (13, 14) AI-associated mortality in the uGIT is reported at up to 67%, which is higher compared to esophageal perforations. (15, 16) Regarding the exceptionally high impending mortality rates, immediate and adequate treatment is crucial in the management of transmural defects of the uGIT. These treatment options include conservative antibiotic treatment, surgical debridement, closure of the dehiscence, or re-attachment of an anastomosis with simultaneous drainage.(17) Procedures such as endoscopic closure with clips, injection of fibrin glue, endoluminal drainage through nasogastric tubes, endoluminal sutures, and the implantation of endoscopic stents are applied. (18, 19) Besides surgical revision and endoscopic stent placement, endoluminal vacuum therapy (EVT) has been successfully established in the management of these defects. Several studies have shown a remarkably high recovery rate of about 90% with a concomitant mortality rate of only 10% after EVT. (20, 21) So far, the only licensed product for performing EVT in the uGIT was launched in 2014 as Eso-SPONGE® (B.Braun, Aesculap AG, Braun Melsungen, Germany) (conventional EVT, cEVT). However, since this system exhibits limitations in the treatment of very small defects with a diameter of less than 10 mm, a special fistula sponge (FS) was included in the clinical treatment algorithm in our department. The FS consists of a porous drainage foil that is sutured to the distal tip of a nasogastric tube (Suprasorb® CNP Wound Foam, Lohmann & Rauscher GmbH & Co. KG, Neuwied, Germany).

To the best of our knowledge, the use of FS has only been reported in small case series but comparative evaluations of both EVT concepts are lacking. (22) Therefore, this study aimed to evaluate indications, technical and clinical success rates, and complications of both EVT systems (cEVT and FS) in a retrospective, comparative manner.

**Methods**

**Study design**

All patients who were treated with EVT due to AI or perforation of the uGIT at the University Medical Center Schleswig-Holstein, Campus Kiel, Kiel, Germany between September 2018 and January 2021 were included in this retrospective, comparative cohort study.

After an interdisciplinary discussion of each patient, EVT was initiated with either FS or cEVT using the Eso-SPONGE®-System (B.Braun, Aesculap AG, Braun Melsungen, Germany) in close collaboration of the Department of Interdisciplinary Endoscopy and the Department of General, Visceral, Thoracic, Transplantation and Pediatric Surgery as a standard therapeutic approach of daily clinical practice. Baseline characteristics and clinical criteria were evaluated during clinical follow up as standard procedure.

The experimental protocols were approved by the ethics committee of the Medical Faculty of Christian-Albrechts-University Kiel, Kiel, Germany (approval number: A141/14). The local IRB had no professional ethical or legal objections to conducting the study. Despite the retrospective character of the study,
patient informed consent was obtained from all patients due to an established “broad consent form” for retrospective data analysis. All experiments, in this regard endoscopic interventions, were performed in accordance with relevant guidelines and regulations.

Prior to the selection of patients, the following eligibility criteria were specified:

**Inclusion criteria:**

- Transmural wall defect of the uGIT
- Independent indication for endoscopic vacuum therapy after interdisciplinary case discussion
- Valid declaration of consent from the UKSH for scientific data collection (“broad consent“ UKSH), in the electronic patient file.

**Exclusion criteria:**

- Deviation from the standard procedure of EVT

**Endpoints**

The primary endpoint was defined as the clinical success, namely the complete resolution of the transmural defect lined with granulation tissue.

Secondary endpoints were: patient characteristics, duration of EVT, number of changes of respective EVT-system, the initial size of transmural defect, complications, rate of morbidity and mortality during follow-up.

**Conventional endoluminal vacuum therapy (cEVT)**

The Eso-SPONGE®-therapy was performed as described in a previous publication. (23) Briefly, after endoscopic evaluation of the transmural defect, the cEVT-system was adapted to the size of the respective defect and then inserted extraluminally into the cavity. Based on the size of the defect, EVT was carried out either by endoscopic insertion of an Eso-Sponge® extraluminally into the abscess cavity, or, in case of a limited defect size and the absence of a cavity, endoluminally into the esophagus itself (Fig. 1). With diminution of the defect over the course of therapy, the sponge placement could be moved from its initial extraluminal location (Fig. 1A) to an intraluminal position (Fig. 1B) allowing for complete cure of a potential residual leakage.

**Fistula sponge therapy**

For fistula sponge therapy, a layered compressed porous drainage foil (Suprasorb® CNP Wound Foam, Lohmann & Rauscher GmbH & Co. KG, Neuwied, Germany) was sutured to the distal end of a nasogastric tube (diameter between 8 and 12 Charriere) at a length of 1–6 cm depending on the depth of the defect in two to five wraps by adjusting the FS-EVT to the diameter of the defect. The suture was made with a non-absorbable braided Mersilene® thread of strength 2 − 0 (Ethicon, Somerville, New Jersey, USA) every 5 mm along the entire length of the drainage foil. This fistula sponge was then inserted endoscopically
into the target using a grasping forceps (FG-244NR, Olympus, Olympus Medical Systems, Tokyo, Japan) and/or a guidewire (Jagwire 0.035 , Bos → n. Scient if ic, Malb or ough, MA, USA) on the esophageal stoma’s request.

The commercially available Eso-SPONGE® and the newly created fistula sponge are shown in Fig. 2 in direct comparison (Fig. 2).

The respective EVT system was then diverted transnasally and connected to a vacuum pump (Smith & Nephew plc, Watford, Hertfordshire, UK) with continuous suction of 120 mmHg.

Changes of the EVT system were scheduled approximately every 3 days until complete resolution of the cavity (as defined) was achieved.

Before removing the respective sponge system, both systems were disconnected and flushed with 20 ml of saline 0.9% to prevent the systems from tearing off due to the granulation tissue growing into the pores.

The location of the transmural defect was assessed endoscopically in centimeters (cm) from the dental arch (DA), the diameter and length were measured using a guidewire and/or biopsy forceps as measuring scale. Data obtained from endoscopy were compared to results from computer tomography (CT) scan. The different locations of the defects were categorized into four sections: (1) 15–23 cm DA, (2) 24–32 cm DA, (3) 33–40 cm DA, (4) > 40 cm DA.

**Data collection and Follow up**

All clinically relevant data were obtained by our hospital information system (Orbis, Dedalus, Bonn, Germany). Patients received a routine follow up after 30 days and 6 as well as 12 months after discharge. Follow up information were collected by our outpatient clinic or respective hospital readmissions.

**Bench study to compare throughput of EVT systems**

To compare the suction capacity of the two EVT options in a standardized way, volume measurements of liquid sucked out of a container by the respective sponge at defined periods of time were recorded (Fig. 3). To compare the suction performance of the two EVT options in a standardized manner, the FS-EVT or the cEVT system were dipped into a container with 2L of drinking water, connected to the mentioned vacuum pump with continuous suction of 120 mmHg simulating the clinical situation in patients. The volume of water drawn from the container was measured after 30, 60, 90, and 120 seconds. Measurements were repeated five times each to minimize fluctuation-induced errors in the readings.

For the cEVT, three sizes of the Eso-SPONGE® were tested: complete Eso-SPONGE® 13 mm, one half and one third of the respective sponge.
For the FS-EVT a nasogastric tube of 12 Ch was used having five wraps of drainage foil at the distal tip over a length of 5, 2.5, and 1.4 cm (length of 100%, 50%, 30%) corresponding to the respective lengths of the cut Eso-SPONGE® 13 mm.

**Statistical analysis methods**

Descriptive statistics of patient characteristics and treatment details were calculated using mean values with standard deviation. The statistical comparison was carried out using unpaired t-tests and Fisher's exact test as appropriate. The significance level was set at a p-value of < 0.05. All statistical analyses and graphical processing were carried out using GraphPad Prism software, version 8.0 (GraphPad Software, San Diego, USA). In case of missing relevant data patients were excluded from further analyses.

**Results**

**Patient characteristics**

A total of 71 patients (13 females, 31.7%) was evaluated in this study, among these 47 (66.2%) were treated with cEVT and 24 (33.8%) with FS-EVT (Fig. 4). Further details of patient characteristics are summarized in Table 1.
Table 1
Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>cEVT</th>
<th>FS-EVT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients [N]</td>
<td>47</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Age [years]</td>
<td>62.8 ± 15.7</td>
<td>65.0 ± 16.3</td>
<td>ns</td>
</tr>
<tr>
<td>Female [N] (%)</td>
<td>11 (23.4%)</td>
<td>2 (8.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Indication [N] (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anastomotic insufficiency</td>
<td>21 (44.7%)</td>
<td>8 (33.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Perforation</td>
<td>26 (55.3%)</td>
<td>16 (66.7%)</td>
<td>ns</td>
</tr>
<tr>
<td>Location of defect from dental arch [N] (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) 15–23 cm</td>
<td>3 (6.4)</td>
<td>2 (8.3)</td>
<td>ns</td>
</tr>
<tr>
<td>2) 24–32 cm</td>
<td>30 (63.8%)</td>
<td>14 (58.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>3) 33–40 cm</td>
<td>10 (21.3%)</td>
<td>7 (29.2%)</td>
<td>ns</td>
</tr>
<tr>
<td>4) &gt; 40 cm</td>
<td>4 (8.5)</td>
<td>1 (4.2)</td>
<td>ns</td>
</tr>
<tr>
<td>Body mass index [kg/m²][mean ± SD]</td>
<td>27.6 ± 8.9</td>
<td>26.0 ± 6.4</td>
<td>ns</td>
</tr>
<tr>
<td>ASA Score</td>
<td>3 (2–4)</td>
<td>2 (1–4)</td>
<td>ns</td>
</tr>
<tr>
<td>Malignancy [N] (%)</td>
<td>31 (65.9%)</td>
<td>18 (75%)</td>
<td>ns</td>
</tr>
<tr>
<td>Neoadjuvant treatment [N] (%)</td>
<td>18 (38.3)</td>
<td>9 (37.5)</td>
<td>ns</td>
</tr>
<tr>
<td>Intervall between surgery and EVT [d] [mean ± SD]</td>
<td>5.8 ± 5.7</td>
<td>6.2 ± 5.5</td>
<td>ns</td>
</tr>
</tbody>
</table>
Table 2
EVT-associated complications

<table>
<thead>
<tr>
<th>EVT-associated complications</th>
<th>cEVT</th>
<th>FS-EVT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>1</td>
<td>0</td>
<td>ns</td>
</tr>
<tr>
<td>Ingrowth/ Tearing off of the sponge</td>
<td>0</td>
<td>0</td>
<td>ns</td>
</tr>
<tr>
<td>Technically not possible</td>
<td>0</td>
<td>2</td>
<td>ns</td>
</tr>
<tr>
<td>Esophageal stricture</td>
<td>8</td>
<td>3</td>
<td>ns</td>
</tr>
<tr>
<td>Fistula recurrence or persistent fistula</td>
<td>4</td>
<td>0</td>
<td>ns</td>
</tr>
<tr>
<td>Complication rate</td>
<td>27.7%</td>
<td>20.8%</td>
<td>ns</td>
</tr>
</tbody>
</table>

**Primary endpoint**

**Rate of defect healing**

Patients receiving cEVT experienced a complete defect closure in 76.6% of cases, whereas FS-EVT resulted in a closure rate of 87.5%, the difference in the rate of success was statistically not significant between these groups (p = 0.355; Fig. 5).

**Secondary endpoints**

**Defect size**

The mean diameter of the wall defect of 9.0 ± 4.3 mm in the FS-EVT group differed significantly from the diameter of 23.3 ± 6.9 mm in the cEVT group (p < 0.0001). The mean length of the lesions did not show a statistical difference between the two groups (FS-EVT = 46.3±25.9 mm; cEVT = 46.7 ± 21.4 mm; p = 0.7; Fig. 6).

**Duration of therapy and number of sponge changes**

The average treatment period in the cEVT group lasted for 15.1 ± 14.3 days, the average treatment period in the FS-EVT group was significantly shorter with only 7.6 ± 12.0 days (p = 0.014, Fig. 7).

During the respective treatment interval, EVT systems were exchanged 1.2 ± 1.6 times in the FS-EVT group compared to 4.2 ± 4.3 times in the cEVT group (p = 0.002, Fig. 8).

**Time interval until the start of the EVT**

For the evaluation of the time interval between initial diagnosis and initiation of EVT, only patients with AI as a result of surgery were considered to avoid bias. All patients with an acute perforation of the uGIT during an endoscopic intervention were immediately treated with EVT in the same session. For the AI group, despite a difference of 6.4 days, the time interval until the start of vacuum therapy did not differ significantly (p = 0.255) between the cEVT group (5.8 ±5.68d) and the FS group (12.2 ±22d).
Complication rate and complication management

Total complication rate was 27.7% (13/47) in the cEVT group and 20.8% (5/24) in the FS-EVT group, p = 0.6. Acute complications (i.e. ingrowth of the sponge into the mucosa, tearing off of the sponge) were not observed in neither of the two groups. In one patient, acute, untreatable hemorrhage from the abscess cavity occurred which was most likely related to the treatment using cEVT, finally resulting in patient's death. The placement of the fistula sponge was challenging in two patients, in one case, due to lack of compliance in the sense of repeated removal of the system by the patient, and the other repeated dislocation occurred due to torqued anatomical conditions.

Complications such as persistent or recurrent fistulas and stenoses of the esophagus in the area of the previous EVT were mainly detected only during the follow-up examinations. Eight patients in the cEVT group developed esophageal stricture after long term follow-up, which, with the exception of one stenosis caused by a tumor recurrence, were successfully treated by balloon dilatation. In the FS group, this was the case in three patients. All three patients could also be successfully treated with balloon dilatation. Persistent fistulas or fistula recurrences occurred in four patients in the control group and none in the FS-EVT group. Three patients in the control group underwent repeat EVT and one patient with an extensive esophagotracheal fistula underwent surgery. Further details of patient complications are

Follow-up, 30day-Mortality

In the control group a total of 10 patients (21.3%) died within 30 days after the initial event (perforation or surgery) compared to 5 patients (20.8%) in the FS-EVT group. A subgroup analysis revealed a EVT associated 30d mortality of 4.3% (cEVT) and 4.0% (FS-EVT) (p = 0.9, Table 3, Fig. 9).

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Overview of mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>cEVT (N = 47)</td>
</tr>
<tr>
<td>Treatment associated 30-day mortality [N] (%)</td>
<td>2 (4.3)</td>
</tr>
<tr>
<td>30-day mortality total [N] (%)</td>
<td>10 (21.3)</td>
</tr>
<tr>
<td>6 months mortality total [N] (%)</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Completed 12 months follow-up</td>
<td>36 (76.6)</td>
</tr>
</tbody>
</table>

Bench testing of suction capacity

Suction capacity was quantified in mL per 30 seconds. The cEVT system showed a constant suction capacity of 60mL/30s, no differences were observed comparing the different lengths of the cEVT. FS-EVT with a 12French (Fr) gastric tube resulted in a significantly increased suction capacity of 92 mL/30s (p = 0.002) independent of the length. The other FS-EVT tests with a 10Fr and 8Fr gastric tube revealed
significantly lower suction levels compared to the 12Fr system (10Fr = 72mL/30s; 8Fr = 43 mL/30s). These amounts were comparable to the cEVT (Fig. 10).

**Discussion**

Esophageal perforation and AI following esophageal resections can lead to serious complications resulting in high morbidity and mortality of the patients. (24, 25) For a long time, the only available therapeutic options for treating perforations were either endoscopic stent placement or surgery. (26)

However, several stent-associated complications such as dislocation, penetration into the wall layers of the digestive tract and formation of extraluminal abscesses are reported in the present literature in 13–21% of patients with the recurrent need of further endoscopic or surgical intervention. (27, 28)

Since 2007, the technique of EVT has been successfully approved for the treatment of AI and perforations of the uGIT. (20, 29, 30) In clinical practice, the commercially available sponges are limited in their use for small wall defects / fistulas < 10mm. For this reason, a special fistula sponge consisting of a gastric tube wrapped with a porous foil that is fixed by sutures was developed and has been used in routine clinical practice at our center since 2018.

So far, the available data evaluating this new technique are very limited and do not assess criteria for patient selection and short- and long-term outcomes.

Loske et al. applied the concept of FS-EVT in eleven patients with duodenal leakages either due to acute perforation or AI. In this cohort, the two EVT methods were used either individually, in combination or consecutively resulting in a complete closure of the defect in all patients after a median duration of therapy of 11 days (range 7–24 days). (22)

In a small case series of nine patients with iatrogenic defect of the esophagus EVT, as either cEVT or FS-EVT, was again successful in 100% of the reported patients after a median treatment period of 19 days. (31)

Based on these studies, criteria for patient selection for the respective EVT cannot be defined, since the reported patient collectives are very heterogenous. Based on our current study, the following patient criteria should be evaluated to design the optimal treatment strategy in an interdisciplinary approach: patient’s general condition, level of infection parameters, diameter and length of the wall defect, presence of an extraluminal wound cavity as well as radiological findings.

In our study, a diameter of the wall defect of < 10mm was defined as cut-off to initiate FS-EVT as first treatment option. Other research groups have treated defects with a size < 15mm with FS-EVT either from the beginning or during the course of therapy after previous cEVT exchanges. (22, 31) According to Kaczmarek et al. defects with a diameter of less than 10 mm can be either treated with FS-EVT or initial balloon dilation followed by cEVT. (32) This second approach is not routinely applied in our center, with the idea to limit the local trauma to the esophageal wall and adjacent wound cavity.
In addition to the case series mentioned above, several case reports have been published that prove the efficiency of EVT with open pore drainage film. Wulfert et al. (2020) reported on the successful treatment of peritonitis after a complicated caesarean section using intrauterine vacuum therapy. In combination with abdominal lavage, FS-EVT led to a control of the septic focus after eleven days, and thus successfully avoided hysterectomy. (33) Loske et al. published a case in 2017 in which, a large defect of the urinary bladder occurred in the course of rectal amputation. After 18 days, continuous vacuum therapy and simultaneous ureteral stenting resulted in complete closure of the bladder wall defect. (34)

All of the published cases reflected a high therapeutic success of the EVT of 100%. In our present study, we observed a mean closure rate of 82.1% (cEVT = 76.6%; FS-EVT = 87.5%). These results stand in line with a multicenter cohort study of cEVT in esophageal wall defects of our group. In a total of 102 patients’ complete closure was achieved through EVT in 86.3% of patients. Among these, closure rate after AI and acute perforation was 91.3% and 75.8% respectively. (35)

Of note, the definition of complete wound healing to terminate EVT differed among participating centers and published case series. Loske et al. terminated vacuum therapy with a significant reduction of the cleaned wound cavity and the formation of granulation tissue with normalized infection parameters in the serum. (36) In our study, supported by the case series of Wichmann et al., defect healing was defined as clean granulation in the wound bed without persistent fistula verified by endoscopic examination as well as X-ray imaging with contrast medium and depth of the residual cavity of less than 10 mm. (37)

Despite the high success rate and ease of implementation, the EVT-associated complications such as ingrowth of the sponge into the mucosa, dislocation of the sponge, bleeding, subsequent stenosis of the uGIT or the development of a fistula recurrence in the course of treatment need to be mentioned. (38–42)

We observed a mean complication rate of 24.3% without significant differences between the intervention groups (cEVT = 27.7%; FS-EVT 20.8%). Except in one patient, only minor complications occurred as enlisted above. In one case in the cEVT-group a hemodynamic relevant bleeding occurred during the course of therapy, resulting in the patient's death. This is a known complication under cEVT described in up to 10% of patients resulting from erosion of a feeding vessels inside the wound cavity. (23, 41) Jung et al. only reported minor bleedings potentially associated to significantly lower suction rates of -20 to -50 mmHg. (43) In general, due to the smaller pores of the drainage foil compared to cEVT, the risk of ingrowth of granulation tissue into the FS-EVT system and the consecutive risk of significant bleeding seems to be lower. So far, this assumption cannot be reliably proved in the available literature including our own study. (44) Nevertheless, to avoid relevant bleeding complications, a reduction of the suction force and an obligatory pre-interventional (angio-) CT-scan, as well as the preferential use of foil-based suction systems in high-risk patients should be further discussed.

Eight of our patients (17%) in the cEVT group developed esophageal strictures during follow-up that could all be successfully treated by endoscopic balloon dilation. In the FS-EVT group strictures occurred in 3 patients (12%) with the same consecutive therapeutic approach and resolution rate. These data
stand in line with other publications that presented scarring stenoses as long-term complications in 4.2–18.5% of treatments for AI or perforations in the uGIT.(23, 39, 43)

In our cohort we observed a treatment associated 30day-mortality rate of 4.3% in the cEVT group and 4.0% in the FS-EVT group. The other patients who contributed to the relatively high total mortality rate of our patient collective suffered from postoperative multi-organ failure occurring directly postoperatively and progression of the underlying oncological disease. Treatment associated mortality rates are comparable to the reported rates of 6.7% – 12.9%.(39, 43, 45) A multicenter study from 2022 of our working group analyzed data from eleven hospitals and a total of 100 patients who received EVT for treatment of a wall defect in the uGIT. The results published here are consistent with mortality rates around 6.7%.(35) The inhomogeneous data situation can possibly be explained by different evaluation criteria, especially with regard to the period in which the death of a patient occurred in relation to EVT, as well as the question of whether the respective cause of death is to be classified as therapy-associated. In addition, it can be discussed whether more patients with serious concomitant diseases were treated and more extensive findings were submitted to endoscopic therapy in our tertiary care university center compared to other hospitals.

**Comparative measurements of suction power**

Since no data were available so far evaluating the suction capacity of the two EVT systems, we performed a bench study to accurately quantify the volume of aspirated fluid per time interval of 30 seconds. Especially the combination of a 12Fr gastric tube and the porous drainage foil resulted in significantly increased suction rate compared to the cEVT and to FS-EVT with 10Fr and 8Fr gastric tube. Of note, the suction capacity is independent from the length of the EVT system but only correlates to the diameter of the drainage tube. These results confirm the observations described by other authors.(37, 44, 46) Due to a lower adherence to the wall, the film-based drainage ensures a more effective removal of fluids. The double-layered film with regularly arranged pores reliably drains secretions inwards via its interstitial space and thus apparently also qualifies this technique for prophylactic use after resections in the uGIT.(47)

The number of patients with transmural wall lesions in the uGIT treated with endoscopic vacuum therapy and a customized fistula sponge made of Suprasorb® film investigated in our work is the largest collection published to date.

Nevertheless, the present study also has its own limitations. In the treatment of wall defects in the uGIT, different practitioners with different levels of experience were involved and accordingly influenced the respective course and outcomes of therapy. Furthermore, the entire study was designed as a retrospective observation of our cohort in daily clinical practice. Future prospective, randomized controlled trials are needed to finally define advantages and disadvantages of the different EVT techniques. Since we only investigated defects of the uGIT in a retrospective manner, the obtained results cannot be generalized to all defects in the whole GIT.
Conclusion

In conclusion, endoscopic vacuum therapy encompasses several outstanding treatment options for transmural lesions in the uGIT. These include the new extraluminal FS-EVT placement using a porous drainage film that represents a safe and effective strategy for treating small wall defects or defects that cannot be negotiated with the cEVT system. In an interdisciplinary setting, this minimally invasive organ-preserving technique is an essential part of our armamentarium for the treatment of potentially life-threatening wall defects in the cases of uGIT.

Abbreviations

AI: Anastomotic insufficiencies
ASA: American Society of Anesthesiologists
cEVT: Conventional endoluminal vacuum therapy
Ch: Charriere
CT: Computer tomographie
DA: Dental arch
EVT: Endoluminal vacuum therapy
Fr: French
FS: Fistula sponge
FS-EVT: Fistula sponge- endoluminal vacuum therapy
GIT: Gastrointestinal tract
uGIT: Upper gastrointestinal tract
UK: United Kingdom
UKSH: Universitätsklinik Schleswig Holstein

Declarations

Ethics approval and consent to participate

The experimental protocols were approved by the ethics committee of the Medical Faculty of Christian-Albrechts-University Kiel, Kiel, Germany (approval number: A141/14). The local IRB had no professional ethical or legal objections to conducting the study. Despite the retrospective character of the study,
patient informed consent was obtained from all patients due to an established “broad consent form” for retrospective data analysis. All experiments, in this regard endoscopic interventions, were performed in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

FR, CC, JH, BR, WvS, JHE and TB have no conflicts of interest to declare about the present study. ME and CS have worked for Aesculap AG as speakers. The authors declare no other conflicts of interest.

Funding

The authors did not receive any external financial support.

Authors’ contributions

FR, CC, JH and ME were responsible for the conception, design of the study and respective data analysis; CS, JHE, BR and WvS were involved in writing of the manuscript, collection and interpretation of data; TB participated in data analysis and interpretation of data and in critically revising the manuscript for important intellectual content. ME was involved in the writing, reviewing and editing of the manuscript. All authors have read and approved the final version of the manuscript.

Acknowledgement

Not applicable.

References


32. Kaczmarek DJ, Heling DJ, Gonzalez-Carmona MA, Strassburg CP, Branchi V, Matthaei H, et al. Management of post-operative pancreatic fistulas following Longmire-Traverso pylorus-preserving...


**Figures**

**Figure 1**

Schematic overview of conventional endoluminal vacuum therapy: (A) Intracavital/extraluminal implantation of conventional endoluminal vacuum therapy; (B) Endoluminal placement of conventional endoluminal vacuum therapy.
Figure 2

Comparison of system for endoluminal vacuum therapy; Eso-SPONGE® and FS-EVT with diameters of 12Fr/10Fr/8 Fr (from left to right). cEVT: conventional endoluminal vacuum therapy, Fr: French, FS-EVT: Fistula Sponge- endoluminal vacuum therapy.
Figure 3

Experimental set-up for comparative measurement of throughput of the two endoluminal vacuum therapy systems.
Figure 4

Flow-Chart of the inclusion of the study. cEVT: conventional endoluminal vacuum therapy, FS-EVT: Fistula Sponge- endoluminal vacuum therapy
Figure 5

Comparison of closure rates of conventional endoluminal vacuum therapy vs. Fistula Sponge-endoluminal vacuum therapy. cEVT: conventional endoluminal vacuum therapy, FS-EVT: Fistula Sponge-endoluminal vacuum therapy, ns: no significance.
Comparison of diameter and length of the wall defects between Fistula Sponge- endoluminal vacuum therapy and conventional endoluminal vacuum therapy groups (***: p ≤ 0.01) cEVT: conventional endoluminal vacuum therapy, FS-EVT: Fistula Sponge- endoluminal vacuum therapy, ns: no significance.
Figure 7

Representation of the treatment period with the endoluminal vacuum therapy in days (*: p = 0.01). cEVT: conventional endoluminal vacuum therapy, FS-EVT: Fistula Sponge- endoluminal vacuum therapy.
Figure 8

Representation of the number of sponge changes of both groups (**: p ≤ 0.01). cEVT: conventional endoluminal vacuum therapy, FS-EVT: Fistula Sponge- endoluminal vacuum therapy.
Figure 9

Forest plot of the associations between endoscopic treatment and mortality after 6 and 12 month.
Figure 10

Comparison of suction capacity ml/30sec. Fistula Sponge-endoluminal vacuum therapy 12Fr showed a significantly improved suction capacity (*: p = 0.01). cEVT: conventional endoluminal vacuum therapy, Fr: French, FS-EVT: Fistula Sponge-endoluminal vacuum therapy.