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DISEASES OF THE ESOPHAGUS

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Original Article

A new hybrid stent using endoscopic vacuum therapy in treating esophageal leaks: a prospective single-center experience of its safety and feasibility with mid-term follow-up

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SUMMARY. **Self-expandable metal stents (SEMS) and endoscopic vacuum therapy (EVT) are endoscopic options for treating leaks of the esophagus. VACStent® is a variant of SEMS that aims to combine the advantages of SEMS and EVT in one device. Due to this unique construction, VACStent® can build a barrier to the leak and facilitate wound healing with EVT, all while maintaining intestinal passage. We present the first prospective feasibility study of VACStent® for treating leaks of the upper gastrointestinal tract. Between September 2019 and November 2020, we performed a prospective, investigator-initiated, single-center study and included all patients who underwent endoscopic stenting with VACStent® for various kinds of esophageal leaks, such as spontaneous, iatrogenic or anastomotic leaks. We included 20 patients, who underwent a total of 24 endoscopic VACStent® implantations. Technical success of the application of the VACStent® was achieved in all interventions ($n = 24$, 100%). Overall, clinical success in closing the leaks with VACStent® treatment was achieved in 60% of patients (12/20). No severe VACStent® treatment-related adverse events occurred. Oral feeding with supplement high-energy drinks failed in all patients due to clogging of the suction tube. VACStent® is a safe and feasible endoscopic treatment option for leaks of the upper gastrointestinal tract. However, our data could not show the expected advantage of orally feeding the patients during the treatment with the VACStent® in its current form. Efficacy of VACStent® compared to EVT or SEMS needs to be investigated in a further study. ClinicalTrials.gov Identifier: NCT03962179.**

KEY WORDS: **VACStent, Stent, SEMS, EVT, esophageal perforation, anastomotic leak, esophageal surgery.**

INTRODUCTION

Esophageal perforations and anastomotic leaks after surgery are serious, potentially life-threatening conditions. Crucial steps to control the local infection and avoid sepsis are leak closure and drainage of the exudate.[1,2]

Apart from surgical repair, various endoscopic treatment options have been developed.[3–7] Treatment with self-expanding metal stents (SEMS) is one established option, while endoscopic vacuum therapy (EVT) has become a promising alternative.[4,8] A recently published meta-analysis by Scognamiglio *et al.* showed a higher sealing rate for EVT compared to SEMS in esophageal leaks, whereas the largest retrospective single-center study by Berlth *et al.* could not demonstrate superiority of either treatment modality. Due to the lack of prospective comparative studies, no firm conclusions concerning the superiority of one treatment option can be drawn at this point.[9–11] Both therapeutic approaches have their designated advantages and disadvantages. SEMS create a barrier to the leak and maintain the intestinal passage, allowing patients to eat and drink. However, migration is a common problem, and treatment usually lasts 4–6 weeks.[12,13] EVT uses negative pressure to heal a wound and can be used in two different ways: intraluminal positioning of the sponge and intracavitary placement to treat a paraesophageal wound cavity.[14,15] Frequent endoscopies are necessary to change the sponge-system, but the overall treatment time can be short.

One novel endoscopic approach for treating esophageal leaks is the use of SEMS in combination with EVT.[16] Invented by the surgeons Stefan Benz

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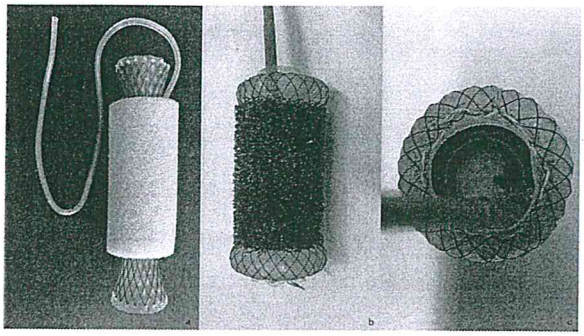

Fig. 1 (a) First prototype of a hybrid stent (2003). (b) VACStent® (2019). (c) Cross-section image of VACStent® (2019).

and Frank Pfeffer in 2003, VACStent® (VACStent MedTech AG, Switzerland) has only been commercially available since 2019 (Fig. 1a).[17] The VACStent® was designed to combine the advantages of SEMS and EVT in one medical device, optimizing the suction efficacy for sealing the leak and keeping the stent in position while maintaining intestinal passage.

The results of our retrospective study of 2019 suggested that VACStent® is both safe and technically feasible in treating leaks of the upper gastrointestinal tract. In this present study, we have added an analysis of prospective data to further evaluate these questions.[18]

METHODS

This prospective, investigator-initiated trial (German Clinical Trial Register, DRKS00019027) was conducted at the Department of General, Visceral, Cancer and Transplant Surgery at the University Hospital of Cologne, Germany, a European high-volume center for tumor entities of the upper gastrointestinal tract. The study protocol was approved by the Medical Ethics Committee and the Institutional Review Board (No 19-105_1, 21 August 2019) and registered in an open access trial database (ClinicalGov.Trial, NCT03962179, Trial registration date: 23 May 2019). Data were collected from our prospectively managed endoscopic database 'Clinic WinData' (Version 8.08; E&L medical system GmbH, Erlangen, Germany), from the 'REDCap' Database (Version 9.1.24) and from our hospital database 'Orbis' (Version 08043301, Agfa HealthCare N.V., Belgium).[19]

Between September 2019 and November 2020, 20 consecutive patients underwent VACStent® treatment for various kinds of esophageal leaks. In this study, we included all patients who suffered from a spontaneous, iatrogenic or post-interventional leak of the esophagus and who gave informed consent to participate. Additional inclusion criterion was a leak of max. 5 cm in length, with no limit concerning the circumferential extent.

Exclusion criteria were simultaneous participation in other interventional exams; endoscopically inaccessible leaks; therapeutic anticoagulation with international normalized ratio (INR) > 1.5, and/or partial thromboplastin time (PTT) > 50 second, and/or severe thrombocytopenia (defined by a platelet count <20 000/µl); hemodynamic instability due to severe sepsis; an immediate need for surgical intervention to control sepsis; clinical signs of bowel obstruction; pregnancy and lactation period; and ages under 18 years.

VACStent®

The VACStent® (VAC Stent Medtec AG, Switzerland) is 72 mm long, with a diameter of 14 mm in the center and 30 mm at the flare ends. The device consists of an SEMS (produced by Micro-Tech Co. Ltd. Nanjing, Republic of China), which is covered by a 50-mm-long open-pore polyurethane foam element in the mid-section (composed by Möller Medical GmbH Fulda, Germany). The VACStent® is made of nitinol wire and is fully covered with a silicone-parylene layer to prevent tissue ingrowth and seal the sponge toward the esophageal lumen. It is applied by a delivery system with a length of 1000 mm and a diameter of 14 mm (42 F). The SEMS is constrained by an outer tube and mounted on an inner catheter containing a drainage tube (length 2000 mm, diameter 10 F), which is connected to the polyurethane sponge. To release the SEMS, the outer tube is retracted (from the distal to the proximal end). When fully extended, the VACStent® has a 'dumbbell' shape, which helps to prevent stent migration. The VACStent® has a European conformity certification (CE) and is currently only available in one size (Fig. 1b and c).

Stent treatment

The VACStent® is placed under endoscopic guidance with a flexible video esophagogastroduodenoscope (e.g. GIF-H190; GIF-XP180N; Olympus Medical Systems, Tokyo, Japan). Depending on the general condition of the patient, the procedure is performed either under sedation with propofol (e.g. Fresenius Kabi Germany GmbH) or under general anesthesia.

In our study, we assessed the size of the leak by visual measurement with the scale of the scope and determined the optimal stent position based on the following criteria: (i) sufficient coverage of the leak by the polyurethane foam and (ii) sufficient distance of at least 1 cm from each flare end to the leak. Size estimation measurements of wound cavities behind leaks were performed with the visual aid of a biopsy forceps (e.g. Radial Jaw™ 4, Boston Scientific, USA).

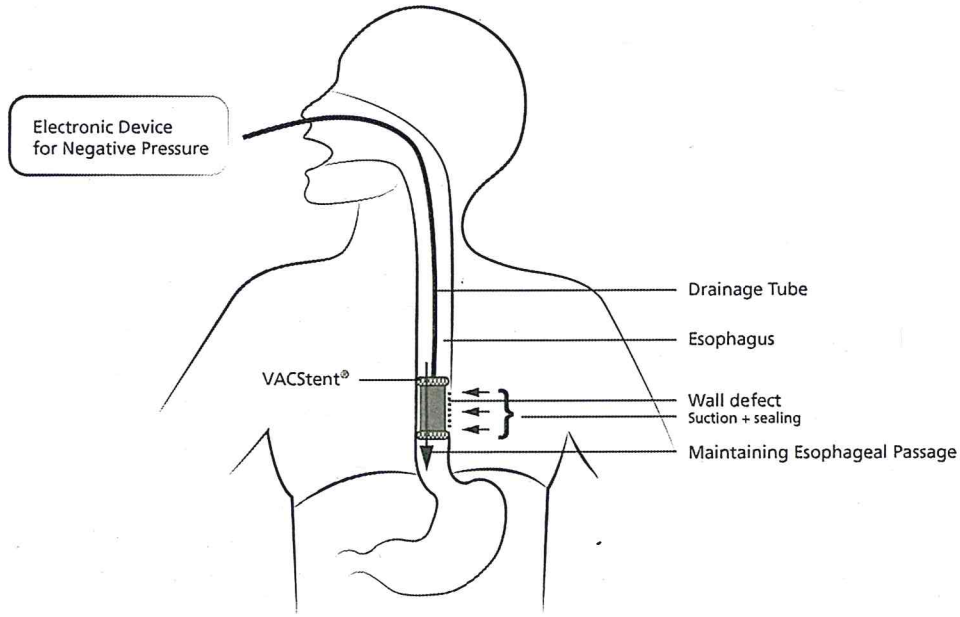

Fig. 2 Principle of VACStent® treatment.

We then advanced the delivery system to the leak over a guidewire (e.g. MTW-Endoskopie W. Haag KG, Germany) and carefully released the VACStent®, verifying adequate expansion by endoscopic guidance. After moving the drainage tube from the oral to the nasal cavity, it was connected to an electric vacuum pump (e.g. VivanoTec®, Hartmann AG, Germany) with a continuous negative suction of 65 mm of mercury (mmHg) (Fig. 2). Finally, the drainage tube was fixed with a nasal tube retaining system (e.g. Bridle Pro®, Applied Medical Technology, Inc. USA).

The VACStent® was exchanged every 3–5 days after each placement. For this purpose, the electric vacuum pump had to be turned off 2 hours prior to the intervention. Directly before the endoscopic extraction, we injected 20 mL of sterile water (e.g. Ampuwa®, Fresenius Kabi Germany GmbH) via the drainage tube to wet the sponge and thus facilitate its removal. Afterwards, the drainage tube was relocated into the oral cavity, and the VACStent® was removed by using a standard rat-tooth forceps while simultaneously pulling on the drainage tube. Finally, we examined the site of the leak to evaluate the healing process and to determine if the VACStent® treatment had already been successful in closing the leak. If the leak was not yet sealed, we evaluated if further VACStent® treatment was an option or if we needed to switch to a different therapy.

Additional treatment

Depending on the etiology of the leak, additional treatments and interventions were performed. In line with our clinical standard for managing esophageal leaks, we applied a triple lumen diverted NGT (e.g. Freka® Trelumina, Fresenius Kabi Germany GmbH) directly after all stent placements to ensure sufficient enteral nutrition and gastric decompression in case of excessive reflux. Further post-interventional treatment included intravenous anti-microbial and anti-fungal therapy as well as ultrasound-, CT-guided or surgical placement of an external drainage in case of extra-luminal fluid collections (D).

Outcome detection

The primary endpoint of this study was technical success, evaluated after each attempt of VACStent® placement and defined as the successful application of the stent in the intended position without adverse events.

As a secondary endpoint, we evaluated the clinical success of VACStent® treatment and defined this as successful closure of the leak irrespective of the number of VACStent® needed. Complete closure was defined as the absence of clinical or radiological signs of a persisting leak with no need for surgical or endoscopical re-intervention.

Unsuccessful treatment was defined as one or several of the following: persistent liquid passage through the leak, persisting fistula, a need for surgical repair, a need to change treatment strategy or death before confirmation of leak closure. After clinical suspicion of unsuccessful treatment, further assessment included endoscopy, contrast esophagogram or computed tomography (CT), with or without oral contrast.

Furthermore, we analyzed VACStent®-associated adverse events, such as bleeding, migration, stenosis, newly developed fistulas or leaks, a need for surgical repair or death.

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Moreover, we evaluated the possibility of oral food intake, duration of treatment, number of interventions and duration of hospital stay. We defined a serious adverse event as any complication associated with VACStent® treatment that required ICU care and/or resulted in death. All patients were scheduled for regular follow-up visits (until 12 months after discharge), including follow-up endoscopies.

Statistics

Distributions of quantitative variables were described as means (±SD), by median and interquartile range, or as a proportion where appropriate. Categorical variables were summarized by count and percentage. Due to the small number of cases, multivariate analyses were not performed. Data were managed with the SPSS Statistics Version 27 (IBM Corp., Armonk, NY, USA) for Windows (Microsoft Corp, Redmond, WA).

RESULTS

Baseline demographics and procedural characteristics

Our study included 20 patients (20 males, mean 61.3 ± 11.84 years), who underwent a total of 24 endoscopic VACStent® implantations. Details of the patients' baseline characteristics and procedural data are shown in Tables 1 and 2.

The following leaks were detected in the patient group: anastomotic leak after esophagectomy ($n = 12$, 60%), gastrectomy ($n = 5$, 25%) and suture leak after esophageal diverticulum resection ($n = 1$, 5%), as well as iatrogenic perforation after endoscopic dilatation ($n = 1$, 5%) and after ingestion of a foreign body ($n = 1$, 5%). The mean width of the leaks was 11 ± 6.81 mm, their mean length was 11.25 ± 7.23 mm and their mean depth was 21.50 ± 20.33 mm.

The most common post-interventional additional treatments were an NGT ($n = 20$) and an escalation of anti-microbial or anti-fungal therapy in 17 of the 20 cases (85%).

Prior to being transferred to our department for VACStent® treatment, 3 of the 20 patients (15%) had undergone endoscopic therapy using SEMS or EVT.

Ten of the twenty patients (50%) were treated at the intensive care unit, including four patients who were exclusively intubated for the endoscopic treatment with VACStent®. All other patients underwent endoscopic stenting in the endoscopy unit and were referred to the regular inpatient unit after the intervention.

Outcome of treatment

We achieved technical success in all interventions ($n = 24$, 100%). Successful treatment without a need for further intervention was reached in 12 patients (60%) (Fig. 3). The VACStent® was used as a first-line treatment in 17 patients (clinical success rate 71%, 12 out of 17) and as a second-line treatment in 3 patients (clinical success rate 0%, 0 out of 3). The median treatment duration was 4.8 ± 2.17 days. All 20 patients were hospitalized for a mean of 22.1 ± 13.99 days. The mean follow-up in our cohort was 109.2 ± 93.13 days. None of the follow-up endoscopies revealed a stenosis at the site of the sealed leak.

We did not achieve clinical success in 8 of the 20 patients (40%), leading to a change in treatment strategy: 7 of these patients received a tailored EVT (e.g. EsoSponge®, B. Braun, Germany), and 1 patient was scheduled for surgical repair. The histopathological examination of this patient's esophagus (#5) showed granulation tissue around the perforation site that had direct sponge contact.

Table 1 Baseline demographic and outcome characteristics of all patients

Variable	Overall
Number of patients	20
Age, mean (SD)	61.3 (11.8)
Sex	
Male, *n* (%)	20 (100.0)
Smoker, *n* (%)	7 (35.0)
BMI, mean (SD)	27.0 (7.0)
ASA score, median (IQR)	3 (1)
No prior treatment, *n* of total patients (%)	17 (85)
Etiology of leak	
Anastomotic leak	18 (90.0)
Iatrogenic perforation	2 (10.0)
Spontaneous perforation	0 (0)
Leak size width, mean (SD), mm	11 (6.81)
Leak size length, mean (SD), mm	11.25 (7.23)
Leak size depth, mean (SD), mm	21.50 (20.33)
Number of VACStent®, median (SD), *n*	1.2 (0.41)
Duration of implantation, mean (SD), minutes	8.29 (3.32)
Duration of explantation, mean (SD), minutes	6.25 (2.52)
VACStent®-associated complications, *n* of total patients (%)	
Migration	0 (0)
Bleeding	0 (0)
Perforation	0 (0)
Hospitalization, mean (SD), days	23.7 (15.05)
Days in ICU, mean (SD), days	8 (10.68)
Duration of VACStent® treatment, mean (SD), days	4.8 (2.17)
Follow-up, mean (SD), days	109.2 (93.13)
Technical success, *n* (%)	24 (100)
Clinical success, *n* (%)	12 (60)

VACStent®-associated adverse events

Although we achieved technical success in 100% of the cases, we faced some technical issues throughout the placement. Firstly, the inner diameter of the stent body did not expand to the full diameter of 14 mm in any of our patients directly after VACStent® placement. This did not affect the function of the VACStent® in terms of migration or suction power.

Table 2 Patient treatment details

Patient no	Leak closure	Age; sex	Diagnosis	Post-op day	Size of the leak, cm	Cavity size, cm	Latency of stenting, days	Previous treatment before stenting	Distance from the teeth, cm	Number of VACStent	Negative pressure, mmHg	Total duration of VACStent treatment, days	Final treatment
#1	yes	71;m	Anastomotic leak after esophagectomy	11	0.5 × 0.5	0.5	0	no	24	1	65	3	None
#2	no	63;m	Anastomotic leak after esophagectomy	11	0.5 × 0.5	0.5	0	no	39	1	65	3	Single EVT
#3	no	64;m	Anastomotic leak after esophagectomy	9	1 × 1	5	0	no	25	1	65	3	Single EVT
#4	yes	76;m	Anastomotic leak after gastrectomy	25	1 × 1	1	0	no	40	2	65	10	None
#5	no	73;m	Leak after resection of esophageal diverticulum	34	1 × 2	4	0	no	29	2	65	9	Surgery
#6	no	71;m	Anastomotic leak after esophagectomy	10	0.5 × 0.5	0.5	0	no	24	1	65	3	Single EVT
#7	yes	62;m	Anastomotic leak after gastrectomy	10	1.5 × 1	2	0	no	46	1	65	4	None
#8	no	56;m	Anastomotic leak after esophagectomy	211	2 × 2	7	9	Single EVT	25	1	65	4	Single EVT
Patient no	Leak closure	Age; sex	Diagnosis	Post-op day	Size of the leak, cm	Cavity size, cm	Latency of stenting, days	Previous treatment before stenting	Distance from the teeth, cm	Number of VACStent	Negative pressure, mmHg	Total duration of VACStent treatment, days	Final treatment
#9	yes	77;m	Anastomotic leak after esophagectomy	3	1 × 0.5	0.5	0	no	25	1	65	3	None
#10	no	67;m	Anastomotic leak after esophagectomy	5	1 × 1	6	0	no	25	1	65	4	Single EVT
#11	yes	31;m	Leak after foreign body ingestion	0	1 × 1.5	2	0	no	23	2	65	7	None
#12	yes	54;m	Leak after endoscopic dilatation	0	2 × 2	2	9	no	39	1	65	2	None
#13	yes	55;m	Anastomotic leak after esophagectomy	11	2 × 2	2	0	no	24	1	65	4	None
#14	yes	38;m	Anastomotic leak after esophagectomy	5	0.5 × 0.5	0.5	0	no	27	1	65	4	None
#15	yes	61;m	Anastomotic leak after esophagectomy	6	1 × 1	4	0	no	27	2	65	6	None
#16	no	71;m	Anastomotic leak after gastrectomy	21	0.5 × 0.5	0.5	11	Single EVT	38	1	65	5	Single EVT
Patient no	Leak closure	Age; sex	Diagnosis	Post-op day	Size of the leak, cm	Cavity size, cm	Latency of stenting, days	Previous treatment before stenting	Distance from the teeth, cm	Number of VACStent	Negative pressure, mmHg	Total duration of VACStent treatment, days	Final treatment
#17	yes	68;m	Anastomotic leak after gastrectomy	7	0.5 × 0.5	0.5	0	no	37	1	65	3	None
#18	no	59;m	Anastomotic leak after gastrectomy	44	3 × 3	3	16	Single EVT	45	1	65	7	Single EVT
#19	yes	52;m	Anastomotic leak after esophagectomy	11	1 × 1	1	0	no	26	1	65	6	None
#20	yes	57;m	Anastomotic leak after esophagectomy	4	0.5 × 0.5	0.5	0	no	27	1	65	6	None

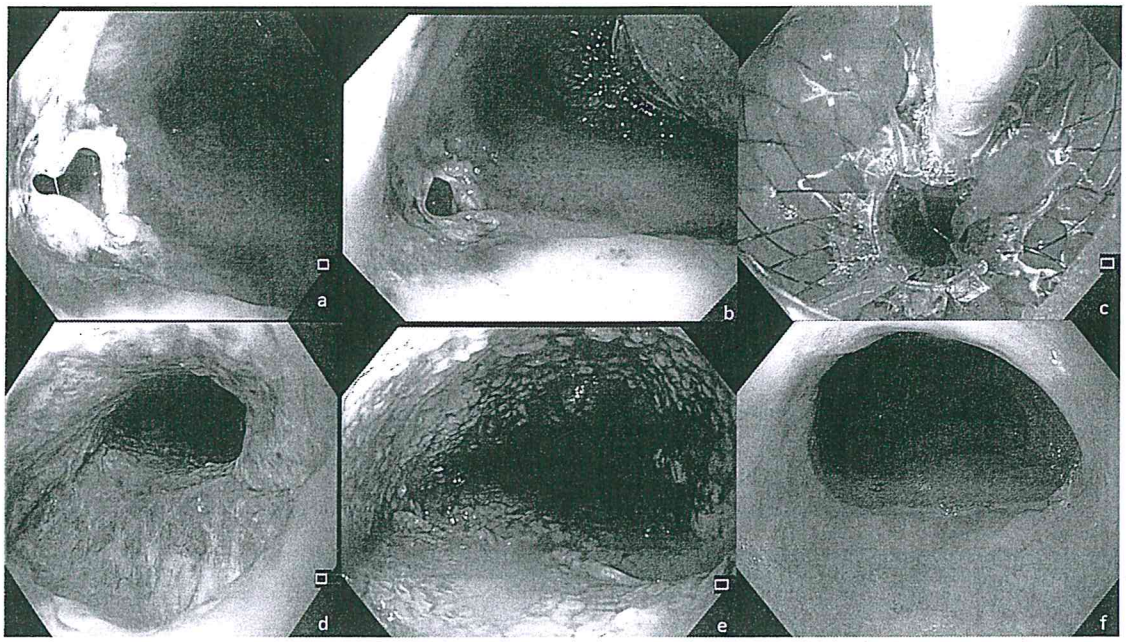

Fig. 3 (a) Endoscopy showing a leak of the esophagogastrostomy before VACStent® treatment. (b and c) Implantation of VACStent®. (d) Area of the upper flare end of the esophagus after VACStent® removal. (e) Sealed anastomotic leak with vital granulation tissue. (f) Follow-up endoscopy, 30 days after discharge.

However, to enable the placement of an NGT, we decided to resolve this issue by using pneumatic balloon dilations (e.g. CRE™ Balloon Dilatation Catheter, Boston Scientific, USA). Secondly, none of our patients were able to drink oral nutritional supplements (e.g. Fresubin Energy Drink, Fresenius Kabi Germany GmbH) or eat soft food during the VACStent® treatment as this led to food particles clogging the drainage tube.

We performed VACStent® implantation under sedation with propofol in 16 of the 20 patients (80%) without any adverse events. No severe VACStent® treatment-related adverse events occurred, and no patient died because of the endoscopic treatment. However, due to the advanced metastatic stage of their malignant disease, 3 patients died 39, 42 and 80 days after the endoscopic stenting with VACStent®.

DISCUSSION

Esophageal leaks are associated with significant morbidity and mortality.[1,2] Endoscopic treatment options play an important role in their therapeutic management.[3–7] A novel endoscopic technology combines SEMS and intraluminal EVT in one medical device: the VACStent®.[16,18] Our prospective study presents the first systematic use of VACStent® for the treatment of leaks of the esophagus and summarizes our single-center experience of treating a heterogeneous group of patients.

In our study, technical success of VACStent® treatment was achieved in all 24 stent placements (100%). Just as we experienced in our earlier retrospective study, we again observed an incomplete expansion of the middle part of the VACStent® directly after deployment in all stent placements.[18] This is an important observation because it may have an impact on the function of the VACStent®. SEMS may take 1–2 days to extend fully, which can be problematic in VACStent® treatment as the common exchange interval for EVT is 3–5 days. Consequently, the SEMS functions properly for only a brief amount of time before the device needs to be exchanged again. A reason for the incomplete expansion of the VACStent® may be the thickness of the sponge itself, which counteracts the radial expansion force. In a previous study, we were able to show that a compression of the middle part of the stent influences the expansion forces of the stent in general.[20]

When using SEMS for the closure of leaks, migration is a common adverse event.[7,12] We observed no stent migration throughout the study, even in intestinal lumen with different diameters (e.g. esophagogastrostomy). A possible explanation might be that the suction power of intraluminal EVT in combination with an SEMS potentiates the stability of the VACStent®. Furthermore, the drainage tube, which is fixed at the nose, helps to prevent migration by acting as an anchor.

Removal of the VACStent® can be challenging and may lead to complications, such as perforations or bleeding.[13] To reduce the risk of these complications, we used a continuous negative pressure of 65 mmHg, switched off the vacuum pump 2 hours before the extraction and moistened the sponge. These precau-

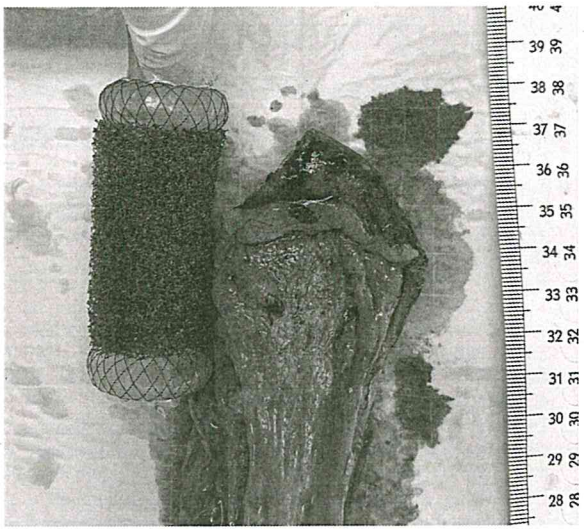

Fig. 4 The VACStent® treatment is shown in patient #5. Position of VACStent® at the esophageal perforation with the typical granulation tissue after endoluminal EVT.

tions may have contributed to the fact that no serious adverse events occurred during the VACStent® treatment. Interestingly, we observed that the treatment with a continuous negative pressure of 65 mmHg was sufficient for sealing and showed equal granulation of the mucosa in the histological analysis as we had observed in our previous study where we applied a continuous negative pressure of 125 mmHg (Fig. 4).[18] While these are promising results, a larger patient cohort is needed to verify our results concerning the ideal negative pressure.

Successful treatment with VACStent® was achieved in 60% of our patients (12 of 20), whereas our previous study reported a rate of 70%. The clinical success rate of this study appears to be lower compared to previous studies focusing on single treatment with EVT or SEMS.[4,12,21] In our study, 5 of 8 patients with unsuccessful VACStent® treatment presented a leak with a wound cavity of more than 2 cm in depth. An explanation for this unsuccessful treatment may be found in the applied EVT technique: VACStent® only allows EVT in the esophagus and thus lacks direct contact to the tissue inside the cavity. In single EVT use, the sponge can be successfully applied into the cavity and as a treatment combination like the SOS method (intracavitary EVT with an intraluminal SEMS) to leak with big cavities, which potentially extends the indication for EVT with regard to the leak size.[15,22,23] Therefore, the variety of single EVT application offers multiple indications for various leak sizes and cavities. This suggests that the spectrum of indications for VACStent® may be limited, but a larger patient cohort is needed before final conclusions can be drawn.

An important purpose of using VACStent® is to combine EVT with the advantage of SEMS to maintain intestinal passage. Since patients were able to drink clear water without complications in our previous study, we assumed that the intake of liquid nutritional supplements might also be possible during VACStent® therapy. Unfortunately, we observed that food particles surrounded the leak after extraction of the VACStent and caused repeated clogging inside the drainage tube. This finding indicates that food particles can pass behind the flare ends of the VACStent® possibly impairing its function.[21] One explanation for this observation may be the design of the VACStent® itself: a possible lack of expansion force, the thickness of the foam cover and the construction of the flare ends—all of which might suggest the need to modify its mechanical properties or cover.[20]

Another reason could be the applied suction power, which could have caused insufficient sealing by the stent flares. Since VACStent® is a new treatment option and combines radial expansion forces of SEMS with endoluminal EVT, the recommendation for the ideal negative pressure has not yet been determined and should be further investigated. Apart from this, the chosen exchange interval of 3–5 days might be too brief to allow a complete sealing between the flare ends of the stent and the esophageal mucosa. A longer replacement interval might be helpful; however, previous experience with EVT shows that frequent exchanges of the sponge are favorable to reduce contamination of the leak and clogging of the sponge.

While VACStent® seems a viable treatment option, it is important to evaluate the treatment costs, especially in times of limited financial resources.

In an earlier study, we compared treatment costs of EVT and SEMS treatment and found that EVT is twice as expensive.[24] Since the sponge system of the VACStent® is similar to that in EVT, it is likely that it will need to be exchanged with a similar frequency. Therefore, overall costs of VACStent® treatment may be greater due to a higher rate of necessary endoscopies and possible VACStent® exchanges. On the other hand, the efficacy of leak closure may be higher, and the optimal exchange interval has yet to be determined.

Based on the results of our study, VACStent® seems to be a safe and feasible procedure as there were no serious adverse events associated with the application of the device itself in our cohort. Since VACStent® is a modified intraluminal EVT technique that cannot be applied inside a cavity, we do not see any superiority in its application in leaks with big wound cavities compared to intracavitary EVT or the SOS method.[22,23] Consequently, possible indications for the VACStent® may be early leaks with or without small wound cavities.

As VACStent® is a new and unestablished treatment option, close patient monitoring is essen-

tial and exit strategies, such as salvage surgery, EVT or SEMS treatment, need to be considered continuously.

Limitations of this study are a limited patient cohort, a lack of different VACStent® designs (length, diameter and short sponge body) and technical deficiencies in the mechanical properties of VACStent®.

In conclusion, VACStent® is a safe and technically feasible endoscopic treatment option for leaks of the upper gastrointestinal tract. However, our data could not support the expected advantage of orally feeding the patients during the treatment with the VACStent® in its current form. A modification of the VACStent® and the identification and evaluation of selection criteria for this advanced endoscopic treatment option are highly recommended.

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