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Multi-modality management of defects in the gastrointestinal tract: Where the endoscope meets the scalpel: Endoscopic vacuum therapy in the upper gastrointestinal tract

Lisanne M.D. Pattynama [a,b,c,d], Wietse J. Eshuis [b,d], Stefan Seewald [e], Roos E. Pouw [a,c,d,*]

[a] Amsterdam UMC Location Vrije Universiteit Amsterdam, Department of Gastroenterology and Hepatology, De Boelelaan 1117, Amsterdam, the Netherlands
[b] Amsterdam UMC Location University of Amsterdam, Department of Surgery, Meibergdreef 9, Amsterdam, the Netherlands
[c] Amsterdam Gastroenterology Endocrinology Metabolism, Amsterdam, the Netherlands
[d] Cancer Treatment and Quality of Life, Cancer Center Amsterdam, Amsterdam, the Netherlands
[e] Centre of Gastroenterology, Klinik Hirslanden, Zürich, Switzerland

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ABSTRACT

Background: Transmural defects in the upper gastrointestinal (GI) tract, such as anastomotic leakage and oesophageal perforations, are associated with significant morbidity and mortality risks. Endoscopic vacuum therapy (EVT) is an efficient and safe treatment option for these patients. With the growing use of EVT in the upper GI tract, it is important to share expertise on the topic.
Aim: This review explores the emerging role of endoscopic vacuum therapy (EVT) as treatment for transmural defects in the upper GI tract. An overview of the mechanism and procedures, outcomes in current literature and challenges of implementation and application are discussed.
Conclusion: EVT exhibits great efficacy and safety for the treatment of transmural defects in the upper GI tract. Current use of EVT is mostly experience-based, emphasizing the importance of sharing expertise and performing research to unlock its full potential.

1. Introduction

Transmural defects in the upper gastrointestinal (GI) tract are defined as a disruption or injury extending through all layers of the oesophageal or gastric wall [1]. These defects can result from various causes, including anastomotic leakage (AL) after oesophago-gastric surgery, iatrogenic perforation, Boerhaave syndrome or trauma. Transmural defects in the upper GI tract are associated with serious consequences, such as leakage of saliva, gastric contents and bile into the mediastinum, triggering an inflammatory response. Untreated or inadequately managed mediastinitis can lead to serious morbidity, sepsis and mortality. Therefore, timely diagnosis and treatment of these defects is crucial [2].

There are several treatment options for transmural defects in the upper GI tract. Conservative management involves a nil by mouth protocol, antibiotics and (percutaneous) drainage. Endoscopic treatments include self-expandable metallic stents (SEMS), through-the-scope clips, over-the-scope clips, suturing with overstitch, and most recently, endoscopic vacuum therapy (EVT) [2,3]. Historically, SEMS has been the most used treatment option for transmural defects in the upper GI tract. However, persisting leakage and complications such as dislocation of the stent are not uncommon [4–6]. Besides that, not all defects are suitable for stenting and additional percutaneous drainage is often necessary, but not always possible.

Surgical treatment, such as a re-anastomosis or resection of the gastric conduit with construction of a cervical esophagostomy is generally required in severely septic patients [2]. The choice of treatment depends on factors such as the location and size of the leakage, severity of symptoms, and presence of conduit ischemia or necrosis.

In the past decade, EVT has been established as an effective and safe endoscopic treatment option, and it was found to be superior in terms of success rate in AL healing compared to other treatments [7–10].

However, the implementation of EVT in clinical practice might be hindered by multiple challenges and questions regarding indications

* Corresponding author. De Boelelaan 1117, 1081, HV, Amsterdam, the Netherlands.
E-mail addresses: l.m.pattynama@amsterdamumc.nl (L.M.D. Pattynama), w.j.eshuis@amsterdamumc.nl (W.J. Eshuis), Stefan.Seewald@gastrozentrum.ch (S. Seewald), r.e.pouw@amsterdamumc.nl (R.E. Pouw).

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and techniques. Sharing expertise on the topic, including mechanism, (contra)indications, procedures, types of EVT, comparison with other treatment options and how to overcome challenges could help facilitate implementation of EVT and avoid common mistakes in daily practice. To prevent centers from having to re-invent the wheel, it is very important to provide clear and accessible guidance on the technique.

2. Overview

2.1. Mechanism

The effect of EVT is based on negative pressure wound therapy, which facilitates multiple aspects of defect closure. Firstly, the vacuum induces approximation of the defect edges and collapse of the extraluminal cavity (if present). Secondly, fluids are actively drained, which helps removing contaminants and infectious material, creating a clean environment conductive to the development of healthy granulation tissue. Thirdly, the negative pressure leads to formation of granulation tissue by inducing angiogenesis, reducing edema and activating cell proliferation and migration of fibroblasts, endothelial cells and other cells involved in tissue repair. This granulation tissue is instrumental in the overall healing of transmural defects in the upper gastrointestinal tract [1,11].

Generally, due to the negative pressure and formation of granulation tissue, the EVT device adheres to the mucosa firmly. To limit ingrowth into the surrounding tissue, it is imperative to exchange the EVT device during the course of the treatment. The regular endoscopies during EVT provide the opportunity to inspect the defect and asses the healing tendency, switch techniques and perform additional nettoyage when necessary.

2.2. Indications

EVT can be used for a variety of indications in the upper GI tract, including anastomotic leaks after oesophago-gastric surgery, iatrogenic perforations, Boerhaave syndrome and trauma (i.e. foreign body ingestion) [11–14]. EVT provides the opportunity to apply a safe and organ-sparing treatment, aimed at maintaining continuity of the gastrointestinal tract.

2.2.1. Contraindications

EVT has few absolute contraindications, including a defect that is not endoscopically accessible, suspicion of fistula formation to a large blood vessel or bronchus and prohibition of access to a defect and adequate placement of an EVT device, for example in case of a stenosis.

Successful application of EVT is only possible if negative pressure wound therapy can be adequately applied, including mechanical closure of the defect, proper drainage and formation of granulation tissue, as described above. There are several defect-related factors that could directly influence adequate application of negative pressure wound therapy, which should be considered before inducing EVT. These factors include defect etiology, time to diagnosis, defect location, defect size and, if present, cavity size and contamination.

Literature shows that early diagnosis and treatment of the defect is related to a higher success rate [13,15]. Therefore, early diagnosed defects or anastomotic leakages (e.g. post-operative day 5–7) are generally suitable for EVT. However, in case of a very early leakage (e.g. post-operative day 1), the possibility of technical failure should be considered, for which surgical revision may be indicated.

In case of a chronic defect, due to increased rigidity of the tissue, there is a risk of inadequate approximation of the defect edges and, in some instances, collapse of the cavity. Therefore, in these cases, it is extra important to assess progress and establish close collaboration between the departments of gastroenterology and surgery to evaluate the best treatment options.

Defect location is an important factor to take into account when deciding which treatment to use. Cervical defects are associated with challenges, due to the small diameter and close proximity to the upper oesophageal sphincter. Therefore, a defect too close to the upper oesophageal sphincter is generally not suitable for EVT, as placement and removal are very challenging. Furthermore, the EVT device may not be well tolerated by the patient. If EVT is the treatment of choice in these cases, we would recommend placement of an EVT device with a smaller diameter.

Generally, intrathoracic defects, for example intrathoracic oesophago-gastric anastomotic leakages, are suited for all types of EVT. On the contrary, EVT for oesophago-jejunal anastomotic leakage could be difficult, as this may be associated with more frequent dislocations in our experience.

A large size and great extent of contamination of a connected cavity are associated with a longer treatment trajectory and possibly a lower rate of successful closure. In these cases, the focus should be on cleaning the cavity and gradually reducing the cavity size, before complete closure can be achieved. In some cases, additional external drainage may be required.

2.2.2. Intracavitary vs intraluminal

The indications for intraluminal or intracavitary EVT are a regularly discussed topic, with only few studies on the topic, showing variable results [15,16]. No superiority can be concluded on the best indications for specific techniques, owing to the few studies with small sample sizes. Therefore, the best EVT technique is currently experience based, where the placement of EVT is determined on a per-patient basis. Generally, large defects and cavities are treated with intracavitary treatment, because this may result in better drainage, while smaller defects are treated intraluminally. The cut-off size in this matter differs according to facilities, experience and preference of the endoscopist. In our experience, efforts should be made to facilitate the transition from intracavitary to intraluminal as fast as possible. The most severe reported complications are associated with intracavitary vacuum-devices. Generally, intracavitary EVT will require an endoscopy to exchange the EVT device on a more frequent interval.

2.3. Types of EVT devices

Various types of EVT devices are used, ranging from commercially available sponges to custom-made variants and innovative solutions like the vacuum-stent.

2.3.1. Vacuum-sponges

During the last couple of years, a range of variations on vacuum-sponges has been reported, including commercially available pre-fabricated sponges and custom-made versions.

A commonly used pre-fabricated sponge is the EsoSponge (EsoSPONGE; Braun B. Melsungen, Germany), a polyurethane sponge measuring 50 mm in length and 13 mm in diameter (Fig. 1). Pre-fabricated sponges are ready to use, come with additional materials to facilitate placement and connection to the vacuum pump and can be cut to the desired diameter. However, in comparison to custom-made vacuum-sponges, the costs are higher, the sponge length is fixed and waste production is increased, as the additional supplied materials are not always used.

For custom-made sponges, there are many possibilities. The regular vacuum-sponge can be made using open-pore foam drainage or open-pore film drainage, a gastric tube and stitches. Open-pore foam drainage is the original technique for EVT, using polyurethane sponge-like material, which is mostly used in practice and literature. Open-pore film drainage is a relatively new technique, using a drainage film, which allows for a small diameter and less tissue ingrowth [17,18]. (Fig. 1)

Another example of a custom-made EVT-device is the combination of a triple-lumen tube, to allow for nutrition using the distal tube, and EVT,

Fig. 1. EsoSponge (top) and a custom-made device using open-pore film drainage material (bottom). Image courtesy of Oesophageal Research Team Amsterdam UMC.

using drainage material on the fenestrated part of the tube [17,19]. (Fig. 2)

In literature, superiority of either technique has not been assessed. Generally, the choice of technique mostly depends on available resources and experience of the physician.

As oral intake is not possible during treatment with a regular vacuum-sponge, it is important to consider placing a feeding tube if necessary.

2.3.2. Vacuum-stents

The vacuum-stent is commercially available as the VAC-Stent (MICRO-TECH Europe GmbH). It consists of a suction catheter attached to a fully covered stent with a polyurethane sponge on its outer surface (Fig. 3).

The stent is inserted within the lumen over the defect and attached to a vacuum pump, establishing a confined space with negative pressure at the defect site. This approach combines the benefits of negative pressure wound therapy with the sealing effect provided by the stent. Additionally, the negative pressure prevents dislocation of the stent, a frequent complication associated with traditional covered stents. Additionally, the stent keeps the oesophageal lumen open, facilitating oral intake.

2.4. Procedures

Generally, two primary approaches are practiced: vacuum-sponge and vacuum-stent procedures.

EVT procedures are performed with patients under deep propofol sedation or general anesthesia. During the initial endoscopy, a meticulous examination and careful cleaning of the defect are standard procedures, determining eligibility for EVT. The EVT location and

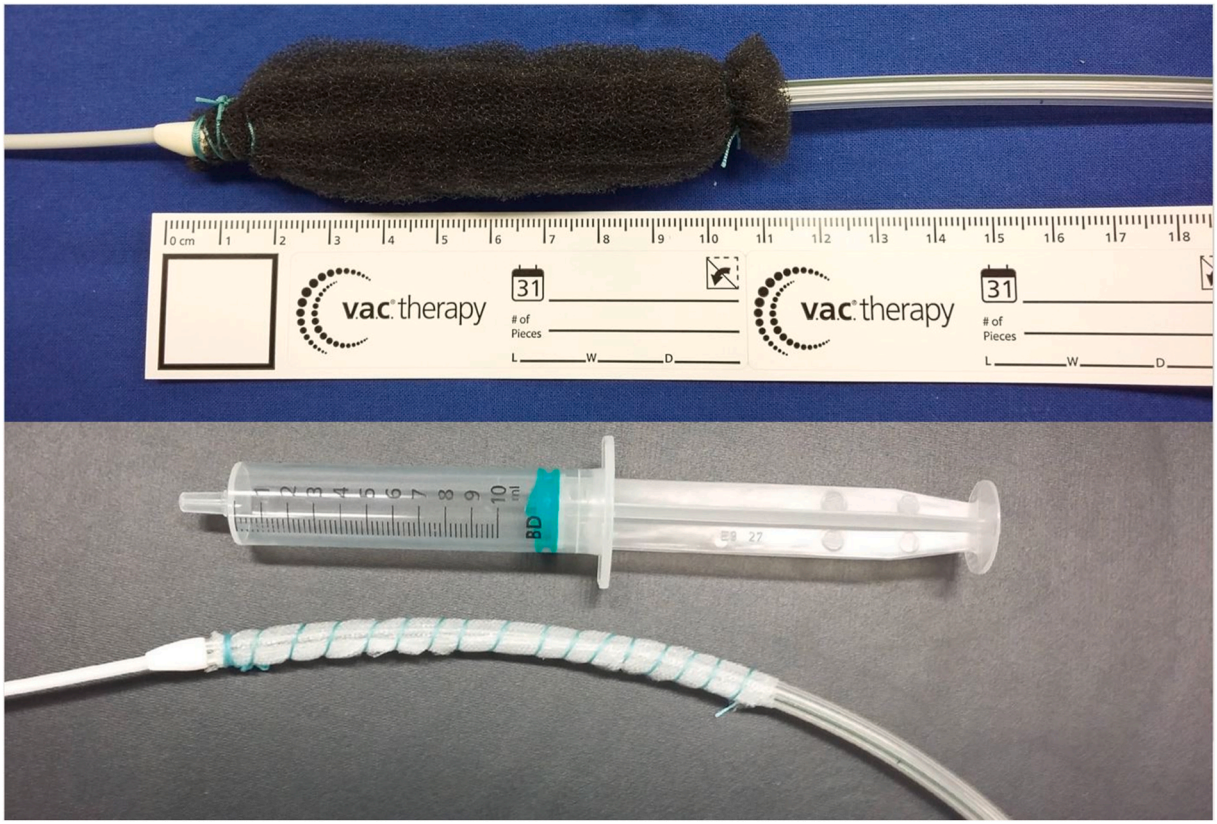

Fig. 2. Tri-lumen EVT-device with open-pore foam drainage (top) and open-pore film drainage (bottom). Image courtesy of Oesophageal Research Team Amsterdam UMC.

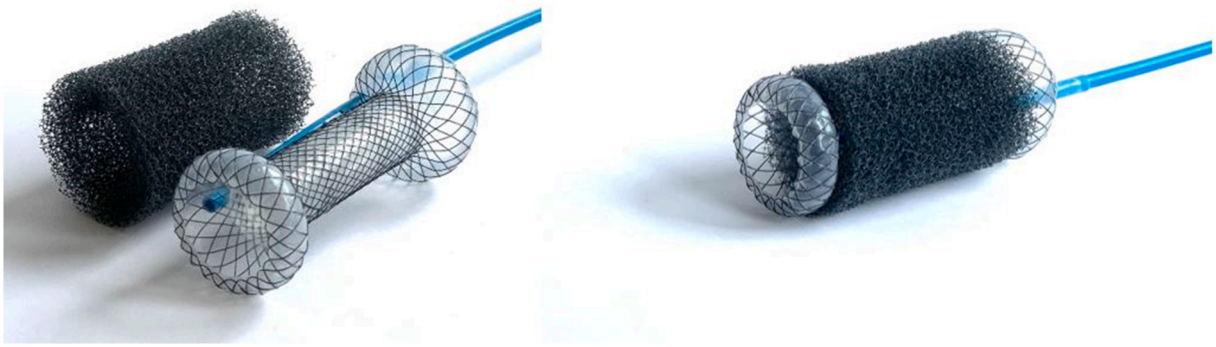

Fig. 3. VAC-Stent with fully covered nitinol stent (length 72 mm, diameter 30-14-30 mm), polyurethane sponge (length 50 mm), and blue suction catheter. Image courtesy of Oesophageal Research Team Amsterdam UMC. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

technique are usually determined by the endoscopist, considering factors such as defect and cavity width, as well as the extent of debris. Generally, patients with defects large enough for endoscope passage and substantial cavities undergo intracavitary therapy initially, while those with smaller defects and cavities can often proceed directly to intraluminal therapy. The type of EVT device is determined based on these defect characteristics, the facilities of the center and the experience of the endoscopist.

2.4.1. Vacuum-sponge

The vacuum-sponge can be used intracavitary and intraluminally. First, the appropriate sponge size is determined and the vacuum-sponge is trimmed or prepared based on the cavity width. Sponge placement can be performed using an overtube or a grasping forceps, as preferred by the endoscopist.

When using the intracavitary technique, it is important to make sure the sponge sticks out approximately 1 cm intraluminally, to prevent a remaining large cavity from closing above the sponge, impeding removal of the sponge.

After sponge placement, the tube of the sponge is guided from the oral cavity to the nose and fixed with plaster onto the nose. Correct positioning is confirmed under endoscopic vision before applying vacuum. Adequate vacuum function can be assessed by observing cavity collapse with the application of vacuum. Generally, the pressure of the vacuum pump (ActiV.A.C.; 3 M Health Care, St. Paul, Minnesota, USA) generally ranges from −50 mmHg (for intracavitary sponges) to −125 mmHg (for intraluminal sponges).

Removal of an EVT device can present challenges as the device adheres to the mucosa. Flushing the EVT-device 3 times per day with 20 cc H_2O and switching off the vacuum pump a few hours before removal could facilitate easier removal. Furthermore, we recommend placing a distal attachment cap on the endoscope, which helps to maneuver the endoscope between the sponge material and the mucosa. If the device is separated completely on the whole circumference with the endoscope, it can be removed in a controlled and easy way while preventing complications.

Additional information and imagery on the procedures of EVT, including presentations, tips and tricks and example cases are available at our web-based platform www.EVT-academy.com.

2.4.2. Vacuum-stent

The placement procedure involves inserting a stiff guidewire (Ø 0.035") into the duodenum, followed by the removal of the endoscope. The VAC-Stent introduction device is then advanced over the guidewire and introduced into the oesophagus. Simultaneously, the endoscope is introduced alongside the VAC-Stent introduction device to ensure proper positioning of the VAC-Stent under visualization, covering the defect with the sponge part of the stent. Subsequently, the VAC-Stent is deployed under endoscopic view via the distal release system, with continuous adjustments to its position during deployment. Following complete deployment, the guidewire and introduction system are removed. Lastly, the blue suction catheter is guided through the nose and connected to a vacuum pump set at −125 mmHg.

After VAC-Stent placement, the negative pressure is reduced to −75 mmHg the next day. On the day of VAC-Stent placement, patients generally adhere to a nil per mouth policy, with the initiation of a liquid diet on the subsequent day, progressing to a soft diet if tolerated. While the VAC-Stent is in place, the insertion of a feeding tube through the stent can be considered if deemed necessary. To maintain the suction catheter's openness and prevent stent ingrowth, the VAC-Stent can be regularly flushed with 20 cc H_2O three times per day.

After 5–7 days, the VAC-Stent can be removed. To simplify the removal process, the vacuum pump can be switched off several hours before the procedure. In addition, a 'tapered hood' distal attachment cap (i.e. DH-28GR Hood; FUJIFILM Corporation, Tokyo, Japan) can be attached to the endoscope tip to facilitate maneuvering between the stent and the mucosa. The stent and sponge are gently loosened from the mucosa by moving the endoscope from the mucosa to the stent in a downward motion on all sides. The proximal site's blue string is then pulled with a grasping forceps to safely remove the VAC-Stent. Post-removal, the defect site is inspected to evaluate closure and determine the need for additional EVT, with the possibility of placing a new VAC-Stent if deemed necessary.

2.5. Complications

As most literature reports on vacuum-sponges, the majority of reported adverse events for EVT are regarding vacuum-sponges. These include minor haemorrhage (2–4%), sponge dislocation (5–8%) and discomfort (e.g. due to the suction tube through the nose or nausea). Furthermore, a stricture can occur on the site of the anastomosis after EVT (5–18%) [1,4,15,20,21]. However, as a stricture also frequently occurs in patients with anastomotic leakage after oesophagectomy with other treatments than EVT, the exact influence of EVT on development of stenosis is unknown [22].

The most severe complications during EVT occur with the development of fistulae. Firstly, tracheo-broncho-oesophageal fistulas have been reported as complication of EVT [20].

Secondly, the development of an aorto-oesophageal fistula has been described as a very rare but possibly fatal adverse event during EVT [23,24]. However, the causal relationship between EVT and the occurrence of fistulas is unknown. Tracheo-broncho-oesophageal fistulas could be interpreted as a result of ineffective primary leakage treatment in an often radiated environment, rather than as a complication of EVT. Moreover, comparable major hemorrhages have been reported after oesophageal defects caused by foreign body ingestion [25–27]. In these

cases, subsequent infection of the mediastinum further contributed to the formation of the aortic pseudoaneurysm, which could also be the case in the described EVT patients. Nonetheless, direct contact with large vessels or airways should be avoided.

Only few adverse events have been described regarding the vacuum-stent. In three case series, with a total of 45 patients, stent migration occurred in one patient and two post-EVT strictures were reported [28–30].

3. Outcomes in literature

It is important to separately assess outcomes of EVT for the different defect etiologies, as these have different underlying mechanisms with their own morbidities and challenges.

3.1. Anastomotic leakage

EVT has shown great efficacy and safety in patients with anastomotic leakage after upper gastrointestinal surgery, with success rates from 80 to 100% and adverse event rates from 0 to 10% [8,21,31,32]. Retrospective studies show that unsuccessful defect closure with EVT might be associated with more complications, lower platelet count at diagnosis, neoadjuvant treatment, the intraluminal technique and higher mortality rate [15,16]. Only few studies have assessed the location of the anastomosis in relation to success rate. Although no significance has been shown yet, EVT might be less effective with cervical and oeseophago-jejunal anastomoses when compared to intrathoracic anastomoses [14].

3.2. Oesophageal perforations

Most literature on EVT reports on the outcomes of all defect etiologies combined, without separately describing oesophageal perforations. In a multicenter study, we have found a success rate of 89% for non-anastomotic oesophageal perforations, including Boerhaave syndrome, iatrogenic defects and 'other defects' (i.e. trauma) [13]. When separately assessed, success rates of Boerhaave syndrome, iatrogenic defects and 'other defects' were respectively 67%, 100% and 100%.

3.3. Preemptive use

There is growing evidence supporting ischemic preconditioning to improve tissue perfusion and prevent occult ischemia [33]. In cases where mild ischemia of the gastric conduit is presumed, EVT could be used to facilitate a clean environment for (re)operation in case of persisting leakage, or even to prevent anastomotic leakage after gastro-intestinal surgery. Felinska et al. used 18 porcine models with a gastric conduit with artificially induced ischemia and applied EVT afterwards, which facilitated a significant increase in tissue oxygenation [34]. Muller et al. showed feasibility of pre-emptive EVT with a vacuum-sponge after minimally invasive Ivor Lewis oesophagectomy, with a 30-day mortality of 0% and an overall anastomotic leakage rate of only 7.5% [35]. Furthermore, Loske et al. report an AL rate of 0% in 43 patients after Ivor Lewis oesophagectomy using preemptive active reflux drainage with a double lumen open-pore film drainage device [36].

3.4. Cost-effectiveness

Literature on cost-effectiveness is scarce and consists of only small retrospective case series.

Baltin et al. describe that EVT is more costly than SEMS, which was mostly contributed to insufficient reimbursements for EVT [37]. Eichelmann et al. retrospectively analyzed the costs of different treatment modalities in patients with anastomotic leakage after oesophagectomy. They described that 75–80% of the total costs were contributed to intensive care stay [38].

Studies suggest that the costs of EVT may decrease, while efficacy will increase with more experience, due to identification of the best indications, prevention of complications and a decrease of procedure time [20,39].

3.5. Quality of life

Only few studies have assessed quality of life (QoL) in patients treated with EVT. Dhayat et al. compared QoL after 1–2 years of patients after gastro-oesophageal surgery treated with EVT with patients after gastro-oesophageal surgery without complications. They only found little differences, concluding that EVT in the upper GI tract is well tolerated [40]. Fair et al. studied long term QoL after 3–5 years in patients with upper GI leaks treated with EVT, compared to other treatment modalities. Scores of all QoL domains were in favor of EVT, with statistical significance in physical functioning, role limitations due to physical health, energy/fatigue and social functioning [41].

4. Challenges in EVT

During implementation of EVT, a variety of challenges need to be overcome, including a learning curve, logistics, cooperation with all involved parties and daily care.

4.1. Learning curve

As the indications and techniques of EVT have to be adjusted specifically to every scenario, which is variable between patients and even in the same patient, the application of EVT is associated with a learning curve. Reimer et al. divided 156 patients treated with EVT into two consecutive equal-sized cohorts. Over time, clinical and endoscopic improvements for EVT were made based on experience. They demonstrated better outcomes in the second group, resulting in accelerated recovery, fewer complications and improved functional outcome [20].

To facilitate adequate implementation and possibly accelerate the learning curve of EVT, we have created a publicly available web-based platform as source of information and training: www.EVT-academy.com.

4.2. Logistics

The unpredictability of the first EVT placement and regular exchanges demand flexibility of the endoscopy schedule, including the endoscopist, endoscopy nurses and anesthesiology. Therefore, it is important to implement a clear protocol with all involved parties on when to perform an endoscopy. Additionally, efficient multidisciplinary cooperation has to be established between the departments of Gastroenterology, Surgery and Anesthesiology. It is important to educate all involved parties, including staff on the ward. This could be done by timely provision of clear protocols and organization of educational meetings and presentations beforehand.

4.3. Daily care

It is essential to involve staff on the ward with education on the mechanisms and regulations regarding EVT. Important to take into account are responsibilities, vacuum pressure, clear dietary restrictions, amount of exchanges and, if applicable, flushing and timing of switching off the vacuum pump.

In specific cases, patients can continue EVT via the outpatient clinic. This is only possible if the outpatient infrastructure allows for close monitoring and an endoscopically experienced outpatient nurse is available. Additionally, the clinical and endoscopic conditions need to be stable, the patient, partner and/or caretaker have to be reliable and confident with the responsibilities, all important risks have to discussed and required actions (i.e. flushing and vacuum pump instructions)

should be explained and practiced. Furthermore, we recommend a very low threshold for contact and to assess inflammatory parameters and clinical status of the patient in between device exchanges. As patients treated with EVT are often hospitalized for a long period of time, continuation of treatment via the outpatient clinic could provide a substantial benefit for the wellbeing of the patient and reduce healthcare costs.

5. Conclusion

EVT is a very efficient and safe endoscopic treatment for defects in the upper GI tract, with success rates ranging from 80 to 100%. Indications, techniques and device type are currently experience based, underscoring the importance of sharing experiences. EVT has the possibility to be a life-saving organ-sparing treatment, improving health for patients and reducing health care costs. Standardization and evidence-based protocols for EVT, focusing on refining techniques and identifying optimal indications, are important to reach its full potential.

6. Summary

Endoscopic vacuum therapy (EVT) is a promising and versatile intervention for managing transmural defects in the upper gastrointestinal tract. Despite challenges, EVT exhibits great efficacy and safety, emphasizing the need for standardized protocols and evidence-based practices. The overview, including mechanism, indications, types of EVT devices and complications provide a comprehensive understanding of EVT, guiding clinicians in decision-making. Common challenges in EVT are highlighted, facilitating adequate implementation of EVT and helping to avoid common mistakes in daily practice. Research focusing on the best indications and techniques is important for standardization and evidence-based protocols, enabling exploration of the full potential of EVT.

Practice points

- Understanding the mechanism of EVT is necessary to be able to apply and adjust the treatment adequately;
- Defect etiology, time to diagnosis, defect location, defect size and, if present, cavity size and contamination should be considered to determine the best management strategy;
- Multidisciplinary cooperation is crucial for successful EVT implementation;
- Adherence to standardized protocols is essential for optimal EVT outcomes;
- Ongoing education is imperative for healthcare professionals involved in EVT procedures.

Research agenda

- Research should aid in the trend from expert-based to evidence-based practices;
- As EVT has already established its efficacy and safety, the focus should be on identifying the best indications and techniques for EVT
  - o Indications: comparative effectiveness research to further delineate EVT's role in specific clinical scenarios. This could include comparison between different EVT devices, including the vacuum-stent and open-pore film drainage;
  - o Techniques: vacuum settings, location, placement, etc.;
- Large prospective studies assessing abovementioned factors are the way to go to establish evidence-based EVT protocols;
- Cost-effectiveness;
- Preemptive endoscopic vacuum therapy to possibly prevent anastomotic leakage after oesophago-gastric surgery.

CRediT authorship contribution statement

Lisanne M.D. Pattynama: Data curation, Writing – original draft, Writing – review & editing. **Wietse J. Eshuis:** Writing – review & editing. **Stefan Seewald:** Writing – review & editing. **Roos E. Pouw:** Conceptualization, Supervision, Writing – review & editing.

Declaration of competing interest

Dr. Roos E. Pouw is consultant for MicroTech Europe.
The other authors declare no conflict of interest.

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