Endoscopic management of complications—endovacuum for management of anastomotic leakages: a narrative review

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Abstract: Anastomotic leakages after esophagectomy are common, yet threatening complications. Possible leakage therapy ranges from reoperation to interventional treatments like stent placement or endoscopic vacuum therapy (EVAC) supported by optimized conservative therapy, ideally at an intensive care unit. Since reoperation is concomitant with high mortality, conservative and interventional therapies are applied on a frequent basis nowadays. Apart from the well-established endoscopic placement of a self-expanding-metal stent (SEMS), the EVAC has been successfully implemented in many centers in recent years. Using the same principles as subcutaneous vacuum therapy, it offers many advantages such as simultaneous drainage therapy and faster healing process. The healing process is supported by controlling the infection of the wound, promoting macro- and microdeformation of the adjacent tissue, and improvement of perfusion. Still, clear evidence about superiority of one interventional therapy strategy—either SEMS or EVAC—is lacking. This article describes the principle and the procedure of EVAC for anastomotic leakages. Current literature regarding efficiency, safety, and possible costs in comparison to SEMS therapy is reviewed. Considering the advantages EVAC therapy is offering, its value for anastomotic leakage therapy is clear. However, to reach standardized clinical application, additional research to improve the applicability and economic efficiency should be conducted.

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Introduction

Esophagectomy with gastric pull up and intrathoracic or cervical anastomosis is a standard part of treatment for esophageal cancer (1). Further indications include benign tumors and esophageal perforation. Most surgical approaches include either intrathoracic (Ivor-Lewis-procedure) or intracervical (McKeown-procedure) anastomoses (2,3). These anastomotic sites are susceptible to postoperative complications like leakages, bleedings, stricture or fistula (4). Thereby, anastomotic leakage remains the most common, yet threatening complication, with reported occurrence rates of 2–25% (5-8). Particularly intrathoracic leakages can cause severe mediastinitis and sepsis. Anastomotic leakage leads to prolonged ICU stay, hospital stay, high postoperative mortality and reduced quality of life (9). Additionally, potential treatment complications like anastomotic stenosis and stricture add up

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to these consequences. Reported risk factors for anastomotic leakages include prior radiation, technical errors, cervical location of the anastomosis and comorbidities as diabetes, active smoking, malnutrition, corticosteroid usage, and atherosclerotic calcification of the aorta (10,11).

As for leakage therapy, surgery is usually only performed in very early postoperative leakage, after failure of conservative treatments or acute unstable patients, given the comparable high mortality rates after reoperation. Nowadays different conservative options are applicable. Indeed, high-volume centers reach lower mortality rates not only by prevention, but also by optimized complication management (12). However, optimal treatment strategy remains unclear. Endoluminal stenting with a self-expanding-metal stent (SEMS) has become standard therapy in recent years, reaching successful healing rates up to 80–85% according to the literature (13). Limitations remain threatening post-interventional complications such as stent migration, defect enlargement and fistula formation, as well as the unsolved problem of sufficient wound drainage. Patients with mediastinitis need additional drainage therapy to relieve potential septic focus.

Most recently, the endoscopic vacuum therapy (EVAC) has been implemented as an innovative endoscopic treatment. Thereby, an open-pore polyurethane sponge with applied suction leading to negative pressure at the defective area is placed endoscopically. First articles of successful treatment with EVAC in the upper Gastrointestinal (GI) tract were published in 2008 (14), followed by several case series and studies reporting a treatment success rate of more than 80%. Although some cohort studies seem to prove superior effectiveness of EVAC compared to SEMS-therapy (15), no clear evidence supported by prospective and randomized studies is available so far (8). We present the following article in accordance with the Narrative Review reporting checklist (available at https://aoe.amegroups.com/article/view/10.21037/aoe-21-16/rc).

Mechanism of EVAC therapy

The idea of the EVAC therapy derived from the well-established vacuum assisted closure therapy (VAC) used for the care of superficial wounds (16). The endoluminal mechanisms treating transmural defects follow the same principles. First endoluminal vacuum therapies were applied rectally for leakage after rectum resection, later the same principle was applied for the upper GI tract (17).

Exudate and infect control

A great part of its efficiency treating anastomotic leakage derives from its ability to drain fluid that forms in and around the defect (18,19). Hence, additional drains put in interventionally are not necessary. The accumulation of fluid intrathoracically and around the defect hinders healing by pressuring local cells and tissue. Some studies also imply local bacterial clearance and reduction of bacterial load to improve healing (20).

Macrodeformation and microdeformation

When suction is applied, two main changes occur to the affected tissue: macro- and microdeformation. Macrodeformation describes the actual shrinking of the defect since the edges are drawn together by the deforming force of the sponge. This leads to collapsing of the preformed holes in the mediastinum or thorax.

Microdeformation on the other hand occurs on a cellular level. Due to mechanical forces, the deformed cytoskeleton initiates intracellular signaling cascades leading to the release of growth factors, upregulation of granulation tissue formation and stretching of the cytoskeleton. Thereby, cell proliferation and migration are promoted (16,21).

Improvement of perfusion

Essential for healing of the defect is sufficient oxygen and nutrient supply afforded by increased blood flow. By inducing low perfusion and hypoxia in the defects' edges, angiogenesis promoting mediators such as hypoxia-inducible factor 1α and vascular endothelial growth factor are locally released by affected cells (22,23). Thus, vessel density increases significantly leading to better perfusion, blood supply and ultimately optimum healing conditions (24).

Procedure

In order to place the sponge at its destination, a nasogastric tube (NGT) is used. The NGT consist of a silicon tube and an open-pore polyurethane foam attached to the tubes head.

Before inserting the NGT, exact evaluation of the defect regarding its dimension must be made endoscopically. The inserted endoscope is at first used for exact determination of the defects' height and secondly used to estimate its size. The sponge size should be individually chosen or cut and prepared onto the tip of the silicon tube. Important to consider is the limitation of the sponges' size due to the diameter of the esophagus. Oversized sponges can hardly be placed under vision and hinder exact positioning. Alternatively, specialized systems like Eso-SPONGE can be used equally (B. Braun Melsungen AG, Melsungen, Germany).

After choosing the right size, a second tube of larger width is placed as splinting catheter or "over tube" ending directly at the defect. Then, in order to prevent damage to the upper esophageal sphincter, the NGT is pushed through the over tube to its final destination.

In case of a defect without or small extramural cavity, it can be placed directly into the lumen of the esophagus (intraluminal). In this case, frequently a long, cylindrical sponge should be used. If an extraluminal cavity of the leakage exist, the preferred placement should be into the cavity (intracavitary) (25). In order to avoid folding of the sponge making it less effective, a shorter, thicker sponge is preferred. If the size of the sponge does not fill the cavity sufficiently, additional sponges can be applied. The lumen of the cavity will collapse, and exudative fluid removed when starting suction.

Afterwards, the pushing instrument and the large tube should be removed.

Final placement can be controlled and corrected under endoscopic visualization with an endoscopic forceps or grasper.

Then, the sponge tube is put from oral to nasal position and continuous suction is applied. Therefore, the NGT is connected to an electronic vacuum pump at a defined vacuum and continuous moderate intensity. The optimal intensity of the suction (mmHg) is under discussion and no evidenced based recommendation is available. A routinely applied vacuum of 125 mmHg is reported, however, vacuum intensity can be varied depending on individual preference. If patients do not tolerate suction well, settings can be changed to intermittent suction (5 min on, 2 min off) at the same pressure.

An alternative way of placing the EVAC, especially used for children, is putting it directly with a forceps to its final destination. The sponge should be lubricated and provided with a prolene stitch at its top to enable grasping and proper positioning. Additionally, the sponge can be placed retrograde through an existing gastrostomy (26). The sponge is put through the gastrostomy and pulled out of the mouth with a forceps. Then, it can be placed into position under fluoroscopic guidance.

If desired, an additional feeding tube can be placed before. Although there is limited data to oral fluid intake during EVAC therapy, especially patients with intraluminal sponges should avoid it strictly.

Just like common VAC therapy, the sponge of EVAC therapy should ideally remain 3–5 d; however, no more than 7 days until replacement. The sponge tends stick to the surrounding tissue making removal harder after some days. Every exchanging procedure the defect must be reevaluated, and the necessity of a new cycle decided. EVAC therapy is completed when the leakage closed completely, or the leakage cavity is well sealed off. Most studies report treatment durations around 15 days (27). However, depending on individual preconditions, treatment duration can vary and should be decided individually (*Figures 1,2*).

Stent-Over-Sponge (SOS)

A further advancement of the EVAC therapy is the SOS concept, first reported in Germany in 2018 (28). Thereby, after placing the NGT with the sponge onto the defect, a partially covered self-expandable metal stent is positioned over the sponge. The idea of this adjustment is potential improved vacuum force from the stents' pressure and maintenance of esophageal passage. In the first small series of 11 patients, this approach has proven to be safe and feasible. It was successfully applied as second-line therapy after failed previous EVAC therapy. However, for clear clinical benefit of this new approach, probably as fist-line therapy, enough evidence is lacking.

Efficiency and comparison to SEMS

Successful EVAC therapy used for anastomotic leakages after esophagectomy has been reported in several case series and systematic reviews (29). First introduced with two successful case reports in 2008 and 2009 by Wedemeyer *et al.* and Loske *et al.* (14,30), first case series followed soon. In 2016, Laukoetter *et al.* treated 39 patients for anastomotic leakage with EVAC and reached successful healing rates of 92.3% (31). Min *et al.* presented 19 of 20 successfully treated patients with EVAC in 2019 (healing rate of 95%). In this study two factors, neoadjuvant therapy and the size of the defect, led to longer treatment duration (27).

Many cohort studies compared EVAC therapy to SEMS therapy indicating equal or better efficiency. In

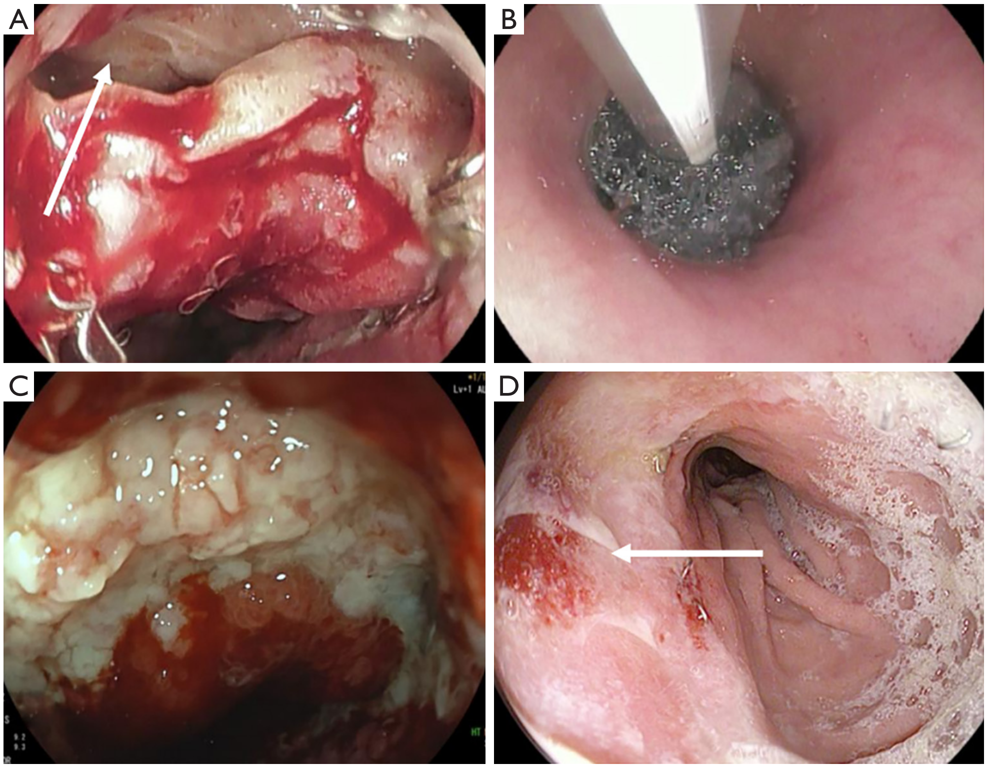

Figure 1 Example of endosponge therapy for anastomotic leakage after esophagectomy for cancer. (A) Anastomotic leakage at 24 cm from mouth with small cavity; (B) placement of intraluminal endosponge at 8. postoperative day; (C) after three days of vacuum treatment, good granulation of defect is visible with small remaining cavity; (D) anastomotic site 12 days after EVAC therapy with closure of the defect. Arrow points at the defect before and after endovacuum therapy. EVAC, endoscopic vacuum therapy.

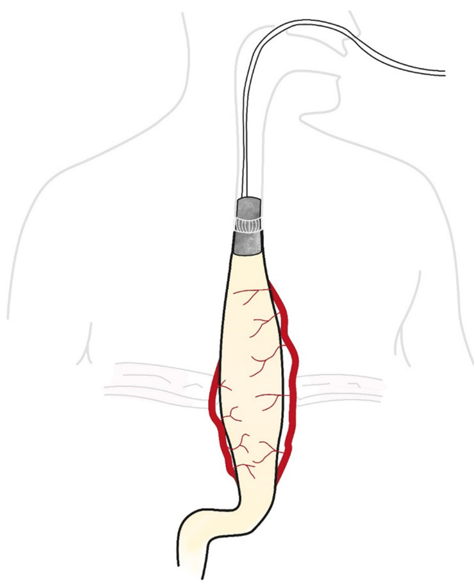

Figure 2 Illustration of EVAC-therapy used for an anastomotic leakage after gastric pull up (copyright, Carolina Mann). EVAC, endoscopic vacuum therapy.

a retrospective study in 2018, Berlth *et al.* analyzed 101 patients either treated with SEMS or EVAC (32). They found no superior outcome for either therapeutic option. On the other hand, another retrospective analysis of 45 patients treated either with EVAC or SEMS by Mennigen *et al.* describes statistically significant better healing rates for the initial vacuum therapy (endoscopic vacuum 93.3%, stent 63.3%; P=0.038). Thirty of the patients received stent therapy, 15 underwent EVAC therapy. Seven patients in the SEMS group were switched to EVAC and four to surgery because of treatment failure. Comparing healing rates of the final therapy, EVAC still reached better outcome (EVAC, 86.4%; SEMS, 60.9%; P=0.091) (15). In a cohort study with 71 patients from Brangewitz in 2013, the overall closure rate was significantly higher in the EVAC group (84.4%) compared with the SEMS/SEPS group (53.8%) (33). Finally, a retrospective study of Schniewind *et al.* in 2013 evaluated different treatment regiments for anastomotic leakage after esophagectomy. Patients treated with endoluminal vacuum therapy had significant lower mortality rates than patients treated with surgery or stent implantation (34). The first meta-analysis conducted, confirmed these findings (35). Still, randomized controlled trials proving superiority of this concept are missing in current literature.

Possible advantages of EVAC

Apart from the proven efficiency, EVAC therapy offers additional advantages. Due to regular sponge exchanges and visualization of the defect, a potential healing problem or deterioration can be managed at an early stage. This on the other hand leads to more interventions and resource consumption compared to stent therapy. As additional important advantage, the EVAC system provides adequate drainage of the wound and control of the infectious site, avoiding sepsis. Therefore, placement of additional drainages and possible complications caused by these interventions (e.g., by interventional radiology) can be obviated.

The sponge can be individually prepared and adapted to various possible defects of the intrathoracic esophagus. Even advanced defects can be treated endoscopically and drainage along the whole esophagus can be provided. In contrast to SEMS therapy, adaption is tension-free at any time, whereas the stiff forces of a stent might hinder wound margins to approximate and heal (33). This stiffness can also cause circular esophageal ulceration leading to formation of scar tissue and anastomotic structure.

As disadvantage of the EVAC therapy the postponed oral feeding has to be mentioned. If endoluminal EVAC is applied, enteral feeding can only be applied by another nasojejunal feeding catheter. Successful placement of SEMS allows oral feeding with fluid and soft foods.

Safety

Taking the published reviews into account, EVAC therapy generally is a safe procedure. Possible minor adverse events include sponge dislocation and minor bleeding after sponge exchange. Sponge dislocation often occurs in a late treatment phase when the cavity has already healed well, and the sponge is placed intraluminally. Coughing and swallowing can then easily cause dislocation. Minor bleedings are mostly self-limiting and can be mitigated by increasing exchange frequency (36).

Regarding post-interventional anastomotic strictures, Min *et al.* report a 35.0% anastomotic stenosis rate after successful EVAC treatment. These strictures clinically present with dysphagia and are successfully treated by repeated endoscopic balloon dilatation. Other studies reported lower stricture rates following EVAC therapy: Brangewitz *et al.* reported 9.4% (3 of 32 cases), Laukoetter *et al.* reported 7.7% (4 of 52 cases), and Schorsch reported 4.2% (1 of 24 cases) rates. However, those studies included other cases of esophageal perforation apart from anastomotic leakages. Taken the underlying cohort as possible bias into consideration, the anastomotic stricture rates after treatment of anastomotic leakage with EVAC might be underestimated.

The most threatening complications of EVAC described in literature are major bleeding due to direct neighborhood of big vessels. In a review of Rausa *et al.* with 163 included patients, two patients in the endoscopic vacuum treatment goup (2.8%) developed fistula between cavity and blood system leading to major bleeding (35). In their study, Pournaras et al report one case of bleeding due to direct communication of an aortic with the cavity. Placing of an aortic stent could stop the bleeding (37). In the cohort study of Laukoetter *et al.* two patients died from massive hemorrhage, again caused by close contact to cardiovascular structure (31). They suggest exact pre-interventional evaluation of anatomic sites by CT-imaging in order to avoid such events. However, an increased provocation of fistula between GI system and airway has not been described (32). In the end, these cases illustrate the need for structured, evidence-based guidelines allowing safe and successful treatment with EVAC.

Comparing EVAC to SEMS, most studies report lower complication rates in the EVAC group (38). Stent placement SEMS often requires re-endoscopy because of stent migration and necessity of replacement. Additionally, since the stent remains longer *in situ* during stent therapy—treatment duration difference of 9 days was found in a meta-analysis (35)—its removal can be extra difficult due to overgrowing tissue, which can lead more postinterventional stenosis or more severe complication like broncho-esophageal fistula (38). Although the same complication might happen during EVAC therapy, a regular sponge exchange after 5 days can prevent these complications.

Cost and duration

In times of increasing health care cost, economic proficiency should also be considered. In terms of treatment duration, most studies found faster leakage closure with EVAC therapy. Still, in order to evaluate proficiency, a comparison to the alternative approach, SEMS implementation, must be conducted. Rausa *et al.* found a pooled mean treatment duration difference of −9 days (95% CI: 16.6–1.4; P=0.021) in favor of EVAC therapy (35).

Another aspect should be the time needed by an endoscopist to reach maximum proficiency as flat learning curves indicate less economic procedures. Ward *et al.* analyzed medium time needed to reach a plateau of average procedure time performing EVAC procedure. An experienced endoscopist obtained this plateau of roughly 43 min after 10 procedures with lower costs when executed in the GI lab (39). This number does not seem high considering performance of approximately four procedures for every patient (38). Although the procedure reaches proficiency fast, it inevitable includes interventions (sponge exchanges) on a regular basis resulting in overall higher therapeutic costs.

Baltin *et al.* analyzed 39 patients treated in Germany between January 2012 and December 2016 with either SEMS or EVAC therapy regarding the average economic burden of both interventions (40). Treatment for patients in the EVAC group caused almost double costs. From an economic point of view, although healing faster with a steep learning curve, EVAC has an inferior standing. However, higher failure rate of stent therapy might lead to costlier second line therapies such as surgery, making EVAC the better choice from the start.

Conclusions

Anastomotic leakage is a common but most burdensome complication after esophagectomy. Mortality can be mitigated by improving complication management. Although SEMS is an easily reproducible method with acceptable success rates, in recent literature EVAC therapy presents as a convincing, safe, and even more efficient alternative. Since for today official guidelines regarding adequate pressure, optimum exchange cycle and treatment set up are missing, many centers have established their own treatment algorithm. Prospective randomized trials are required to reach a consensus about ideal therapeutic strategy. Nevertheless, although being not as cost efficient as SEMS therapy, EVAC therapy should be valued as an important part of complication management for anastomotic leakages following esophagectomy.

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