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Pull-through endoscopic vacuum-assisted closure therapy for complicated leaks of the gastrointestinal tract: Novel technique

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ABSTRACT

Background and study aims Endoscopic vacuum-assisted closure (EVAC) of postsurgical leaks is an increasingly applied technique. Precise intracavitary sponge placement is technically challenging. Here, we describe a novel EVAC therapy using a combined external and endoluminal, pull-through technique.

Patients and methods In this retrospective cohort study, we included all patients treated with pull-through EVAC for post-surgery leaks. During endoscopy, the proximal tip of the percutaneous drainage was visualized within the extraluminal abscess cavity, grasped with forceps, and pulled out orally while maintaining the distal end of the drainage above skin level. A foam sponge was fixed to the tip of the percutaneous drainage and sutured to a gastric tube at the other end. The sponge was placed in the cavity by pulling at the percutaneous drainage. Finally, the gastric probe was channeled nasally and suction was applied. Reinterventions comprised pulling the gastric tube, exchanging the sponge, and re-positioning, as described above. Therapy was stopped after closure or complete epithelialization of the leakage.

Results Overall, seven patients were included between 2021 and 2023. Median duration of pull-through EVAC therapy was 30 days (interquartile range [IQR] 11–37 days) and the median number of endoscopic interventions was six (IQR 4–10). Technical and clinical success was achieved in all (100%) and in six of seven patients (85.7%), respectively. In total, one major bleeding complication associated with EVAC therapy occurred (14.3%).

Conclusions Pull-through EVAC therapy is safe and effective in patients with large and challenging postsurgical leaks of the upper gastrointestinal tract.

Introduction

Postsurgical leaking of the gastrointestinal tract is a serious complication that is associated with early and long-term morbidity and mortality [1, 2, 3, 4]. Endoscopic vacuum-assisted closure (EVAC) has proven to be a well-tolerated and effective therapeutic option for treatment of major leaks and is an increasingly accepted method [3, 5, 6, 7]. In particular, gastrointestinal leaks following sleeve gastrectomy, esophago-jejunostomy, esophago-gastrostomy, pancreato-gastrostomy, and duodenal suturing represent severe and difficult-to-treat complications. Leak-associated mortality is high in such cases, reaching up to 31% after pancreatic anastomosis in duodenopancreatectomy, and precise placement of the EVAC system is often technically challenging [8, 9].

A pull-through technique with the help of a previously placed, percutaneous drain might facilitate the endoscopic interventions in severe cases. Here, we describe the method and the outcome in seven patients treated with EVAC therapy using a combined external and endoluminal pull-through technique.

Patients and methods

Study population, indication, and data selection

All patients in whom pull-through EVAC therapy was attempted between 2022 and 2023 at the University Medical Center Schleswig-Holstein for postsurgical leaks were included. Exclusion criteria were decline of participation and age younger than 18 years, neither of which was met. The indication for pull-through EVAC was technical unfeasibility of intracavitary EVAC placement or dislocation of the sponge upon exchange and lack of therapeutic response. The outcome of classical EVAC was evaluated by septic parameters, imaging, and endoscopy. Lack of response was assumed when radiology showed progress of the abscess or laboratory/circulatory sepsis parameters deteriorated. The study was designed as a retrospective cohort. Four patients had undergone duodenopancreatectomy, two had undergone sleeve gastrectomy, and one patient had Roux-en-Y reconstruction and duodenal suture following knife stabbing. Patient data were retrospectively evaluated for procedure, clinical, and laboratory characteristics. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki, as reflected in a priori approval by the appropriate institutional review committees.

Endoscopic procedures

Placement and removal of the pull-through EVAC system were performed as follows All of the patients had abscessing complications due to gastrointestinal leakage and prior percutaneous drainage or intraoperatively placed drainage. Endoscopy was performed using a regular orthograde endoscope (Gif-Q165, Gif-Q180H, Gif-Q190; Olympus). The proximal tip of the percutaneous drain was visualized within the necrotic cavity and grasped with forceps (Olympus, Hamburg, Germany; Boston Scientific, Marlborough, Massachusetts, United States). If the drain was considered too short, it was exchanged for a longer one, mainly a Robinson-type drain (Robdrain; B. Braun, Melsungen, Germany). The drain was pulled out orally while maintaining the distal end of the drain above the skin level (▶ **Fig. 1a**). A polyurethane foam sponge (pore size 400–600 µm; Smith & Nephew, Hamburg, Germany) was affixed to the tip of a gastric tube with a mersilene suture (Freka Tube, 15 Ch; Fresenius Kabi, Bad Homburg, Germany; 0.35 mm; Johnson & Johnson, St-Stevens-Woluwe, Belgium). The sponge was required to be smaller than the wound cavity to promote collapse and subsequent closure of the fistula. The EVAC was sewn to the tip of the percutaneous drain, which had been pulled out orally (▶ **Fig. 1b**). Then, the sponge was placed precisely in the cavity by pulling on the percutaneous drain (▶ **Fig. 1c**). Sponge movement was visualized endoscopically. Forceps were used to adjust the angle of the sponge rather than pushing it. Last, the gastric tube was channeled nasally and intermittent suction of 50 to 100 mm Hg was applied using a vacuum pump (KCI, Smith&Nephew) while the percutaneous drain was adapted to a drainage bag (B. Braun) (▶ **Fig. 1d**). Reinterventions were performed by stopping the suction, pulling on the gastric tube, exchanging the foam sponge, and repositioning the percutaneous drain as previously described. Therapy was stopped when the base of the cavity appeared to be firmly closed or the cavity was completely epithelialized/granulated. The sponge and oral drain were separated and the external drain was retracted into the cavity under endoscopic guidance. Retraction of the external drain was done stepwise. Follow-up was guided by clinical appearance and by endoscopy or imaging on demand. ▶ **Fig. 2** shows endoscopic images of the procedure and results.

Laboratory analysis

C-reactive protein (CRP) and a complete blood count were evaluated upon detection of the leakage and after completion of EVAC therapy.

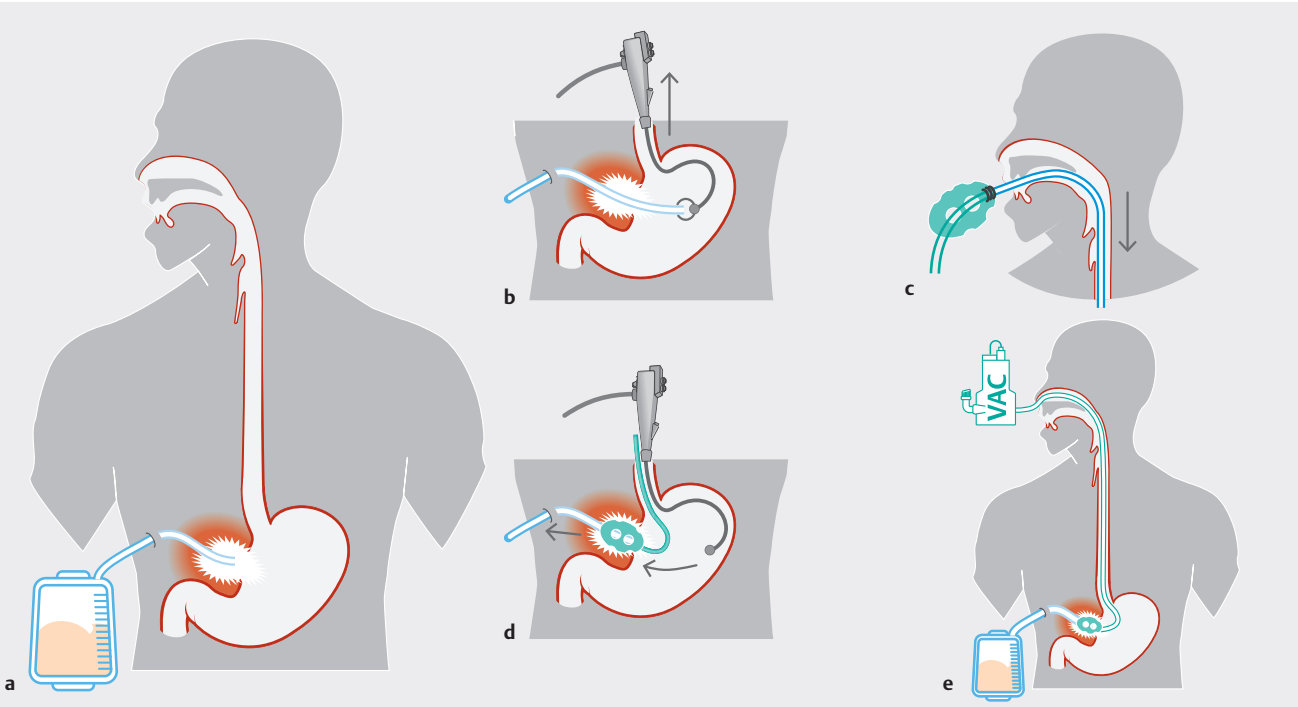
Statistical analysis

Statistical analyses were performed using SPSS 26.0 (SPSS Inc., Chicago, Illinois, United States). Continuous variables were represented as medians and interquartile ranges (IQRs). Differences between medians were compared using the Wilcoxon signed-rank test. $P < 0.05$ was considered significant. Overall survival (OS) was assessed using the Kaplan-Meier estimation.

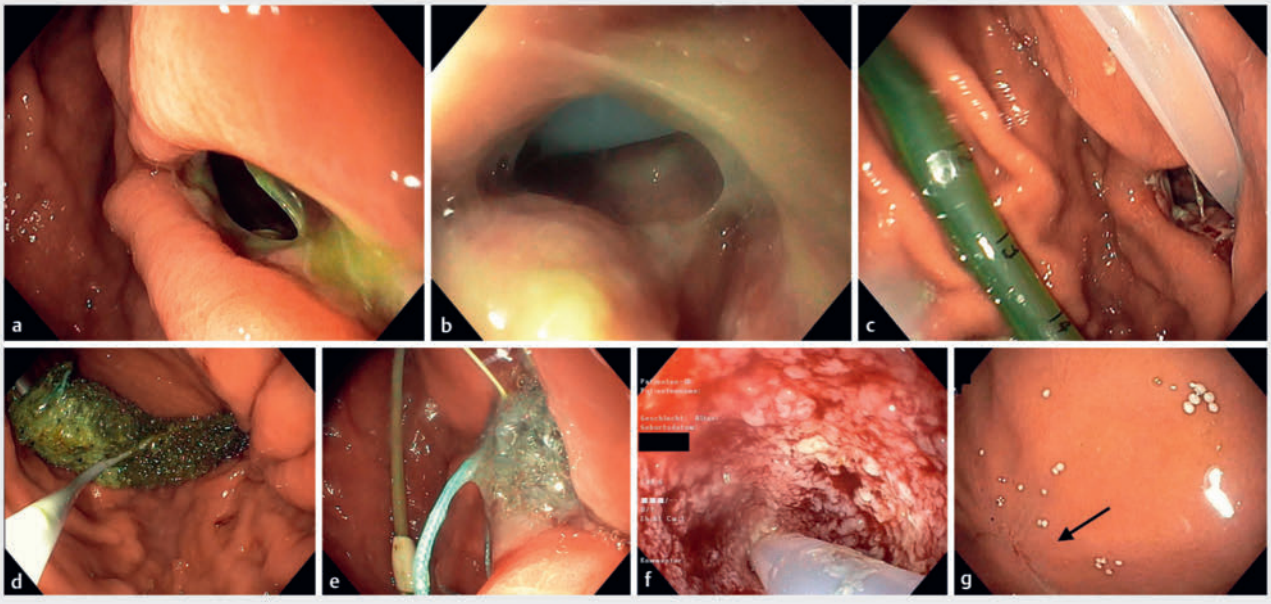
Results

Demographics

Overall, seven patients were treated with pull-through EVAC for complicated postsurgical leakage of the upper gastrointestinal tract between 2021 and 2023. The majority of the patients were male (n = 6/7; 85.7%) and middle-aged (median 51 years; range 45–66). Four patients had undergone duodenopancreatectomy, two had undergone sleeve gastrectomy, and one patient had Roux-en-Y reconstruction and duodenal suture following a knife stabbing. All but one patient had previously failed surgical attempts to close the leakage. One patient was not deemed a surgical candidate due to comorbidities (body mass index 41 kg/m²). Patient characteristics are summarized



▶ **Fig. 1** Technique of pull-through EVAC application. **a** Percutaneous drain is placed radiologically or during surgery. The proximal tip drainage is visualized within the necrotic cavity, grasped with forceps and pulled out orally, while maintaining the distal end of the drainage above the skin level. **b** A polyurethane foam sponge is fixed to the tip of a gastric tube with a mersilene suture. The sponge size is required to be smaller than the wound cavity to promote collapse and subsequent closure of the fistula. The EVAC is sewed on the orally pulled-out tip of the percutaneous drainage. **c** The sponge is placed precisely in the cavity by pulling at the percutaneous drainage with endoscopic support. **d** The gastric probe is channeled nasally and intermittent suction of 50 to 100 mm Hg is applied using a vacuum pump, while the percutaneous drainage is adapted to a drainage bag.



▶ **Fig. 2** Example of pull-through EVAC. **a** Endoscopic image on the postoperative Day 16 showing a suture dehiscence of the ventral gastrostomy following PPPD. **b** Visualization of drain that had been applied radiologically, inside the necrotic cavity. **c** The drain was exchanged for a Robinson-type tube and has been pulled out orally. It is shown exiting the necrotic cave. The second tube is a nasogastric tube. **d** Introduction of the sponge by pulling at the percutaneous drainage with endoscopic support via forceps. **e** The sponge is placed successfully inside the cavity. The nasogastric tube has been exchanged for a triple lumen feeding tube. **f** Complete granulation of the cavity on the postoperative Day 27 after a single exchange of the EVAC system. At this point, EVAC treatment was stopped and the external drainage was retracted stepwise. **g** Late result showing complete closure of the dehiscence 2 months later (arrow).

▶ **Table 1** Patient characteristics.

	Value (n = 7)
Age - median years (IQR)	51 (45–66)
Male sex - no. (%)	6 (85.7)
Prior interventions - no. (%)	7 (100.0)
▪ Sleeve gastrectomy	2 (28.6)
▪ Pylorus-preserving pancreaticoduodenectomy	3 (42.8)
▪ Whipple pancreatoduodenectomy	1 (14.3)
▪ Gastric sewing, segmental jejunectomy, right hemicolectomy (after abdominal knife stabbing)	1 (14.3)
Time surgery to leakage-median days (IQR)	15 (7–21)
Time surgery to EVAC-median days (IQR)	15 (7–21)
Median abscess size-cm (IQR), n = 4	8.4 (3.8–12.0)

EVAC, endoscopic vacuum-assisted closure; IQR, interquartile range.

▶ **Table 2** Procedure characteristics and outcomes.

	Value (n = 5)
Duration of EVAC therapy-median days (IQR)	30 (18–51)
Duration of pull-through EVAC therapy-median days (IQR)	30 (11–37)
Median EVAC exchange procedures-no. (IQR)	6 (4–10)
Median pull-through EVAC exchange procedures-no. (IQR)	3 (2–6)
Successful closure of leckage-no. (%)	5 (71.4)
Major complications-no. (%)	1 (14.3)
▪ Erosion of gastric artery-no. (%)	1 (100.0)
Death-no (%)	1 (14.3)
▪ Death due to EVAC therapy	0 (0.0)
Median Follow-up-days (IQR)	87 (69–99)
Median time to discharge-days (IQR)	77 (69–85)
Median duration of ICU treatment-days (IQR)	57 (31–68)

EVAC, endoscopic vacuum-assisted closure; ICU, Intensive Care Unit; IQR, interquartile range.

in ▶ **Table 1**. The detailed course of each case is summarized in Supplementary material 1.

Endoscopic procedures

Median time to diagnosis of leakage after initial surgery was 15 days (IQR 7–21). In all patients, leakage became clinically apparent with fever, pain, and/or an increase in laboratory inflammation parameters. Diagnosis of leakage was confirmed by flexible endoscopy of the lower gastrointestinal tract, as described previously. In three duodenopancreatectomy cases, the pancreaticogastrostomy showed dehiscence, and in one patient, the ventral gastrotomy was leaking. Two patients had insufficiency of the staple line after sleeve gastrectomy. The patient who had been stabbed showed dehiscence of a duodenal suture. In most cases (6/7, 85.7%), the EVAC system was placed at the time of diagnosis in the Intensive Care Unit (ICU). One patient was subsequently treated with conventional EVAC after the percutaneous drain had dislocated. Median duration of pull-through EVAC therapy was 30 days (IQR 11–37), during which a median of six interventions (IQR 2–7) were performed. Of these, a median of three (IQR 2–6) has been applied using the pull-through technique. Procedure characteristics and outcomes are summarized in ▶ **Table 2**. Use of the pull-through technique was chosen in three cases (42.9%) due to dislocation of the sponge upon exchange and lack of therapeutic response. In four cases (57.1%), pull-through EVAC was primarily applied due to technical unfeasibility of intracavitary EVAC placement. In five patients (71.4%), an external drainage was used that had already been placed during the initial surgery, whereas in two patients (28.1%), a prior radiological pigtail drain was used. (Supplementary Table 1).

Laboratory values

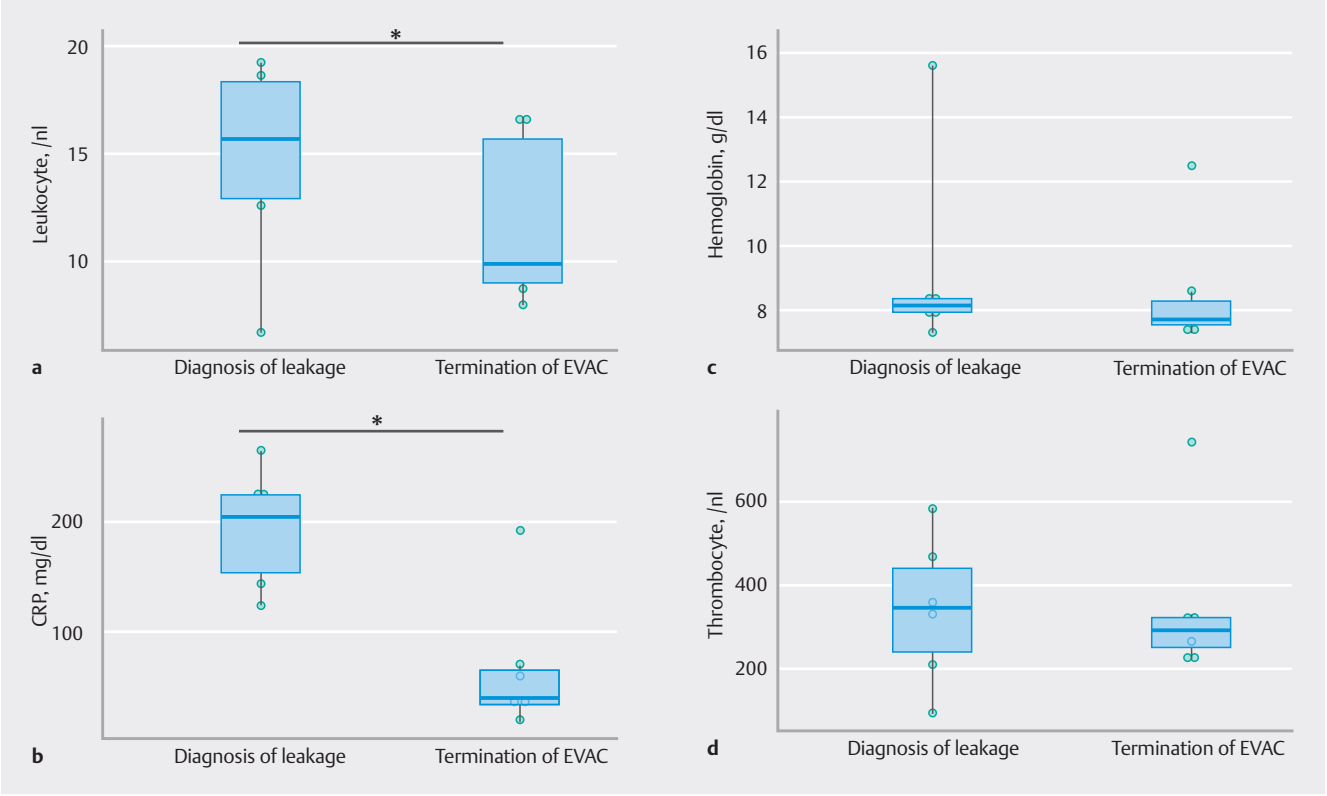
As an indicator of treatment success, median levels of CRP (204.5 mg/dL [IQR 139.3–235.0] to 40.9 mg/dL [IQR 34.5–71.7]; $P = 0.045$) and leukocyte count (18.1/nL [IQR 9.4–19.1] to 14.8/nL [IQR 8.4–16.6]; $P = 0.046$) decreased significantly after EVAC therapy. Median hemoglobin (8.1 g/dL [IQR 7.8–10.2] to 7.7 g/dL [IQR 7.5–8.6]; $P = 0.223$) and median platelet count (344/nL [IQR 180–496] to 291/nL [IQR 232–329]; $P = 0.674$) did not change significantly. Laboratory values are shown in ▶ **Fig. 3**.

Safety

An EVAC therapy-associated complication—major bleeding from the hepatic artery, which was successfully managed with an endovascular stent graft—occurred in one patient (14.3%). Another patient died from intraabdominal hemorrhage due to spontaneous rupture of the hepatic artery (distant from the EVAC location at the anterior stomach).

Efficacy and outcome

Application of the pull-through EVAC system was successful in all patients (technical success rate 100%). In five of seven patients (71.4%), EVAC therapy led to closure or complete epithelialization of the leakage. One patient refused further endoscopic evaluation but showed no clinical signs of persistent leakage during follow-up of 86 days. Overall, clinical success with discharge from the hospital was achieved in six of seven patients (85.7%). Median time to discharge after first diagnosis of leakage was 77 days (IQR 69–85). According to the severity of the illness, median time of intensive care treatment was 57 days (IQR 31–68). Mean OS was 202 days (95% confidence in-



▶ **Fig. 3** Laboratory changes during EVAC therapy. Comparison of laboratory values upon diagnosis of the leakage and after EVAC therapy shows a significant decrease in **a** leukocyte count and **b** CRP, whereas **c** hemoglobin and **d** thrombocyte count remain the same.

terval 155–251). One patient (14.3%) died from intraabdominal hemorrhage, which was not associated with EVAC therapy.

Discussion

In this study, we present pull-through EVAC as a valuable addition to existing techniques for management of difficult-to-treat cases of anastomotic leakage. This postsurgical complication is serious and may be addressed by reoperation and/or endoscopic interventions. Use of EVAC has expanded the therapeutic armamentarium. It is increasingly used in specialized centers and spares high-risk re-surgeries in many cases [10, 11, 12]. EVAC has also replaced self-expanding metal stents (SEMS) for leakage of the upper gastrointestinal tract in many centers due to its highly effective results [3, 13]. In previous studies, treatment success was high with closure rates up to 91% and low mortality rates of 2% [3, 14]. In a single-center study, EVAC outperformed SEMS therapy in direct comparison with a closure rate of 84.4% vs. 53.8% and it was also associated with a lower complication rate (9.4% vs. 28.2%) [13].

Despite these promising data, success rates are derived mostly from retrospective studies and, therefore, may be prone to underestimation of technical difficulties in EVAC placement [15]. In particular, gastrointestinal leaks following complex surgery, including leaks from a gastroenterostomy, pancreatogastrostomy, or duodenal/jejunal suture, represent technically challenging and difficult-to-treat cases with a frequent need for repeated reinterventions in clinical practice. In this regard, leaks following pancreaticoduodenectomy—which rank among the most complex abdominal surgeries with morbidity and mortality rates of 27.4% and 4.3%, respectively—drive mortality rates up to 31% [8, 16]. In contrast, sleeve gastrectomy is generally a safe procedure with a low mortality rate of 0.2% [17]. Staple line leaks, although rare (1.5%), are the most important driving factor for mortality, resulting in an 18.5-fold increase in it.

EVAC treatment strategies in complex postsurgical cases have scarcely been described to date. Suggestions for facilitation of EVAC placement have mainly been restricted to overtube insertion. Here, a commercially available overtube is placed over the endoscope and inserted into the cavity [17]. The endoscope is retracted and sponge placement is done directly through the overtube [14, 18]. However, due to difficult angles and length limitations of 60 cm, this system is not applicable to most leakages distal to the esophagus [19]. An interesting approach to overcoming placement problems is another pull-through technique using a 20 Ch percutaneous gastrostomy (PEG) [20, 21]. The suction tube is inserted through the PEG and retracted orally. A sponge is sutured to its tip and pulled into the stomach, overcoming difficulties in introducing the sponge through the esophagus. Final sponge placement is done endoscopically with rat tooth forceps. Due to the direct exit through the abdominal wall, dislocation while retracting the endoscope is minimized and patient comfort is probably

better compared with the nasal exit of the tube. This technique, however, does not offer support for intracavitary sponge placement.

Intracavitary EVAC has been reported to be associated with a lower EVAC failure rate compared with intraluminal placement and, therefore, should be pursued for large or difficult leaks (21.2% vs. 46.5%) [22]. However, intracavitary placement may be technically complicated for leaks distal from the esophagus and/or angulated positions. Pull-through EVAC is an approach designed to overcome this difficulty. The technique has been described in single case descriptions of patients with leaks after pancreatic resection and endoscopic perforations [20, 23, 24]. Owing to the nature of case reports, no caveats or possible pitfalls have been described.

In this study, we investigated this novel technique in the largest patient cohort to date, where conventional EVAC placement was technically not feasible (n = 4, 57.1%) or not sufficient (n = 3, 42.9%). The response to conventional EVAC was defined as insufficient when a patient deteriorated clinically and/or when improvement of the cavity was lacking on endoscopic or radiologic imaging. Percutaneous pulling resulted in a more precise placement of the sponge compared with pushing with the help of endoscopic forceps because leakage cavities were characterized by difficult positions and/or angulations in all of these cases. All patients had undergone complex surgery such as duodenopancreatectomy, duodenojejunostomy, or sleeve gastrectomy. Leaks appeared at the sites of pancreaticogastrostomy, ventral gastrotomy, duodenal suture, and stapler line after sleeve gastrectomy. The technical success rate was 100%. Successful closure of the leakage was achieved in 71.4% of patients, which is comparable to results from bigger studies examining conventional EVAC technique in less complicated cases [3, 25]. Overall, the clinical success rate was high, at 85.7%. None of our patients developed cutaneous fistulas, although the technique requires a temporary, continuous connection of the skin to the intestinal lumen. Also, no leaking air was detected by the vacuum pump system. Successful therapy was accompanied by decreasing CRP levels, in accordance with our previous study, which showed a significant correlation between decreased CRP levels and treatment success [4]. Measurement of inflammatory activity, therefore, may support early-onset evaluation of response to therapy. The exchange interval of 5 to 7 days used in this study has been described before and proved sufficient. Management, besides EVAC therapy, was resource-intensive and was only possible in the setting of a prolonged stay in the ICU. Median duration of pull-through EVAC therapy was 30 days (IQR 11–37), during which a median of six interventions (IQR 2–7) were performed. With respect to the severe illnesses of the patients, this therapy duration seems acceptable and is comparable with previous reports describing therapy durations between 16 days and 6 weeks [20, 23].

Common complications described with EVAC therapy are stenosis, bleeding, dislocation of the sponge, and visceral injury [15]. Indeed, one patient had erosion of the hepatic artery due to EVAC therapy. One patient (14.3%) died of hemorrhagic shock, which was not associated with EVAC therapy because of the distance to the EVAC location (**Supplementary Fig. 1**). Caution regarding proximal vessels and continuous surveillance for signs of bleeding are advised. We encourage use of this technique only in facilities that have access to interventional radiology and an ICU. In conventional EVAC studies of the upper gastrointestinal tract, the overall mortality rate is comparable (8.6%-15.6%). Bleeding complications are rather rare (2.5%) and are mostly associated with exchange procedures. In our study, however, bleeding occurred spontaneously, most probably due to deep, extraluminal sponge placement. Therefore, endoscopists should be very cautious about a possibly increased, serious bleeding risk [3, 13]. None of our patients developed strictures, underscoring the further advantage of intracavitary sponge placement.

The main limitation of this study is its retrospective nature and the sample size. Our cohort—although the largest described to date—is too small to identify factors that drive therapy success and predict mortality. Further, prospective studies are needed to evaluate the technical feasibility and clinical success of this rescue therapy. A randomized, head-to-head comparison of pull-through vs. conventional intraluminal or intracavitary EVAC therapy regarding safety and efficacy would be of great interest. A special focus on risk factors for bleeding should be considered in study design. Future approaches to this complicated cohort might also combine the interesting method of exiting the suction tube through a percutaneous endoscopic gastrostomy tube described by Glatz et al. with our technique [20]. Hereby, the advantages of intracavitary placement could be enhanced by improved comfort and safety. Another limitation is lack of standardization of endoscopic follow-up, because it was guided only by clinical appearance and by endoscopy or imaging on demand. Therapy was stopped after closure or complete epithelialization of the leakage. We recommend endoscopic or radiologic evaluation of the cavity after 3 to 5 days and stepwise extraction of the external drain. Treatment response should be evaluated by endoscopy and/or imaging. Prospective studies including a predefined treatment strategy are urgently needed.

Conclusions

In summary, here we present a safe and effective possibility for treating patients with complicated postsurgical leaks of the upper gastrointestinal tract that are not amenable to surgical closure and for whom conventional EVAC therapy is technically not feasible or insufficient.

Conflict of Interest

The authors declare that they have no conflict of interest.

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