Journal of Gastrointestinal Surgery (2019) 23:1037–1043
https://doi.org/10.1007/s11605-018-04082-z

HOW I DO IT

Endoluminal Vacuum Therapy: How I Do It

Steven G. Leeds[1,2] · Marissa Mencio[2] · Estrellita Ontiveros[1,2] · Marc A. Ward[1,2]

Received: 19 September 2018 / Accepted: 12 December 2018 / Published online: 22 January 2019

Abstract

Perforations and leaks of the gastrointestinal tract are difficult to manage and are associated with high morbidity and mortality. Recently, endoscopic approaches have been applied with varying degrees of success. Most recently, the use of endoluminal vacuum therapy has been used with high success rates in decreasing both morbidity and mortality. Under an IRB-approved prospective registry that we started in July 2013, we have been using endoluminal vacuum therapy to treat a variety of leaks throughout the GI tract. The procedure uses an endosponge connected to a nasogastric tube that is endoscopically guided into a fistula cavity in order to facilitate healing, obtain source control, and aid in reperfusion of the adjacent tissue with debridement. Endoluminal vacuum therapy has been used on all patients in the registry. Overall success rate for healing the leak or fistula is 95% in the esophagus, 83% in the stomach, 100% in the small bowel, and 60% of colorectal cases. The purpose of this report is to review the history of endoluminal wound vacuum therapy, identify appropriate patient selection criteria, and highlight "pearls" of the procedure. This article is written in the context of our own clinical experience, with a primary focus on a "How I Do It" technical description.

Keywords Gastrointestinal leak · Perforation · Intra-abdominal sepsis · Endoluminal wound vacuum (EVAC) therapy · Endoscopic debridement

Background

Perforations and leaks of the gastrointestinal tract, especially in the esophagus and rectum, are difficult complications to manage and are associated with high morbidity and mortality.[1–3] Methods for management have ranged from surgical diversion of luminal contents, primary repair, and endoscopic techniques.[4–9] Traditionally, surgical exploration and endoscopic techniques, such as clipping or stenting, have been the primary treatment method. A pooled analysis by van Boeckel et al.[10] in 2011 demonstrated 267 patients and their treatment with self-expanded metal stents (SEMS) showing an 85% healing rate for esophageal leaks. However, a 31% migration rate was noted for an overall complication rate of 36%.

✉ Steven G. Leeds
Steven.leeds@bswhealth.org

1 Center for Advanced Surgery, Baylor Scott and White Health, 3417 Gaston Avenue, Suite 1000 East, Dallas, TX 75246, USA

2 Department of Minimally Invasive Surgery, Baylor University Medical Center, Dallas, TX, USA

Endoscopic clipping is also used to manage gastrointestinal leaks with varying degrees of success.[11,12] Due to the potential disastrous consequences of leaks at these anastomotic sites, the need for additional management options is needed. This prompted the use of endoluminal wound vacuum (EVAC) therapy as another potential therapy.

The first uses of EVAC started in Germany by Wedemeyer et al.[13] and Weidenhagen et al.[14] in 2008. Both recognized the need for another therapy in patients with esophageal and colorectal anastomotic leaks following surgery. Wedemeyer et al. began its use for intrathoracic anastomotic leaks following esophagectomy. Both patients in the study had failed alternative management with surgery and stenting. They went on to heal their leak at the anastomosis with a median of 15 days using EVAC. Subsequent uses of EVAC emerged, such as Brangewitz et al.[15] who performed a retrospective review of their patients with esophageal intrathoracic leaks treated with intra-esophageal stents versus EVAC. The overall closure rate of leaks with regard to EVAC versus stents was 84% and 54% respectively. Additionally, the EVAC group was associated with less strictures (9%) when compared to those with stents (28%). These results were matched in 14 patients undergoing EVAC for esophageal perforations by

Bludau et al. with an 86% closure rate.[16] Several reports followed including our own early cohort of 4 esophageal perforations and leaks with a 100% closure rate,[17] followed by our complete database evaluation of 15 esophageal leaks with 100% closure rate.[18] The largest esophageal experience was reported by Bludau et al. in 2017 with 77 patients and a 78% closure rate.[19]

The promising success of EVAC in the esophagus has led to its use throughout the gastrointestinal tract. Our center has become a major referral source for complications following bariatric surgery prompting us to expand use of EVAC in the stomach. The first report of gastric use of EVAC was in 2 patients where both healed successfully at our institution.[17] Further usage at our facility for gastric leaks in 21 patients showed an 86% closure rate with the majority of the patients being gastric sleeve leaks.[18] With this experience, we noted that EVAC had other positive attributes other than wound closure. These included wound debridement, tissue reperfusion, and maintained source control by adhering to adjacent tissues.[20] Since these publications, the use of EVAC has grown with several applications throughout the GI tract ranging from the esophagus to the rectum.

It is important to recognize that gastrointestinal leaks are an extremely heterogeneous disease, and as such, no one specific technique is suitable to treat all patients. Surgeons who care for these patients should be prepared to try several different therapies and interventions. In our experience, EVAC therapy has been extremely successful in both acute and chronic settings. As a result, we advocate that EVAC be in the repertoire of any surgeon treating perforations and leaks of the GI tract.

Patient Selection

In our early experience, acutely ill patients in septic shock with hemodynamic instability underwent traditional surgical therapy first, and EVAC was initiated following the failure of this intervention. When patients had no acute hemodynamic instability, we managed them with EVAC keeping surgical intervention as a second line therapy. As our experience and comfort level grew with EVAC, all patients with a leak or perforation became candidates for EVAC; while surgical intervention was initiated in cases when EVAC therapy failed.

Early endoscopic evaluation is required to identify the perforation site and to characterize the fistula or abscess cavity. Small perforations, usually less than 8 mm, were managed with intraluminal placement of the endosponge or other endoscopic techniques. Within this group of patients, dilation of the fistula tract was considered when access to a larger fistula cavity was needed. Large perforations with a defect size greater than 3 cm are difficult to manage with EVAC due to the limitation of the size of endosponge that can be passed down the esophagus or through the rectum. An endosponge that fails to occlude the defect will generate a leak into the cavity and contamination will still occur. Most of the time, these patients underwent surgical intervention early on given the high likelihood of other endoscopic technique failure.

Another group of patients that respond poorly to EVAC are those patients that have an atmospheric fistula component. EVAC relies on its ability to create negative pressure in order to keep the defect and fistula cavity closed. Atmospheric exposure prevents its desired effect and usually results in dressing malfunction and failure. We have attempted to plug the fistula at the skin level with occlusive dressings in cases of enterocutaneous fistulas, but this does not maintain a negative pressure seal, leading to moisture buildup and eventual failure.

Hemodynamically, unstable patients are candidates for EVAC. In our experience, we now recognize that EVAC can help stabilize patients by obtaining source control without surgical intervention. Using EVAC in this setting is not recommended until a robust experience using EVAC is accomplished.

Operative Indications

EVAC has its limitations like any other procedure. We have defined success of EVAC as defect closure with resolution of the leak or perforation with restoration of GI continuity and the initiation of an oral diet. In the instance of a patient's failure to resolve the leak, and patients that become acutely unstable during EVAC from failure to maintain source control should promptly undergo reevaluation and surgical intervention if needed. It is essential that the management team adequately assess patients at the time of failure and progress to surgical intervention when warranted. Resuming a leak in a patient that is already malnourished and institutionalized can have severe consequences, especially when dealing with the known morbidity and mortality consistent with esophageal or rectal leaks.

Failure of progression towards healing should also prompt surgical intervention, or a change in therapy. These patients are surveyed endoscopically twice a week, and it should be clear that the wound continues to debride, revascularize, and contract. Failure of these parameters to progress indicates that EVAC efficacy needs to be reevaluated. This does include radiological evaluation to asses for an undrained abscess, endoscopic interrogation of the cavity with abrasion therapy or other inflammatory provoking techniques, or the need to proceed to surgery. Our current data shows that there is an increasing failure rate with an increased time to starting EVAC intervention. The best results seem to be found within 4 weeks of the initial leak in the peritoneal cavity. Thus, in patients with more chronic fistulas, we utilize two options: (1) consider surgical intervention after a short duration of EVAC

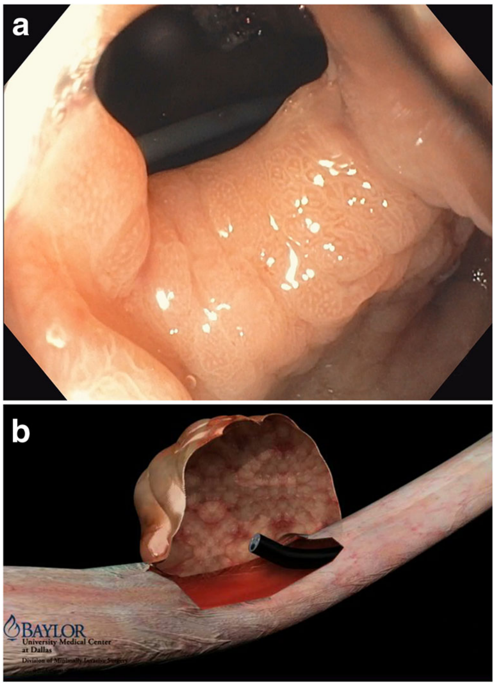

Fig. 1 **a** The appearance of perforation in stomach. **b** Animation depiction of exploring the cavity outside the lumen of the GI tract

(about 2 weeks) to give time for debridement and source control, then proceed to surgery, or (2) immediately upon arrival proceed to surgery knowing there is a high likelihood the patient will fail endoscopic intervention, prolonging their hospital stay, amplifying their malnutrition, and worsening their psychological stress.

Typically, patients with leaks or perforations have a complex collection that needs broad evaluation. Early leaks can enter a cavity such as the peritoneal or pleural cavities allowing for widespread contamination. In these cases, the endosponge will likely be sufficient to obtain source control, but not debride the entire cavity. These patients need radiologic evaluation for percutaneous drainage or damage control surgery. On the other hand, transferred patients typically arrive after surgical intervention and have drains in place. These drains need radiologic evaluation to assess placement and efficacy, and additional drainage may be needed as well as surgical intervention for debridement or washout. Most of the time, we feel that these drains need to be removed in order to allow for healing once EVAC is initiated which will maintain the source control internally.

How I Do It: EVAC

The patient is brought to the operating room or endoscopy suite. All patients undergo general endotracheal anesthesia. This provides safe management of their airway during passage of the endosponge both on removal and placement. There also tend to be large amounts of secretions in the esophagus and contained in the endosponge when removed that causes a dangerous aspiration risk.

Once the endotracheal tube is secured in place, the bite block is placed in the patient's mouth with the elastic band to maintain its position. The patient remains in the supine position, and the head is not rotated like traditional upper

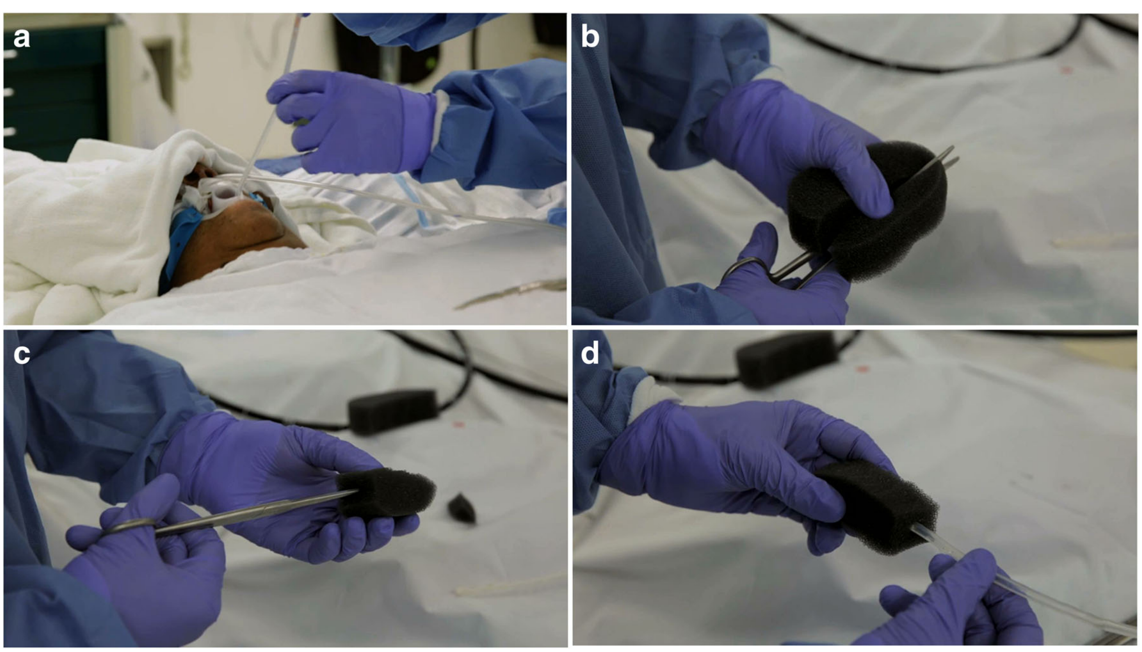

Fig. 2 **a** Passing the NGT through the patient's nostril and pulling it out of the patient's mouth through the bite block. **b** Cutting the endosponge to appropriate size. **c** Creating the tunnel within the endosponge. **d** Placing the NGT into the tunnel

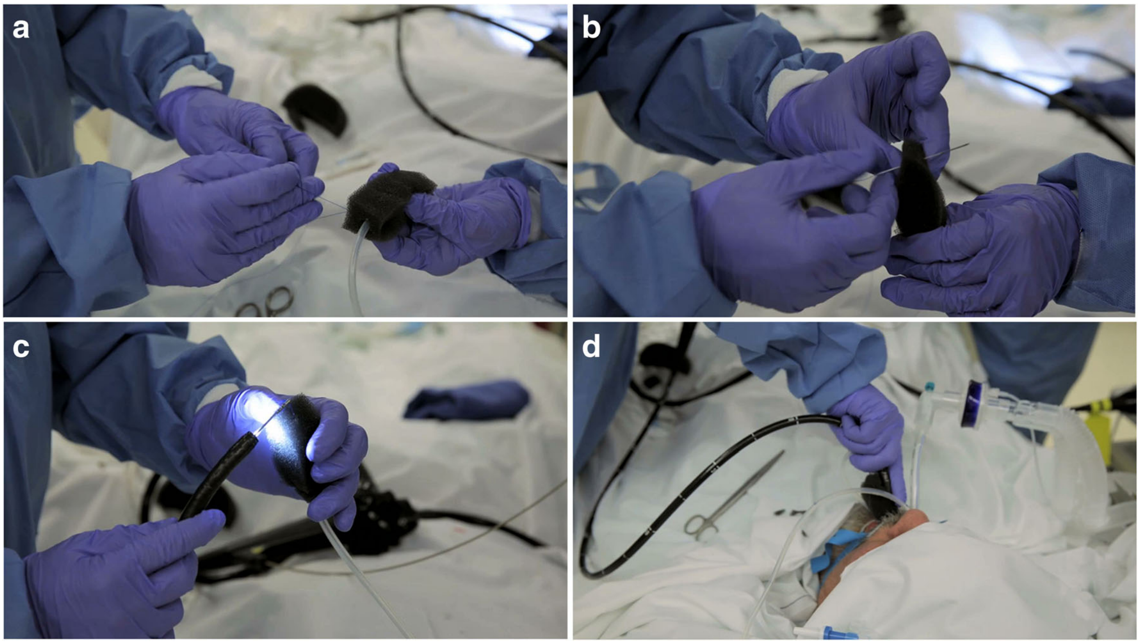

Fig. 3 **a** Suturing the endosponge to the NGT. **b** Passing the needle through the NGT within the tip of the endosponge to create the air knot. **c** Grasping the air knot with the rat tooth grasper. **d** Passing the NGT and endosponge through the bite block

endoscopy. Perioperative antibiotics are indicated, but these patients are typically already receiving broad-spectrum antibiotic coverage. For initial evaluation of the fistula and perforation, the endoscope is passed into the esophagus in the standard fashion. Once the perforation or fistula is identified, it is our preference to irrigate and debride the cavity as much as possible (Fig. 1a, b). Previous imaging can provide a guide to the fluid collections that need to be explored. Once the entire fistula cavity is explored and irrigated, the size of the cavity should be taken into consideration. This will help to create an adequate endosponge to fit the cavity. Dimensions of the fistula cavity are estimated using the size of the endoscope. The endoscope is then removed to facilitate endosponge placement.

A silicon 16-Fr nasogastric tube (NGT) (Medtronic/Covidien—Minneapolis, MN) is placed through the patient's nares and retrieved through the mouth and through the bite block. We will use a 10-Fr NGT in cases where the actual perforation is small to maximize the amount of endosponge that can be placed into the cavity. Retrieval of the NGT in the oropharynx can be done by using a finger, swiped around the bite block or by grasping the tubing using the endoscopic rat tooth grasper. We prefer the silicon NGT for comfort of the patient because it is softer, more pliable, and causes less pharyngeal irritation. Once the NGT is pulled through the bite block and out of the mouth, attention turns to the creation of the endosponge. The small granulofoam piece is used from the KCI wound vac set (KCI/Acelity—San Antonio, TX). A limitation to this procedure is the endosponge size which is limited to the diameter of the esophagus. A more than adequate endosponge can be constructed with the small piece of foam. Based on the dimensions obtained during the diagnostic endoscopy, the foam can be cut to fit the fistula cavity. It must be kept in mind that overestimation of the foam size can hinder your ability to see the perforation due to the small diameter of the esophagus and limited working room. The standard size of the endosponge is generally 8–6 cm in length and 2–4 cm in diameter (Fig. 2).

Once the piece of foam is cut and tailored to the fistula cavity, a tunnel is created within the foam, through the long axis, to span the entire length of the foam, but not through the other side. This will be for the placement of the tip of the NGT. A scissor is typically used to perform this task by spreading the tines within the piece of foam. The NGT is then placed into the created lumen of the foam and pushed to the end. The NGT should be examined to ensure that all the fenestrations are within the foam. If there are fenestrations outside the foam, the tip of NGT should be trimmed and replaced back into the tunnel. It has helped to make sure the NGT is at the most distal part of the tunnel and will provide the best results for using the piggyback technique that will be described later.

Using a permanent suture, we prefer 2–0 or greater nylon or prolene on a straight needle; a U stitch is placed at the proximal end of the foam and passing both sides of

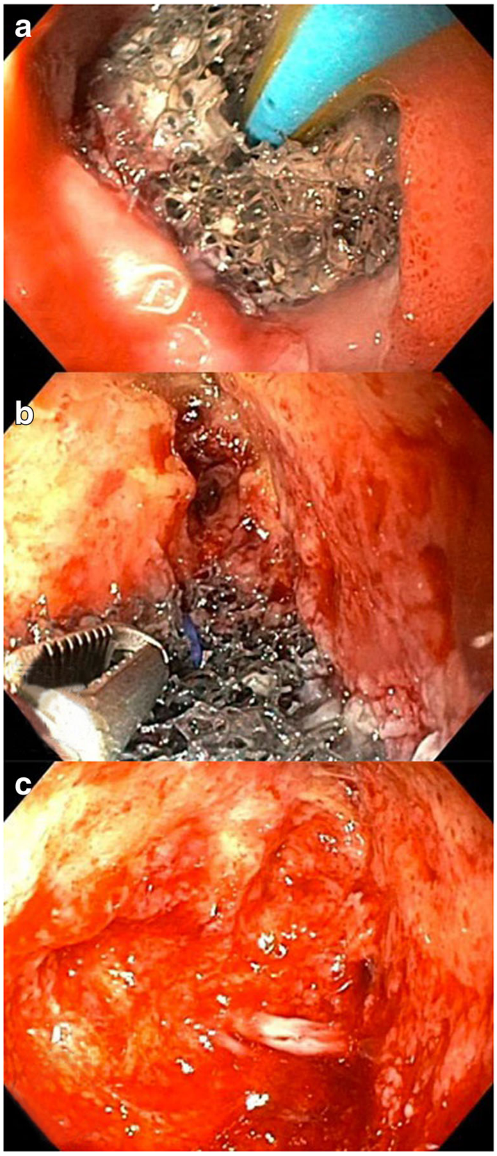

Fig. 4 **a** Perforation with endosponge in place within the fistula cavity. **b** Peeling the endosponge away from the adjacent tissue. **c** Fistula cavity appearance once the endosponge has been removed to demonstrate the granulation tissue and the reperfusion

the stitch through the tubing. A knot is secured and the tails of the suture are passed around the endosponge circumferentially to pinch down the proximal portion. This aids in proper visualization during manipulation of the endosponge into the fistula cavity. Any extraneous edges of the foam can be trimmed. Next, the same suture is used to place a single pass through the tip of the NGT and foam. A small air knot should be created. The air knot should not extend too far passed the edges of the foam because this will allow the foam to be further away from the tip of the endoscope during placement. The tails of this suture should be cut short (Fig. 3).

The rat tooth grasper should be placed through the working channel of the endoscope while it is outside of the patient. Once the rat tooth is seen at the tip of the endoscope, it should be opened and the air-knotted suture at the tip of the NGT should be placed within it, and the grasper closed. By grasping the tip of the endoscope and NGT with the same hand, and ensuring the rat tooth grasper has the suture tight at the tip of the endoscope, it should be placed into the bite block with a small amount of flexion of the tip of the endoscope to guide it down to the larynx. An assistant should provide a jaw thrust maneuver to aid in the endoscope, NGT, and foam to pass through the larynx and the upper esophageal sphincter (UES). Once the foam passes the UES, the resistance felt with the endoscope advancement should improve and ends the duration needing the jaw thrust maneuver.

Depending on the location of the fistula cavity, the endoscope is advanced until this is encountered. The endoscope should be driven through the perforation and into the fistula cavity if possible to carry the endosponge into the fistula cavity. At the distal part of the cavity, the rat tooth grasper can be advanced as the endoscope is slowly withdrawn, eventually releasing the air knot leaving the endosponge in the desired location. The endosponge should be seen passing into the perforation. As the endoscope is withdrawn proximal to the foam, the rat tooth grasper can be used to push the endosponge further into the fistula cavity. Once this is in a satisfactory position, the wound vac settings should be activated to 175 mmHg, continuous, and on high intensity. We use these settings to aid in overcoming the amount of secretions present in the GI tract and compensating for the increased dead space within the tubing used. We have not studied any other settings, and this is not from any recommendations other than the reasons stated above. The endoscope is withdrawn leaving the endosponge in place. The NGT is then secured to the patient's nose either with tape or a bridle. The decision on which to use is chosen on a patient to patient basis. If there is a sump port, this needs to be sealed to prevent air to flow into the system. The provided valve can be inverted, or some other method can be utilized.

Removing an Endosponge Already in Place

If there is an endosponge in place, the endoscope is passed down to the level of the endosponge. It needs to be removed from the surrounding tissue (Fig. 4). This task can be done in several ways. The most effective method we have found is to drive the endoscope at the tissue/endosponge interface to dislodge the endosponge from the granulating tissue and this can be done circumferentially. Once this is accomplished, gentle pressure on the attached NGT will dislodge the endosponge back into the lumen of the GI tract. It must be emphasized that tugging on the endosponge with NGT

Table 1 A total of 61 patients in the registry for EVAC use and their combined outcomes by anatomical location

Organ	Type	No. of patients	Days to 1st endosponge	EVAC therapy			Complete closure
				Avg no. endosponge Δ's	Avg daysb/e Δ's	Avg duration EVAC therapy	
Esophagus	Leak	2	17.5	6.5	4.5	27.5	2/2
	Perforation	17	12.8	5.2	4.4	23.8	16/17
Stomach	Leak	26	51.3	8.7	4.8	44.2	21/26
	Perforation	3	12.0	6.0	5.2	29.7	3/3
Small bowel	Perforation	3	4.3	2.7	4.4	13.7	3/3
Colorectal	Leak	10	171.4	6.0	4.0	23.2	6/10

will not assist in dislodging it. Granulation tissue grows into the endosponge pores and perpendicular tension will not disengage this tissue. What can occur is dislodging the NGT. Once this occurs, retrieving the endosponge becomes very difficult and drastically increases procedure time.

The endosponge will not pass through the nose, so it needs to be pulled out of the mouth in upper GI tract cases. This can be done by grasping the tubing in the oropharynx with a finger or by using the rat tooth grasper with endoscopic guidance. Once it is outside of the mouth, the NGT is cut with scissors. The NGT and foam are then discarded.

Postoperative Care

The level of care postoperatively is under the discretion of the managing physician and dependent on the patient's comorbidities.

Interval for Endosponge Exchange

In our experience, the interval of exchange should be between 3 and 7 days. We have shortened our interval based on the finding that a 3–4 day serial exchange regimen will decrease their hospital length of stay. The interval can vary, but the longer the endosponge is in place, the more likely GI secretions will overwhelm the fenestrations in the foam and the suction dwindles. Also, prolonged time between endosponge exchanges can lead to significant granulation tissue ingrowth, which makes dislodging the foam from the surrounding tissue more difficult.

Educating Your Staff

Using the NGT through the nose poses a significant problem and potential errors from those not familiar with EVAC. Nursing and anesthesia staffs are prone to mistake this tubing for a functional NGT. It is important to clearly mark the tubing that it is not a typical NGT. It is also pertinent to manage the air port (or sump port) with occlusion. Once again, staff unfamiliar with the function of the endosponge may attempt to open the air port by reversing the filter valve or un-occluding subsequent attempts to occlude the air port. This will allow air into the system and create poor suction through the endosponge.

Table 2 Outcomes from bariatric surgery complications and use of EVAC

Type	No. of patients	Avg BMI	Avg age	Days to 1st endosponge	EVAC therapy			Complete closure
					Avg no. endosponge Δ's	Avg days b/e Δ's	Avg duration EVAC therapy	
LSG leak	24	33.3	46.6	53.8	8.7	4.9	45.5	19/24
RYGB leak	2	37.9	45.5	22.5	8.5	3.3	29.0	2/2

Complications

Fortunately, no major complications have been seen with our experience that have come directly from EVAC. However, there have been cases were EVAC had to be aborted and surgical intervention immediately instituted.

Results

We have shown the usage of EVAC therapy in cases involving the esophagus, stomach, small bowel, and colorectal anastomoses. Our IRB-approved prospective registry consists of total of 68 patients. Seven patients are not included in any evaluation because the procedure was used as a bridging technique to surgery, or potentially through a withdrawal of care effort. Of the remaining 61 patients, 19 are esophagus, 29 are gastric, 3 are small bowel, and 10 are colorectal. In the esophageal leak patients, 18/19 closed successfully (95%). In the gastric leak patients, 24/29 closed successfully (83%). In the small bowel leak patients, 3/3 closed successfully (100%). In the colorectal leak patients, 6/10 closed successfully (60%), and all patients were diverted with an ileostomy for the duration of EVAC therapy (Table 1).

In the bariatric surgery leak patients, 21/26 patients closed successfully. Further divided, a total of 24 patients had a gastric sleeve leak, and 19 closed successfully (79%). There were 2 gastric bypass patients treated, and both are healed (100%) (Table 2).

Conclusion

Given the experience and outcomes presented above, we have integrated EVAC into an algorithm to help guide care for these patients. Since GI leaks and perforations can vary in size, timing, and degree of contamination, there is not a single therapy that can be all encompassing in dealing with these issues. However, a treatment repertoire that includes endoscopic, laparoscopic, and open therapies including EVAC can successfully treat patients while limiting morbidity and mortality as much as possible. With any new technique or procedure, the future directions are plentiful. Data collection is paramount to better characterize the uses and outcomes of EVAC. Finally, we need to refine the procedure to promote ease of use and lower the learning curve to make it more widely accessible and available.

Statement of Author Contribution The authors have participated in the drafting of this manuscript and take responsibility for its content. Each author has substantially contributed to the concept, acquisition of data, and presentation. Each author has participated in the revising process of the manuscript as well as its final approval. All agree to be accountable for all aspects of the manuscript.

References

1. Shearer, R., et al., *Have early postoperative complications from laparoscopic rectal cancer surgery improved over the past 20 years?* Colorectal Dis, 2013. **15**(10): p. 1211–26.
2. Biancari, F., et al., *Current Treatment and Outcome of Esophageal Perforations in Adults: Systematic Review and Meta-Analysis of 75 Studies.* World Journal of Surgery, 2013. **37**(5): p. 1051–1059.
3. Juza, R.M., et al., *Gastric sleeve leak: a single institution's experience with early combined laparoendoscopic management.* Surg Obes Relat Dis, 2015. **11**(1): p. 60–4.
4. Schaheen, L., S.H. Blackmon, and K.S. Nason, *Optimal approach to the management of intrathoracic esophageal leak following esophagectomy: a systematic review.* Am J Surg, 2014. **208**(4): p. 536–43.
5. Markar, S.R., et al., *Technical factors that affect anastomotic integrity following esophagectomy: systematic review and meta-analysis.* Ann Surg Oncol, 2013. **20**(13): p. 4274–81.
6. Rajan, P.S., et al., *Role of endoscopic stents and selective minimal access drainage in oesophageal leaks: feasibility and outcome.* Surg Endosc, 2014. **28**(8): p. 2368–73.
7. Persson, S., et al., *Predictors for failure of stent treatment for benign esophageal perforations - a single center 10-year experience.* World Journal Of Gastroenterology: WJG, 2014. **20**(30): p. 10613–10619.
8. Dasari, B.V.M., et al., *The role of esophageal stents in the management of esophageal anastomotic leaks and benign esophageal perforations.* Annals Of Surgery, 2014. **259**(5): p. 852–860.
9. Lee, S., et al., *Clinical outcomes of endoscopic and surgical management for postoperative upper gastrointestinal leakage.* Surg Endosc, 2013. **27**(11): p. 4232–40.
10. van Boeckel, P.G., et al., *Systematic review: temporary stent placement for benign rupture or anastomotic leak of the oesophagus.* Aliment Pharmacol Ther, 2011. **33**(12): p. 1292–301.
11. Kirschniak, A., et al., *The Over-The-Scope Clip (OTSC) for the treatment of gastrointestinal bleeding, perforations, and fistulas.* Surg Endosc, 2011. **25**(9): p. 2901–5.
12. Jacobsen, G.R., et al., *Initial experience with an innovative endoscopic clipping system.* Surg Technol Int, 2012. **22**: p. 39–43.
13. Wedemeyer, J., et al., *Endoscopic vacuum-assisted closure of upper intestinal anastomotic leaks.* Gastrointest Endosc, 2008. **67**(4): p. 708–11.
14. Weidenhagen, R., et al., *Endoscopic vacuum-assisted closure of anastomotic leakage following anterior resection of the rectum: a new method.* Surg Endosc, 2008. **22**(8): p. 1818–25.
15. Brangewitz, M., et al., *Endoscopic closure of esophageal intrathoracic leaks: stent versus endoscopic vacuum-assisted closure, a retrospective analysis.* Endoscopy, 2013. **45**(6): p. 433–438.
16. Bludau, M., et al., *Management of upper intestinal leaks using an endoscopic vacuum-assisted closure system (E-VAC).* Surg Endosc, 2014. **28**(3): p. 896–901.
17. Smallwood, N.R., et al., *The use of endoluminal vacuum (E-Vac) therapy in the management of upper gastrointestinal leaks and perforations.* Surg Endosc, 2015.
18. Mencio, M.A., et al., *Use of a novel technique to manage gastrointestinal leaks with endoluminal negative pressure: a single institution experience.* Surg Endosc, 2018.
19. Bludau, M., et al., *Results of endoscopic vacuum-assisted closure device for treatment of upper GI leaks.* Surg Endosc, 2018. **32**(4): p. 1906–1914.
20. Szymanski, K. and E. Ontiveros, *Endolumenal Vacuum Therapy and Fistulojejunostomy in the Management of Sleeve Gastrectomy Staple Line Leaks.* 2018. **2018**: p. 2494069.