Use of a novel technique to manage gastrointestinal leaks with endoluminal negative pressure: a single institution experience

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Abstract

Background Perforations and anastomotic leaks of the gastrointestinal tract are severe complications, which carry high morbidity and mortality and management of these is a multi-disciplinary challenge. The use of endoluminal vacuum (EVAC) therapy has recently proven to be a useful technique to manage these complications. We report our institution’s experience with this novel technique in the chest, abdomen, and pelvis.

Methods This is a retrospective review of an IRB approved registry of all EVAC therapy patients from July 2013 to December 2016. A total of 55 patients were examined and 49 patients were eligible for inclusion: 15 esophageal, 21 gastric, 3 small bowel, and 10 colorectal defects. The primary endpoint was closure rate of the GI tract defect with EVAC therapy.

Results Fifteen (100%) esophageal defects closed with EVAC therapy. Mean duration of therapy was 27 days consisting of an average of 6 endosponge changes every 4.8 days. Eighteen (86%) gastric defects closed with EVAC therapy. Mean duration of therapy was 38 days with a mean of 9 endosponge changes every 5.3 days. Three (100%) small bowel defects closed with EVAC therapy. Mean duration of therapy was 13.7 days with a mean of 2.7 endosponge changes every 4.4 days. Six (60%) colorectal defects closed with EVAC therapy. Mean duration of therapy was 23.2 days, consisting of a mean of 6 endosponge changes every 4.0 days. There were two deaths, which were not directly related to EVAC therapy and occurred outside the measured 30-day mortality.

Conclusion Our experience demonstrates that EVAC therapy is feasible and effective for the management of gastrointestinal perforations/leaks throughout the GI tract and can be considered as a safe alternative to surgical intervention in select cases.

Keywords Esophageal perforation · Endoluminal vacuum therapy · Gastrointestinal leaks · Anastomotic leak · Bariatric complication · Sleeve leak
the establishment of general guidelines and indications for EVAC therapy use in these three anatomic areas.

Methods

Patients

This is a retrospective review of a prospectively collected Institutional Review Board approved registry for patients treated with EVAC therapy for healing of gastrointestinal defects from July 2013 to December 2016. Defects reported encompassed two general etiologies: GI tract leaks and perforations. GI tract leaks were defined as anastomotic or staple line disruptions and perforations were defined as full thickness gastrointestinal wall defects. Defects involving the entire gastrointestinal tract, from esophagus to rectum, were included for a total of 55 patients. We excluded patients undergoing EVAC therapy for uses other than the intent to heal a perforation or leak. In these excluded cases, the endoluminal vacuum concept was used as an exploration for possible other uses of the negative pressure and not for the intent of the concept explored in this review (Fig. 1).

Patient demographics are shown in Table 1.

The primary endpoint collected was the closure rate of the GI tract defect with EVAC therapy. Defect closure was defined as resolution of the leak or perforation with restoration of GI continuity and the initiation of an oral diet. However, these are complex patients and in a select few, two of whom had gastrocutaneous fistulas, and the primary endpoint was more to avoid surgery, get the individual to a controlled, low output fistula and oral diet tolerance. EVAC therapy failure was defined as patients requiring surgical intervention due to loss of source control or failure of healing to progress with EVAC therapy thus requiring a different intervention. Secondary endpoints include average number of endosponge procedures required for closure, hospital and ICU length of stay (LOS), days with leak or perforation prior to starting EVAC therapy, number of days between endosponge changes, discharge diet and discharge disposition. Days with leak or perforation prior to EVAC therapy

![Figure 1](image)
was defined as time period from the initial gastrointestinal tract surgery, iatrogenic event (i.e., ERCP or nasogastric tube placement), or in some of the more delayed cases, symptom onset, to the day of first endosponge placement.

**Technique**

Initial endosponge placement in the upper GI tract

EVAC therapy is performed in the operating room or endoscopy suite. All patients undergo general endotracheal anesthesia unless they have a tracheostomy. This provides safe management of their airway during passage of the endosponge near the airway both on removal and placement. A bite block is placed in the patient’s mouth. Perioperative antibiotics are not indicated unless the patient is already on scheduled antibiotics. The endoscope is passed into the esophagus to locate the site of the fistula or leak. The cavity is irrigated and debrided taking into consideration the size of the cavity. The endoscope is then removed and the endosponge is created by using 16 French silicon NGT that is placed through the patient’s nares and retrieved through the mouth and through the bite block. A piece of granulofoam (KCI/Acelity, San Antonio, TX) is used to create the endosponge. Based on the dimensions obtained during the diagnostic endoscopy, the granulofoam can be cut to fit the fistula cavity. The esophageal lumen is usually the limiting dimension, so the endosponge can be about 3 cm in diameter. A tunnel is created within the endosponge, through the long axis, to span the entire length of the foam, but not through the foam. A 2–0 nylon or Prolene suture on a straight needle is used to create a U-stitch at the proximal end of the foam to secure the endosponge to the NGT. Another suture is placed through the tip of NGT and endosponge and tied with an air knot on the distal end. A rat tooth grasper is placed through the working channel of the endoscope while outside of the patient, and used to grasp the suture at the tip of the NGT. The endoscope is used to guide the endosponge through the bite block and down the esophagus to the site of the perforation or fistula. The NGT is connected to suction tubing contiguous with the KCI wound vacuum canister. Once the endosponge is in a satisfactory position, the negative pressure is activated to 175 mmHg, continuous, and on high intensity. These settings have not been recommended by KCI, but were used to maintain negative pressure overcoming the large circuit created with the NGT and suction tubing.

Initial placement of EVAC in the lower GI tract

EVAC therapy is performed in the operating room or the endoscopy suite. The endosponge can be created in the same manner as described above. Placement can be performed digitally with lower rectal leaks, or can be manipulated into place with a flexible endoscope and rat tooth grasper similar to that done with the foregut leaks.

Removal of the endosponge

The endoscope is passed into the GI tract to locate the endosponge and used at the endosponge/tissue interface to dislodge it circumferentially. Once it is freed, the endosponge is pulled into the lumen of the gastrointestinal tract and withdrawn from the patient. In the upper GI tract, the endosponge should be pulled from the patient’s mouth, out of the bite block, and cut from the NGT instead of trying to retrieve it through the nares.

Results

Of the 49 patients included in this database, 42 (86%) were successfully treated with EVAC therapy. Major surgical intervention to repair the GI tract defect was required in 7 patients (14%; 4 colorectal and 3 gastric anastomotic leak patients) making them EVAC therapy failures. EVAC therapy treatment characteristics and results, subdivided by organ, are summarized in Table 2.

<table>
<thead>
<tr>
<th>Organ</th>
<th>Type</th>
<th>#Patients</th>
<th>Days to 1st endosponge</th>
<th>EVAC therapy</th>
<th>Complete closure</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avg # endosponge Δ’s</td>
<td>Avg days b/e Δ’s</td>
</tr>
<tr>
<td>Esophagus</td>
<td>Leak</td>
<td>2</td>
<td>17.5</td>
<td>6.5</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Perforation</td>
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<td>14.6</td>
<td>5.5</td>
<td>4.8</td>
</tr>
<tr>
<td>Stomach</td>
<td>Leak</td>
<td>18</td>
<td>61.8</td>
<td>10.5</td>
<td>5.2</td>
</tr>
<tr>
<td></td>
<td>Perforation</td>
<td>3</td>
<td>12.0</td>
<td>6.0</td>
<td>5.2</td>
</tr>
<tr>
<td>Small bowel</td>
<td>Perforation</td>
<td>3</td>
<td>4.3</td>
<td>2.7</td>
<td>4.4</td>
</tr>
<tr>
<td>Colorectal</td>
<td>Leak</td>
<td>10</td>
<td>171.4</td>
<td>6.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>
Complications

There were no complications directly related to EVAC therapy, even in those patients who failed EVAC therapy. Two patients, who were excluded from the study, died while still undergoing EVAC therapy. The reason for their exclusion was that these deaths were unrelated to EVAC therapy and both patients demonstrated healing at the endoscopic evaluation immediately preceding their clinical demise. One patient, undergoing EVAC therapy for rectal stump leak after a total colectomy for ischemic colitis, died of multisystem organ failure unrelated to healing rectal disruption. The other patient had an iatrogenic tracheoesophageal fistula from previous stent placement and ultimately died of respiratory failure.

The Clavien-Dindo classification system was used, where applicable, to demonstrate the severity of the post-operative complications leading to EVAC therapy [20]. Of the 49 patients in the database, 9 individuals (7 esophageal, 2 small bowel) had non-surgical etiologies (i.e., Mallory-Weiss tear, foreign body ingestion, perforation following endoscopy). Of the 40 post-operative complications, 24 (1 esophageal, 12 gastric, 1 small bowel) were type IIIb complications, 9 were type IVa (4 esophageal, 5 gastric), 7 were type IVb (3 esophageal, 4 gastric).

Esophagus

There were a total of 15 patients with esophageal injuries that were further subdivided into leaks versus perforations. There were 2 leaks from esophagogastric anastomoses. The etiologies of the 13 perforations were 8 iatrogenic, 3 spontaneous, and 2 foreign body ingestion. All 15 patients with esophageal defects achieved complete closure with EVAC therapy. Injury closure was after a mean of 27.5 days for the 2 patients with anastomotic leaks and a mean of 27.1 days for the 13 patients with esophageal perforations. The 2 patients with anastomotic leaks required a mean of 6.5 endosponge changes occurring with a mean of every 4.5 days. Similarly, those patients with esophageal perforations had a mean of 5.5 endosponge changes with a mean of every 4.8 days (Table 2).

Average time to first endosponge placement for esophageal perforations was 14.6 days (range 0–40 days) from the initial injury. The two esophageal leaks had the first endosponge placed after an average of 17.5 days (range 12–23 days).

Stomach

There were a total of 21 patients with gastric defects that were further subdivided into those with leaks and those with perforations. Seventeen of the 18 leaks were gastric sleeve staple line leaks and 1 was a gastric pouch anastomotic leak following gastric bypass revision of the pouch and gastrojejunostomy. In total, 18 of 21 patients (86%) had complete closure with EVAC therapy. In the staple line leak category, 15 of 18 (83%) closed after a mean of 55.3 days. Fourteen of these successes were gastric sleeve staple line leaks and one was the gastric pouch anastomotic leak. These 15 patients healed with a mean of 10.5 endosponge changes occurring every 5.2 days on average (Table 2). Bariatric patients were separated from this section and are shown in Table 3. The three gastric perforations had different etiologies other than bariatric surgery. One was an iatrogenic injury missed during repair of a recurrent paraesophageal...
hernia; one was a leak following Collis gastroplasty and one was traumatic following a motor vehicle accident that failed initial surgical repair. Regardless of etiology, all three patients (100%) healed after a mean of 29.7 days, with a mean of six endosponge changes, occurring every 5.2 days on average (Table 2).

Gastric perforations had the first endosponge placed at a mean of 12 days (range 10–14 days) from the sentinel surgery or event. Gastric leaks were present for a mean of 61.8 days (range 5–250 days) before starting EVAC therapy (Table 2).

**Small bowel**

There were 3 patients with small bowel defects consisting of 2 patients with iatrogenic perforations from endoscopic examination and 1 patient with a jejunal perforation from a marginal ulcer. All 3 patients were poor surgical candidates. One patient had an acute concomitant stroke, one patient had active Crohn’s disease, and another had a perforation to the second portion of the duodenum. Mean time to first endosponge placement was 4.3 days (range 0–10 days). All 3 patients (100%) healed after a mean of 13.7 days of EVAC therapy. Healing took an average of 2.7 endosponge changes occurring with a mean of every 4.4 days (Table 2).

**Colorectal**

There were a total of 10 patients with colorectal anastomotic leaks (nine following low anterior resection, one after sigmoidectomy). Six of the 10 patients (60%) had complete closure of their anastomotic leaks. Leak closure occurred after a mean of 23.2 days of EVAC therapy, with a mean of six endosponge changes occurring every 4.0 days (Table 2). Colorectal defects came to EVAC therapy intervention at a mean of 171.4 days (range 6–534 days) following the initial injury. Seven out of the 10 patients (70%) were diverted with a loop ileostomy at the time of initial operation. Of the patients that did not get diverted, one underwent EVAC therapy and was readmitted 1 month after perceived complete resolution for peritonitis and was subsequently diverted with loop ileostomy and designated as a failure. One patient was diverted after anastomotic leak was detected in the immediate post op period prior to initiation of EVAC therapy. One patient was diverted after stenting failed to resolve the patient’s pelvic abscess and fistula.

**Leaking into the chest, abdomen, or pelvis**

The 42 patients with complete resolution were separated into anatomical region (chest, abdomen, and pelvis) rather than organ involvement (Table 4). Only healed patients were chosen to outline the characteristics of EVAC success. There were 17 patients with defects in the chest that were successfully healed with EVAC therapy. These patients included all of the esophageal defects with the addition of 2 patients who had gastric staple line leaks following esophageal lengthening procedures where the leak was above the diaphragm. Time to closure was 27.3 days (3–63 days) of EVAC therapy. They underwent a mean of 5.8 endosponge changes (range 1–14) every 4.8 days (range 3.0–6.4 days) on average. Their total hospital stay averaged 52.4 days. Fifteen of the 17 (88%) patients required ICU care and had a mean ICU stay of 15.7 days.

Figures 2 and 3 depict the discharge disposition and diet, respectively, of these patients. Ten of the 17 patients (59%) with mediastinal leaks were discharged home and 7 (41%) required discharge to a facility [i.e., skilled nursing facility, long-term acute care hospital (LTACH), or acute rehab facility]. Twelve (71%) of these patients were safely tolerating oral intake at time of discharge. Ten patients (59%) had been advanced to a solid diet and 2 (12%) to a liquid diet. Five patients (29%) remained NPO at the time of discharge. Two patients were successfully healed but remained ventilator dependent at the time of their transfer to LTACH. One patient had a bronchoesophageal fistula following

![Final discharge disposition of patients successfully healed with EVAC therapy](image1)

![Diet at discharge of patients successfully healed with EVAC therapy](image2)
lung transplant and a negative esophagram at time of discharge. This individual was kept NPO an additional week given an immunosuppressed state. Initiation of oral intake occurred following a negative repeat esophagram as an outpatient. Two patients had small residual fistulas, without mediastinal communication; they were re-examined on an outpatient basis, and both started on PO diets within 1 month from time of final endosponge removal.

The 19 patients with intra-abdominal defects, including 16 gastric defects and 3 small bowel defects, healed after a mean of 44.6 days (range 3–102 days). They averaged 8.4 endosponge changes (range 1–20) every 5.2 days (3–7.2 days). This group had the longest average hospital stay at 65.6 days. Twelve of the 19 patients (63%) required ICU care with an average of 8.5 ICU days. Thirteen of the 19 patients (68%) with intraperitoneal leaks went home at time of discharge and 5 patients (26%) were sent to a rehab facility. One patient (5%) died prior to discharge; however, the death was due to multisystem organ failure and unrelated to EVAC therapy, which had successfully healed the leak prior to death. At time of discharge, 16 out of 19 patients (84%) were tolerating oral intake, 6 (32%) solid and 10 (53%) liquid diets. Two patients (11%) were still NPO at time of hospital discharge (Figs. 2, 3). Of these 2 patients, one had a gastrocutaneous fistula and was originally started on an oral diet but experienced increased fistula output resulting in NPO status with tube feeding. The other patient had a marginal ulcer leak and was given an additional 4 weeks to allow for continued healing prior to oral diet initiation.

The 6 patients with pelvic anastomotic leaks healed after an average of 30.2 days (6–79 days) of EVAC therapy. Treatment consisted of a mean of 7.7 endosponge changes (range 2–17) occurring, on average every 4.0 days (3.0–5.7 days). Mean hospital stay for this group was 30.2 days with no days spent in the ICU. All patients were discharged home on a solid diet following final endosponge removal (Figs. 2, 3).

Discussion

EVAC therapy has an ever-growing presence as a means of healing difficult leaks and perforations throughout the gastrointestinal tract. Our closure rate for the 49 patients included in the study was 86% with a 0% 30-day mortality and no immediate complications directly related to endosponge use. The benefit of the endosponge over other endoscopic interventions is the ability to maintain source control while also performing serial debridement of the leak cavity, thereby promoting healing through secondary intention [15, 21]. At our institution, EVAC therapy is a supported first line treatment for management of these patients, preferred over endoscopic stenting. This has provided our institution with experience across a variety of anatomical locations.

We have found that healing with EVAC therapy for the bariatric patients is prolonged when compared to other types of leaks in the abdomen, and in comparison to the leaks in other anatomical areas (Table 2). The clinical significance for why bariatric patients heal slower is likely multifactorial and is not unique to EVAC therapy. This patient population is predisposed to pre-existing comorbidities such as diabetes and obesity-related immune deficiencies. Additionally, these individuals are at higher risk for protein and micronutrient deficiencies both pre- and post-bariatric procedures [22, 23]. This observation needs further examination in future studies. At this time, caution should be exercised in applying EVAC therapy as a primary treatment strategy in the bariatric patient reserving it for use in those individuals who have failed to heal with other management options or in conjunction with other modalities. We have begun to integrate other adjunct procedures such as laparoscopic fistulojejunostomy, esophagojejunostomy, and laparoscopic washout with evacuation of an intra-abdominal abscess when EVAC therapy is slow in the progression of healing based on the presented data. The advantage of EVAC therapy is the ability to serially monitor healing progression. This provides a distinct opportunity to convert to another treatment modality with stalled progression. The data from the successfully healed EVAC patients has guided our institution in the management of these complex patients. We are now able to recognize unlikely healing early on, allowing care to be shifted toward another modality such as surgical intervention.

This study was underpowered to identify an association between the factors contributing to the slow healing rate in the bariatric population, or the accelerated rate in the other sub groups. The rate of closure and larger patient numbers are needed to better understand this relationship and the contribution of pre-existing co-morbidities such as diabetes, nutritional status, and bacterial load and species at the fistula site.

The use of EVAC therapy in the management of esophageal leaks and perforations in the chest is well established in the current literature. In 2013, comparative analysis of endoscopic and surgical management as rescue therapy for esophagectomy leaks [19] showed that endoscopic management resulted in 100% clinical success with 0% mortality compared to the 33% mortality in the surgical arm. Schniewind et al. compared EVAC therapy to stenting, surgery, and conservative management for patients with anastomotic leak following esophagectomy [15] and demonstrated that the use of EVAC therapy in critically ill patients (matched by APACHE II score) had significantly lower mortality and shorter ICU stay compared to surgical and stent cohorts. Our data yielded similarly favorable results for EVAC therapy use in the chest with 100% closure.
rate and 0% mortality. The 17 patients included in this group were esophageal and gastric patients; the clinical courses and EVAC therapy duration were similar. We suspect that the distinct physiology of the chest is responsible for the favorable outcomes seen in this group, regardless of the organ of defect origin. EVAC therapy overcomes the physiologic negative pressure of the thorax, preventing extraluminal contamination and maintaining source control [24].

The use of EVAC therapy in the management of small intestine leaks and perforations is far less prevalent in the literature. Endoscopic intervention here is limited by inability to reach a more distal defect because of endoscope length. Perhaps for this reason, surgery has remained the mainstay of treatment for small bowel defects. Additionally, small bowel perforations are usually free perforations with acutely ill patients who require prompt surgical intervention over attempted endoscopic management. However, in anatomical areas such as the second part of the duodenum, which cannot be easily resected or accessed surgically, EVAC therapy may have a clinically significant role. In our experience, all three patients were poor surgical candidates and we achieved a 100% closure rate in relatively short treatment duration of 13.7 days. These are very small numbers and further investigation will be needed to substantiate use in the small intestine.

EVAC therapy in the pelvis is primarily for management of anastomotic leaks after low anterior resection (LAR). The primary goal is to prevent pelvic sepsis and subsequent development of a chronic presacral fistula [25]. All 10 patients in the pelvic category in our study developed leaks, with subsequent fistula formation. This was following LAR for 9 patients and status post-sigmoidectomy for 1 patient. This group had the lowest closure rate, at 60% (6/10 patients). Likely reasons for this include longer time to first endosponge placement (mean 171.4 days), radiation treatment to the pelvis, and the presence of ischemia as the underlying cause of the majority of leaks. Colorectal leaks have the benefit of relatively inconsequential proximal diversion, unlike foregut leaks, and 9 of the 10 patients in our study had proximal diversion. Diversion reduces the incidence of severe pelvic sepsis in response to leak and is the standard of care for source control in the case of leak [26]. In the setting of diversion, the expected outcomes are unique from those of the foregut. Our data support the use of EVAC therapy for source control and cavity debridement in patients with established bowel diversion. However, it is unlikely that EVAC therapy can effectively maintain source control, as it does in the other areas of the GI tract, without fecal diversion given the high bacterial burden of the colon despite NPO status [27]. We use return of GI tract continuity and resumption of a PO diet as the primary endpoint for judging foregut defect resolution, but this is different for the colorectal population. In colorectal leaks and perforations, fecal diversion excludes the damaged portion of the GI tract allowing for return to a PO diet before defect resolution. This distinct difference in treatment management endpoints makes the indications for EVAC therapy use in the foregut and hindgut different. Further controlled studies are needed to elucidate a treatment algorithm that is different from foregut indications.

This data is limited by its retrospective nature and heterogeneity of organ involvement and underlying pathology of the leak/perforation. Our early experience in this prospectively collected registry was with chronically ill patients who were not fit for surgical intervention, making EVAC therapy a palliative measure. As our experience broadened, this institution’s clinicians were able to integrate EVAC therapy into a variety of leaks and perforations, at any point in patient’s clinical condition. As such, this study also is limited by the lack of standardized treatment protocols with management plans driven by patients’ clinical condition and physician discretion. Our patients were managed in a multi-disciplinary approach with at least two advanced endoscopists involved. Differences in training backgrounds, surgeon or gastroenterologist, could have created discrepancies in the clinical paths of each patient. However, a multi-disciplinary approach in managing these complex patients is essential and is the basis for establishing consensus guidelines as emerging technologies enter clinical practice. Using the endpoints of the successfully healed patients will help initiate a standard breakdown for effective EVAC therapy use.

Our use of EVAC therapy continues to grow and we have incorporated it into the management of all patients presenting with leaks and perforations of GI tract. This is a feasible therapy for select patients, most efficacious in the setting of a multi-disciplinary team approach. Greater experience is needed to refine indications and formal treatment regimens as well as to determine the value of EVAC therapy amongst the armamentarium of treatment options for gastrointestinal perforations and leaks.

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Compliance with ethical standards


References