



# Endoscopic vacuum assisted wound closure (EVAC) device to treat esophageal and gastric leaks: assessing time to proficiency and cost

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## Abstract

**Background** Endoluminal vacuum therapy (EVAC) is an emerging procedure used to treat anastomotic leaks and/or perforations that would otherwise require surgery. The aim of this study was to determine time to proficiency in EVAC and the cost effectiveness of the procedure.

**Methods** We retrospectively reviewed a prospectively maintained IRB approved database for all patients undergoing EVAC after esophageal and gastric complications between October 2013 and December 2017. Proficiency was determined by obtaining predicted estimates and analyzing the point at which average procedure time plateaued based on case volume. Total cost was calculated based on supplies and location where the procedure was performed.

**Results** There were 50 patients (17 males, 33 female), with a mean age of 52.1 years. EVAC was placed in 23 (46%) patients with esophageal injuries and 28 (56%) with gastric injuries. Two advanced endoscopists performed all EVAC procedures in this study (1 surgeon, 1 gastroenterologist). The average procedure time for all patients was 43.5 min and the average wheel in/wheel out time for all patients was 75.6 min. Analysis of the trend based on average procedure times for EVAC revealed that proficiency was obtained after 10 cases. Total cost of the procedure is significantly lower in the GI lab compared to the operating room (\$4528 vs. \$11889). The majority of EVAC were performed in the GI lab (62%) compared to the operating room (38%).

**Conclusion** Successful outcomes in managing anastomotic leaks or intestinal perforations non-operatively has led to an increased interest in EVAC. For advanced endoscopists, time to proficiency is approximately 10 cases. Performing the procedure in the GI lab has a 2.5 reduction in total cost compared to the operating room.

**Keywords** Endoscopic vacuum assisted closure · Proficiency · Cost utilization · Anastomotic leak · Intra-abdominal perforation

## Abbreviations

EVAC Endoscopic vacuum assisted closure  
GI Gastroenterology laboratory  
NG Nasogastric tube

OR Operation room  
TEF Tracheoesophageal fistula

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Endoluminal vacuum therapy (EVAC) is an emerging endoscopic technique used to treat anastomotic leaks or perforations that would otherwise require surgery [1]. This technique was first described by Weidenhagen et al. to manage anastomotic leaks following colorectal surgery [2] and Wedemeyer et al. to manage leaks after esophagectomy [3]. EVAC is constructed using an endosponge attached to a nasogastric tube (NGT) that is endoscopically placed into an abscess cavity or adjacent to the site of perforation [4, 5]. Once the endosponge is in the desired position, the end of the NGT is connected to continuous negative pressure. EVAC helps to obtain source control by decreasing infection, wound secretions, and reducing edema in order to allow

healthy granulation tissue to develop [6, 7]. The average time the endosponge is left in the cavity is approximately 3–5 days [8, 9]. Endosponges are changed regularly to assess and facilitate healing of the perforation or anastomotic leak site. Although endosponges may increase the overall length of hospital stay for patients, they create an environment that allows the patient to rid potential infection and heal without needing further surgery.

The EVAC procedure can be technically challenging depending on the amount of contamination as well as the size and location of the perforation. Good clinical outcomes following EVAC have led to an increased interest in learning this technique across the country [5]. In addition, the components of EVAC (endosponge, endoscope, NGT, negative pressure therapy) are stocked at the majority of centers who might utilize this treatment option in practice. However, cost and time to proficiency of this procedure have yet to be defined. There are two aims for this study. First, to determine the time, it takes to become proficient in EVAC based on case volume and second, to determine the cost-effectiveness of the procedure. This information will help clinicians considering EVAC whether it is worthwhile to bring this procedure to their respective institution and possible industry involvement.

## Materials and methods

### Patients

This is a retrospective review of a prospectively maintained Institutional Review Board (IRB) approved registry of all patients who underwent EVAC between October 2013 and December 2017. Indications for EVAC placement encompassed two general gastrointestinal etiologies: leaks and perforations. GI tract leaks were defined as an anastomotic or staple line disruption, while perforations were defined as full thickness gastrointestinal wall defects. The database includes EVAC placed throughout the entire gastrointestinal tract; however, only EVAC placed in the stomach and esophagus were included in this study. The reason for this was twofold; (1) esophagus and stomach disruptions account for most of our EVAC patients and (2) EVAC placed in the colorectal setting was often accompanied by diversion of intestinal contents, which has the potential to skew the overall data.

All patients undergoing EVAC therapy are inpatients. All EVAC procedures were done by one of two providers. Average procedure time and the average wheels in/wheels out time were collected for each patient. The procedure time was defined as the time between the start of the procedure until the end of the procedure, excluding the time for anesthesia. The wheels in/out time was defined as the time the patient entered the operating room, or the GI lab (which is

located in the inpatient hospital), until the patient exited the room. Subset analysis was performed to assess the difference depending on the physician type (surgeon vs. gastroenterologist) and location (OR vs. GI lab). A cost analysis for EVAC was calculated based on supplies and the location where the procedure was performed.

### Technique

All patients receiving EVAC routinely receive general endotracheal anesthesia. It is important to have a secure airway when removing or placing the endosponge. A bite block is placed in the patient's mouth and perioperative antibiotics are not indicated unless the patient is already on scheduled antibiotics. The leak site or perforation is identified endoscopically. At this time, the cavity is irrigated and debrided endoscopically. The time of debridement can vary based on the degree of contamination present at initial endoscopy. Decision to proceed with endosponge therapy vs. other options (stent, laparoscopic drainage, etc) is decided at the initial endoscopy. Once it is decided to proceed with EVAC, the endoscope is removed and the endosponge is created using a 16 French silicone NGT that is placed through the patient's nares and retrieved through the mouth and bite block. A piece of granulofoam (KCI/Acelity, San Antonio, TX) is used to create the endosponge. The dimensions of the cavity obtained from our initial endoscopy are used to cut an appropriate sized endosponge to fit the fistula cavity. The esophageal lumen is the limiting factor; thus, the maximum dimension of the endosponge is roughly 3 cm in diameter. The endosponge is then attached to the NGT using a 2–0 prolene suture on a straight needle to create a U-stitch at the proximal end of the tube. A second suture is placed at the tip of the NGT and tied with an air knot to act as a handle for a rat tooth grasper to guide the endosponge down the esophagus and into proper position. Once the endosponge is in the desired location, the NGT is connected to the KCI wound vacuum to 175 mm Hg of continuous suction on high intensity.

Removal of the endosponge begins by taking the NGT off suction. The endoscope is used to bluntly dissect the endosponge circumferentially from the surrounding tissue. Once freed, the endosponge is pulled into the mouth and withdrawn from the patient cutting it away from the NGT.

### Statistical analysis

Each patient had numerous EVAC procedures. The data point for each patient was determined by averaging the time of all the EVAC procedures per patient. The relationship between patient number and procedure time was evaluated. We assessed trend by fitting a non-linear curve to this relationship and obtaining predicted estimates. The fitted

nonlinear estimates were assessed to determine threshold at which rate of change (slope) for the outcome (procedure or wheels in/out time) stabilized with increased experience. Proficiency was determined by obtaining predicted estimates and analyzing the point at which average procedure time plateaued based on case volume.

Procedure times and wheels in/out times were summarized by mean and standard deviation. Differences between GI lab and OR average times were compared using independent sample *t*-test. Statistical analysis was conducted using SAS 9.4 (SAS Institute, Cary, NC) software. *p* values < 0.05 were considered statistically significant.

## Results

There were 50 patients, 33 females (66%), who underwent EVAC placement in either the esophagus or stomach within the specified timeframe. The mean age of these patients was 52 ( $\pm 15.6$  years) and the mean BMI was 29.2 ( $\pm 7.7$  kg). Of the 50 patients, 23 had EVAC placed due to esophageal complications (21 esophageal perforations; 2 tracheoesophageal fistula), while 27 patients had EVAC placed for gastric complications (25 staple line leaks; 2 gastric perforations). The surgeon and gastroenterologist performing EVAC in this study each performed exactly 50% of the procedures. Selection of the endoscopist was based on referral patterns from outside physicians. The majority of EVAC were performed in the GI lab (62%) compared to the operating room (38%).

The average procedure time for all patients was 43.5 ( $\pm 14.4$ ) min and the average wheel in/wheel out time for all

patients was 75.6 ( $\pm 17.3$ ) min. When analyzing the trend of predicted estimates based on average procedure times for all patients, proficiency was obtained after 10 cases (Fig. 1). Subset analysis of proficiency based on provider (surgeon vs. gastroenterologist) can be seen in Fig. 2. No significant differences were seen between the average procedure times (44 vs. 42 min) or the average wheels in/ out time (70 vs. 79 min) between the surgeon and gastroenterologist, respectively (Table 1). When comparing procedures based on location, it appears there is a significantly shorter wheels in/ out time [66.9 vs. 80.8 ( $p < 0.003$ )] in the operating room compared to GI lab (Table 2).

Total cost based on supplies and location utilization (GI labs vs. OR) can be seen in Table 3. There is a significant lower cost when performing EVAC in the GI lab compared to the operating room (\$4528 vs. \$11,889, respectively). CPT code 43241 (endoscopic placement of feeding tube) is used when placing an endosponge and CPT code 43247 (endoscopic removal of foreign body) is used when removing one.

## Discussion

Managing surgical complications using endoscopic therapies is becoming more common due to decreased morbidity and improved outcomes compared to additional surgery [6, 10]. EVAC joins other endoscopic therapies, such as clips and stents, as a non-surgical option to control intestinal perforations and anastomotic leaks. Although EVAC is relatively new, it has shown superior outcomes when

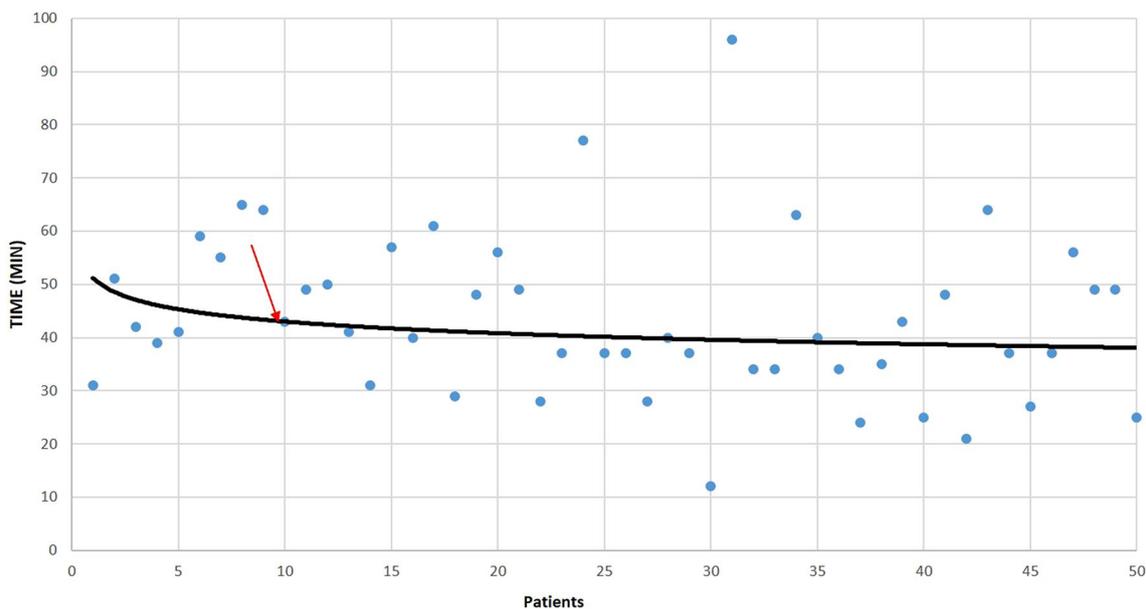
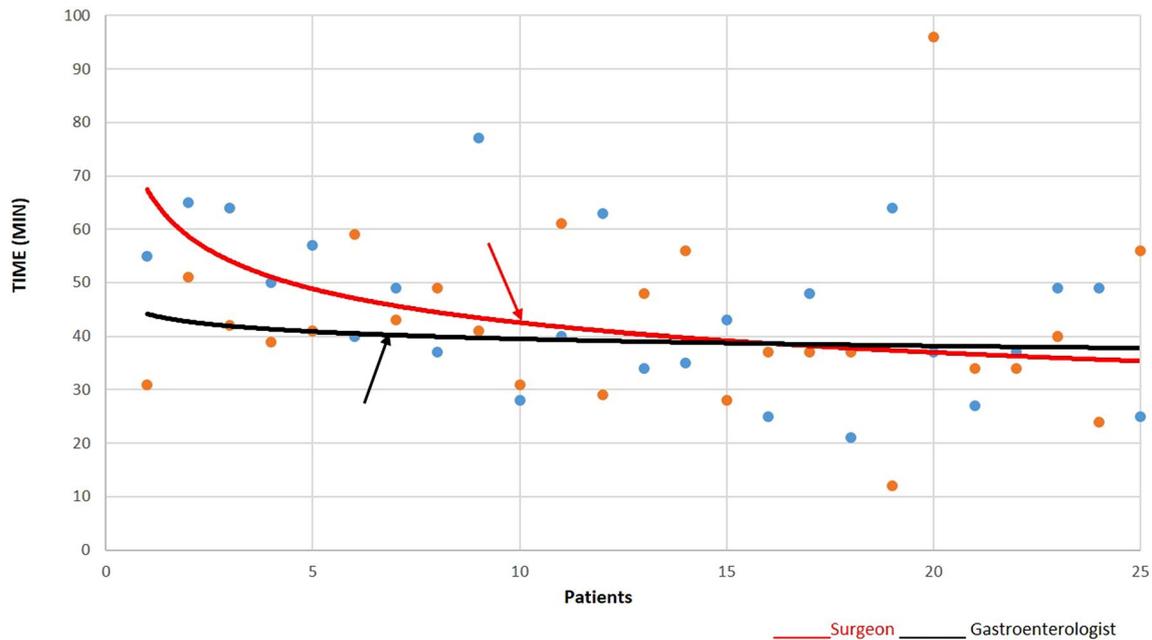


Fig. 1 Total average procedure times



**Fig. 2** Average procedure times for surgeon versus gastroenterologist

**Table 1** Difference between average times based on location of procedure

	GI	OR	<i>p</i> value
Procedure time (min)	45.5 ± 15.3	40.2 ± 15.2	0.23
Wheels in/out time (min)	80.8 ± 15.0	66.9 ± 18.1	<b>0.003</b>

Bold value indicates statistically significant ( $p < 0.05$ )

**Table 2** Difference between average times based on type of interventionalist

	Surgeon	Gastroenterologist	<i>p</i> value
Procedure time (min)	43.9 ± 14.2	42.2 ± 15.7	0.69
Wheel in and out (min)	70.5 ± 15.9	79.04 ± 16.4	0.74

compared to many of its counterparts especially in the upper GI tract. Brangewitz et al. showed EVAC to be superior to self-expanding metal stents in the management of esophageal leaks with a higher closure rate (84% vs. 53%), lower mortality (15% vs. 25%), shorter median treatment time (23 vs. 33 days), and lower stricture rate (9% vs. 28%) [6]. Schniewind et al. showed that EVAC was superior to stent placement or conservative management in managing anastomotic leak following esophagectomy (12% vs. 42% vs. 50%, respectively) [10]. We recently showed that EVAC was highly successful in closing defects of the upper GI tract, with 100% success in esophageal defects

and 83% of gastric defects at our institution [5]. Given these outcomes, interest in EVAC is growing.

One advantage to EVAC compared to other potential therapeutic options is that the supplies needed to do the procedure are stocked at most hospitals. Since most facilities already carry an endoscope, suture, NGT, endosponge, suction tubing, and continuous negative pressure, the only limitation for some institutions is a clinician with advanced endoscopic skills. Advanced skills are required to do sufficient endoscopic debridement of the contaminated area as well as place the endosponge in the appropriate location especially when space is limited due to anatomical concerns or difficulty maintaining visualization.

Given the technical complexity, possible post-surgical anatomy, active infection, and infrequency of cases, we sought to define the case-volume needed to become proficient at EVAC. This study was restricted to two high-volume advanced endoscopists comfortable placing EVAC in a variety of post-surgical and non-surgical complications of the esophagus and stomach. As expected, both physicians spent more time performing the procedure early on in their experience. However, as case-volume increased, procedure time and wheels in/ out time decreased. Analyzing the slope of the curve based on average procedure times, we show that it takes approximately 10 cases for endoscopists to become proficient in EVAC. It is at this point where the slope of the curve plateaus and the average procedure time is roughly 43 min. Clinicians wanting to start EVAC can use this information to understand both case volume needed and the potential learning curve they might encounter at the onset.

**Table 3** Cost per procedure based on location

GI Lab	Charge amount
Sedated wound dressing change	857.39
NG tube	898.35
DRSG FM GRNFM VAC 4×1.5IN SM	175.4
CANISTR SUC GEL INFOVAC 500ML	183.41
EGD	2414.21
Total charge	\$4528.76
OR	Charge amount
112913 Tube Salem Silicone 16	84.3
Dressing granufoam small VAC	189.2
OR procedure group 2 GEN	8280.18
OR time-15 min-level 3 GEN (in-room chargeable staff and time)	3335.68
Total charge	\$11,889.36

It is important to note, that although early procedure times were longer, there was no increased frequency of complications compared to other EVAC reports [6].

Another hurdle institutions face in bringing in a new procedure is cost. Cost utilization is at the forefront of many provider, department, hospital, and political conversations. At our institution, we always perform these procedures under general endotracheal anesthesia for airway protection. When possible, we try to perform these operations in the GI lab; however, sometimes if patient's are unstable, or has ongoing systemic inflammatory response syndrome (SIRS), a higher level of care is needed. In these instances, we utilize the operating room for EVAC placement. One downside to EVAC is the number of endosponge exchanges that are required (4–5 per patient) [5, 6, 10, 11]. Often when these patients are transferred to our facility, we do the initial assessment endoscopically and place the endosponge in the operating room. Once the patient's inflammatory response is controlled, we try to perform subsequent endosponge exchanges in the GI lab due to the dramatic reduction in cost. According to our study, performing EVAC in the GI lab is 2.5 times less than the operating room (\$4528 vs. \$11,889, respectively). This dramatic difference in cost, despite equivalent equipment arises from two factors at our institution. First, the facility fee for the operating room is approximately \$8000.00 and second there is a fee per 15 min spent in the operating room that is not present in the GI lab. In the GI lab, the global fee for the upper endoscopy is \$2400.00. Our decision to perform EVAC in the OR is based on the safety of the patient, and we don't hesitate to utilize the OR until the patient is clinically stable.

This study has both strengths and weaknesses. The strengths include that all patients underwent placement of EVAC by a multidisciplinary team that included involvement with at least two advanced endoscopists. Although differences in training

backgrounds, surgeon, or gastroenterologist could have created discrepancies between patients, this was not reflected in any of the outcomes measured in this study. Weaknesses include the retrospective nature of the study, the limited number of patients with the inability to intervene on all patients from their respective complications at a specified time point. However, since we have become a referral site for these types of complications, this represents a clinically relevant scenario for practicing gastroenterologists and surgeons who hope to provide a similar service at their facility.

## Conclusion

EVAC is a promising intervention in the treatment of post-surgical complications and upper intestinal perforations. To provide EVAC, clinicians must have some basic supplies and advanced endoscopic skills. To become proficient in this procedure, it requires approximately 10 cases for either gastroenterologists or surgeons. Performing EVAC in the GI lab costs significantly less; however, complex patients should be managed in the operating room.

## Compliance with Ethical Standards

**Disclosures** Steven Leeds is a consultant for Ethicon, which has no relevance to the information produced in the manuscript above. Marc Ward, Tarek Hassan, and James Burdick have no conflicts of interest or financial ties to disclose.

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