Endoscopic Esophageal Vacuum Therapy: A Novel Therapy for Esophageal Perforations in Pediatric Patients.

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Endoscopic Esophageal Vacuum Therapy: A Novel Therapy for Esophageal Perforations in Pediatric Patients

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ABSTRACT

Background: Esophageal perforation is a potentially life-threatening problem if not quickly diagnosed and treated appropriately. Negative-pressure wound therapy, commercially known as V.A.C. therapy, was developed in the early 1990s and is now standard of care for chronic surface wounds, ulcers, and burns. Adapting vacuum sponge therapy for use intraluminally for perforations of the esophagus was first reported in 2008. We report the first pediatric experience on a customized esophageal vacuum–assisted closure (EVAC) device for closure of esophageal perforations.

Aim: To evaluate the technical feasibility, safety, and efficacy of EVAC in a pediatric population with esophageal perforations and compare efficacy to a cohort of patients who underwent stenting for esophageal perforation.

Methods: We performed an institutional review board–approved retrospective chart review on all patients who underwent EVAC for esophageal perforations (October 2013–September 2017) and who underwent externally removable stent placement for esophageal perforation (January 2010–December 2017) at our institution. Our primary aim was to evaluate technical feasibility, efficacy, and safety in the treatment of pediatric esophageal perforations. A secondary aim was to compare the efficacy of EVAC to esophageal stenting in healing esophageal perforations in our pediatric population.

Results: A total of 17 patients with esophageal atresia underwent therapy for esophageal perforation. Eight sponges were placed for surgical perforation and 9 were placed after endoscopic therapy perforation. The median age of patients was 24 months with the youngest patient being 3 months of age. The success rate of EVAC to seal all esophageal perforations was 88% (15/17). The success rate was similar in both subgroups: surgical anastomotic leaks at 88% (7/8) and endoscopic therapy leaks at 89% (8/9). There were no technical failures with placement. The stent group had a total of 24 patients: 19 were placed secondary to perforations from endoscopic therapy and 5 were placed secondary to surgical anastomotic perforations. The success rate of stents to seal all esophageal perforations was 63% (15/24). The success rate in the subgroups was 74% (14/19) for endoscopic therapy leaks and 20% (1/5) for surgical anastomotic leaks. In comparing success of EVAC and stent therapy, we found a statistically significant difference in favor of EVAC in healing surgical anastomotic perforations (P = 0.032). There was, however, no statistical difference in healing endoscopic therapy perforations (P = 0.360).

Conclusions: EVAC is a novel, promising technique for the treatment of esophageal perforations in a pediatric population. This treatment is comparable to esophageal stenting in iatrogenic endoscopic therapy perforations and superior to stenting surgical perforations. Further prospective studies are needed to compare the effectiveness of EVAC to esophageal stenting. Improvement in device design and customization could further improve success and ease of placement.

Key Words: esophageal atresia, esophageal leak, esophageal perforation, esophageal stent, esophageal vacuum–assisted closure, negative-pressure wound therapy

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What Is Known

• Esophageal stenting is an established treatment for esophageal perforations.
• Stenting does require long duration of therapy up to 8 weeks and may require external chest tube drainage.
• Endoscopic esophageal vacuum–assisted closure therapy is a very new treatment therapy for esophageal perforations in adults utilizing the principles of negative-pressure wound therapy.

What Is New

• Esophageal vacuum–assisted closure is a novel therapy for esophageal perforations in pediatric patients.
• Esophageal vacuum–assisted closure appears superior to stenting in treating surgical anastomotic perforations and is comparable to stenting in iatrogenic esophageal perforations.
• Esophageal vacuum–assisted closure therapy appears to treat perforations in a shorter timeframe than the reported treatment time for esophageal stenting, based on prior pediatric and adult studies.

Esophageal perforation is a potentially life-threatening problem if not quickly diagnosed and treated appropriately. In pediatrics, the etiology of esophageal perforation includes postsurgical anastomotic leak, postsurgical dilation or other adjunct endoscopic therapy to treat esophageal strictures, traumatic esophageal injury secondary to a foreign body or food impaction, and Boerhaave syndrome. Our institution is a large international referral treatment center for the management of complex congenital esophageal disease and injury including caustic and other traumatic injuries. Therefore esophageal perforation is not an infrequently encountered clinical challenge in our facility.

Traditional management of esophageal perforations or leaks in children includes making the patient nil per os, broad-spectrum antibiotics, and esophageal decompression with the placement of a nasoesophageal tube to low wall suction. External wound drainage with a chest tube is considered in the setting of a large fluid collection in the chest. If these measures fail, then surgical repair
is the next option. In recent years, esophageal stenting has been shown to be effective in adult patients with esophageal perforations, and has become a first-line treatment, with a reported clinical success rate of 85% with a mean stent duration time of 6 to 8 weeks (1). Our group and others have also reported similar benefits of esophageal stents in pediatric patients (2,3). In our experience, esophageal stents also have drawbacks, especially in children with a surgically repaired esophagus as in the esophageal atresia (EA) population. Well-known complications of esophageal stenting include migration and overall patient discomfort, including pain and retching. Esophageal stents may also, however, lead to local pressure necrosis of the esophagus, which may worsen the existing esophageal perforation, and erosion into surrounding structures such as the airway and major blood vessels. Lastly, stenting does not facilitate drainage of the fluid collection around the esophagus, and can in fact trap infection in the chest; thus, facilitating abscess formation unless external drainage is initiated at the time of stent placement.

Vacuum-assisted closure (VAC) is a well-established technique to treat chronic open wounds, ulcers, and burns. VAC uses the principles of negative-pressure wound therapy (NPWT), which stimulates wound healing in several significant ways, including removing fluid from the perforation site, decreasing infection and tissue edema, and promoting blood flow to the area and granulation tissue formation (4). More recently an adaptation of the VAC device for intraluminal use to treat esophageal perforations was first reported in adult case series with good success (5,6). We retrospectively looked at our experience using a customized esophageal vacuum–assisted closure (EVAC) device, with the aim of evaluating technical feasibility, efficacy, and safety in the treatment of pediatric esophageal perforations. Lastly, we compared EVAC efficacy to a cohort of patients who underwent externally removable stent treatment for esophageal perforations at our institution.

METHODS

We performed an institutional review board approved retrospective review on all patients who underwent EVAC for treatment of esophageal perforation from September 2014 to December 2017 at our institution. In addition, a retrospective review was done on all patients who underwent externally removable stent placement at our institution for esophageal perforation from January 2010 to December 2017. All stents used were fully covered self-expanding metal stents. The vast majority of these stent patients had been treated before our institution’s first use of EVAC therapy. Some of the stent data have been previously reported (2). Pertinent clinical data were recorded from patient charts, including endoscopy, surgical, and radiology reports. Recorded patient information included sex, age, weight, etiology of esophageal perforation, duration of EVAC and stent therapy, number of EVAC and stent sessions per patient, adverse events, and clinical outcome of perforation. Clinical success was defined as closure of esophageal perforation without requiring surgical closure. All patients had a minimum of 3-month follow-up, with both endoscopy and fluoroscopic studies confirming healing. Technical success was only looked at in the EVAC group and was defined as closure of esophageal perforation without requiring surgical intervention. In two cases where the cavity was exceptionally large, the sponge was placed within the cavity and as the cavity reduced in size the replacement sponges were placed in the top or bottom of the sponge with the endoscope.

In the majority of our patients, the sponge was placed in the esophagus across the perforation. In two cases where the cavity was exceptionally large, the sponge was placed within the cavity and as the cavity reduced in size the replacement sponges were placed in the esophageal lumen abutting the closing perforation.

Statistical Analysis

Normality was assessed by the Shapiro-Wilk test for each continuous variable. Because of skewness, all continuous variables are reported with medians and interquartile ranges (25th–75th percentile). Categorical variables are reported with frequencies and percentages. Continuous variables were compared between stent treatment and EVAC treatment groups using the Wilcoxon rank-sum test, and categorical variables were compared between the 2 groups using the Chi-square test and Fisher exact test. Statistical significance was set at \( P < 0.05 \). All statistical analyses were performed using Stata version 13.1 (StataCorp, College Station, TX).

Endoscopic Esophageal Vacuum Therapy

Anterograde Esophageal Vacuum–assisted Closure Placement

Before EVAC device assembly, the suction tubing that will be used needs to be placed through either nare and then advanced to the posterior pharynx. The tube is then pulled out of the mouth. This can be accomplished either with endoscopic retrieval or in many instances by having the anesthesiologist retrieve it under laryngoscope vision and using Magill forceps.

A custom EVAC device is assembled using a V.A.C. GranuFoam dressing sponge (KCI USA, San Antonio, TX). The GranuFoam sponge is cut to size based on fluoroscopic images of the esophagus and the perforation, but in general the diameter of the sponges ranged from 1 to 2 cm and up to 7 cm in length. The sponge dressing then needed to be attached to suction tubing. The tubing that the sponge was attached to was either a Salem Sump tube sizes 10, 12, 14, or 16 Fr (Bard, Covington, GA) or a Jackson Pratt 15 Fr round (Cardinal Health, Waukegan, IL). The suction tube is driven lengthwise throughout the center of the sponge until the end of the tube protrudes by approximately 5 mm. The sponge is secured to the tubing on both ends with silk ties. In order to help facilitate endoscopic placement and retrieval, a 2-0 Prolene suture (Ethicon, Cornelia, GA) is driven through the end of the tube and tied into a short loop (Fig. 1A).

Once the EVAC device is assembled, the sponge is soaked with water-soluble contrast to allow for fluoroscopic-assisted placement. The sponge is lubricated and inserted into the mouth and directed so the end of the EVAC is facing the esophagus (Fig. 1B). The sponge is then guided to the proper position by advancing more tubing via the nare, and/or with the endoscope, by grasping the Prolene loop stitch with a forceps. A pediatric endoscope Olympus XP190 series is used in the advancement. Proper positioning of the sponge is confirmed with fluoroscopy and also by visualizing the top or bottom of the sponge with the endoscope.

In the majority of our patients, the sponge was placed in the esophagus across the perforation. In two cases where the cavity was exceptionally large, the sponge was placed within the cavity and as the cavity reduced in size the replacement sponges were placed in the esophageal lumen abutting the closing perforation.

Retrograde Esophageal Vacuum–assisted Closure Placement

An alternative approach that we developed can be used when a patient has an existing gastrostomy site. The same type of suction tubing, as described above, is advanced into the stomach via the gastrostomy. An endoscope is advanced into the stomach to retrieve the tube with forceps and pull it out of the mouth (Fig. 2). The sponge is then loaded onto the suction tubing as described above. The sponge is advanced into position by pulling the tubing at the level of the gastrostomy under fluoroscopic guidance. Minor adjustments of the sponge can be accomplished with the endoscope by grasping the Prolene loop stitch.

Vacuum-assisted Closure Therapy Unit Set Up

Once the sponge is in proper position, the suction tubing is hooked up to the VAC Therapy unit and canister (KCI USA). The
FIGURE 1. A, Picture of esophageal vacuum–assisted closure (EVAC): vacuum-assisted closure (VAC) GranuloFoam sponge rimmed to size and fitted over a Salem Sump before placement into the esophagus. There is a Prolene loop stitch at end to facilitate endoscopic placement and removal. B, After placing the Salem Sump into the nose and pulling out the most, the VAC GranuloFoam is attached to the sump tube, before placement into the esophagus. The sponge has been soaked with water-soluble contrast and coated with water-soluble lubricant.

FIGURE 2. A, Use of the gastrostomy to place a retrograde esophageal vacuum–assisted closure (EVAC). B, Fluoroscopic documentation of placement of the retrograde EVAC in good position across the perforation in the esophagus.
suction catheter with the attached sponge is attached to the canister tubing using a custom adapter. The VAC therapy setting is 125 mm Hg of pressure at continuous moderate intensity. If the patient is too uncomfortable with continuous setting or if there is pooling of secretions above the VAC sponge then the therapy was set to intermittent 5 minutes on and 2 minutes off at the same pressure of 125 mm Hg.

**Esophageal Vacuum–assisted Closure Removal or Exchange**

In our experience EVAC sponges should only remain in place from 4 to 7 days. The longer the sponge remains in place, the more difficult to remove, because the sponge embeds into the esophageal tissue. EVAC removal is performed under general anesthesia by first releasing the suction for few minutes before removal and then using a combination of placing traction on the suction tubing, gently passing the Olympus XP 190 series endoscope between the sponge and the esophageal wall to loosen attachments, and grasping the Prolene loop suture with the endoscope. Once EVAC removal was complete, the endoscope was reintserted to evaluate the area of perforation for healing by both direct visualization of the area and fluoroscopically, using water-soluble contrast. If there was still evidence of a perforation, a new EVAC was placed with the sponge resized based on current dimensions of the perforation. If the area appeared healed, the EVAC was not replaced.

**RESULTS**

**Clinical Characteristics**

The clinical characteristics of the patients who underwent EVAC and stent placement are summarized in Table 1. A total of 17 patients underwent EVAC therapy for esophageal perforation. Nine of the esophageal perforations were secondary to endoscopic therapy and 8 were postsurgical anastomotic leaks. All patients had the underlying diagnosis of EA. The median age of patients was 24 months with the youngest patient being 3 months of age. Five patients had the EVAC placed retrograde. The stent group had a total of 24 patients, 19 were placed secondary to perforations from endoscopic therapy and 5 were placed secondary to postsurgical anastomotic perforations.

**Comparison of Both Groups**

Table 1 summarizes the statistical comparison between the EVAC and stent groups. There was no statistical difference in age, weight, sex, and duration of therapy in the stent and EVAC groups. In comparing success of EVAC and stent therapy, we found a statistically significant difference in favor of EVAC in sealing surgical anastomotic leaks (P = 0.032). There was, however, no statistical difference in sealing endoscopic therapy perforations (P = 0.360). In comparing overall success in closing all perforations (endoscopic and surgical together, EVAC approached clinical significance (P = 0.067).

**Adverse Events**

All adverse events are summarized in Table 2. There was 1 significant adverse event in our EVAC group. This was a device failure in which the EVAC sponge was unable to obtain adequate suction and drainage. The patient went a total of 12 hours with the EVAC not draining the esophagus. This led to worsening of the leak and infection, and this patient ultimately went on to surgical repair.

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**TABLE 1. Comparison of stent treatment and esophageal vacuum–assisted closure treatment groups**

<table>
<thead>
<tr>
<th></th>
<th>Stent (n = 24)</th>
<th>EVAC (n = 17)</th>
<th>Total (n = 41)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mo</td>
<td>16 (8–23)</td>
<td>24 (7–38)</td>
<td>16 (7–31)</td>
<td>0.340</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>8.5 (6–11)</td>
<td>12.5 (6–13)</td>
<td>9 (6–13)</td>
<td>0.239</td>
</tr>
<tr>
<td>Female sex</td>
<td>11 (46%)</td>
<td>6 (35%)</td>
<td>17 (42%)</td>
<td>0.500</td>
</tr>
<tr>
<td>Duration of therapy, days</td>
<td>8 (7–14)</td>
<td>8 (6–13)</td>
<td>8 (7–14)</td>
<td>0.947</td>
</tr>
<tr>
<td>Number of stents</td>
<td>1 (1–1)</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Number of sponges</td>
<td>.</td>
<td>2 (1–3)</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Type of leak</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoscopic</td>
<td>19 (79%)</td>
<td>9 (53%)</td>
<td>28 (68%)</td>
<td></td>
</tr>
<tr>
<td>Surgical</td>
<td>5 (21%)</td>
<td>8 (47%)</td>
<td>13 (32%)</td>
<td></td>
</tr>
<tr>
<td>Sealing of all perforations</td>
<td>15/24 (63%)</td>
<td>15/17 (88%)</td>
<td>30/41 (73%)</td>
<td>0.067</td>
</tr>
<tr>
<td>Sealing of postendoscopic therapy perforations</td>
<td>14/19 (74%)</td>
<td>8/9 (89%)</td>
<td>22/28 (79%)</td>
<td>0.360</td>
</tr>
<tr>
<td>Sealing of postsurgical anastomotic leaks</td>
<td>1/5 (20%)</td>
<td>7/8 (88%)</td>
<td>8/13 (62%)</td>
<td>0.032*</td>
</tr>
</tbody>
</table>

*Values are median (interquartile range) for continuous variables and frequency (%) for categorical variables. P values comparing the stent treatment group to the EVAC treatment groups obtained using the Wilcoxon rank sum test, Fisher exact test, or the Chi-square test as appropriate.

**P < 0.05.**
Because the EVAC causes complete collapse of the esophagus around the sponge, 3 patients had pooling of secretions above the sponge which led to retching and discomfort. Symptoms improved when the suction was switched to intermittent from continuous. In general, the EVAC was well tolerated; most complaints concerned having the tube in the nose. Although a smaller sample size (n = 5), the retrograde EVAC placement had minimal complaints of discomfort.

In the stent group, there were 5 patients who had undergone stent placement for esophageal perforation that resulted in worsening of the esophageal perforation. One of these patients had this occur after we began performing the EVAC procedure. This patient then underwent successful perforation closure with EVAC. In the stent group, 13% (3/24) had stent migration requiring a repeat procedure. Lastly, 25% (6/24) of stent treated patients had significant pain and retching requiring pain medication and antinausea medication.

**DISCUSSION**

This is the first study demonstrating both technical and clinical success of EVAC therapy in the treatment of pediatric esophageal perforations. EVAC therapy was first reported in the esophagus separately by Wedemeyer et al (5) and Loske and Muller (6). Since that time, there have been numerous adult case series showing the benefits of this therapy with a reported success in the literature ranging from 70% to 100% (7–13). This therapy has

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**TABLE 2. Adverse events associated with esophageal vacuum–assisted closure and stent therapy**

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>EVAC (n = 17)</th>
<th>Stent (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation increased in size due to therapy</td>
<td>6% (1/17)</td>
<td>21% (5/24)</td>
</tr>
<tr>
<td>Migration</td>
<td>0% (0/17)</td>
<td>13% (3/24)</td>
</tr>
<tr>
<td>Pain or retching</td>
<td>18% (3/17)†</td>
<td>25% (6/24)</td>
</tr>
</tbody>
</table>

EVAC = esophageal vacuum–assisted closure.
†Symptoms resolved by switching vacuum settings from continuous to intermittent suction.
similarly been reported successful in closing rectal perforations and perforations after bariatric surgery (14,15).

Based upon the principles of NPWT, EVAC seems to be a sound treatment method for esophageal perforation, and has a number of advantages over stenting for treatment of esophageal perforation. The negative pressure of the EVAC helps counteract the physiologic low intrathoracic pressure created with breathing, which can pull secretions and other fluids from the esophagus through the perforation into the chest. This in turn will increase the potential for contamination, infection, and abscess. The NPWT EVAC, alternatively, will pull secretions from chest into the esophagus and also prevent new fluid from entering the chest. This will decrease contamination and reduce infection risk. Although stents may provide a barrier to prevent further contamination into the esophagus, assuming a tight stent seal can be achieved, they can also trap existing infection in the chest. This may be why esophageal stenting often requires a concomitant chest tube for external drainage. EVAC also has the added benefit of promoting blood flow and granulation tissue growth into the perforation site to aid healing and closure. Furthermore, the smaller size and minimal rigidity of a sponge compared to a stent can reduce the chance of further injury and perforation of the esophagus through pressure necrosis. This is evident in our study, in which esophageal perforation worsened in 5 patients in the esophageal stent group.

In adults, first-line treatment for esophageal perforations is stenting. There have been 2 retrospective comparative efficacy studies of EVAC with stenting in adults. Brangewitz et al similarly compared 15 EVAC patients to 30 stent patients; this was a homogenous group all with anastomotic leaks. The reported success was 93.3% for EVAC and 63.3% for stents (P = 0.038), respectively (17). Mennigen et al similarly compared 15 EVAC patients to 30 stent patients; this was a homogenous group all with anastomotic leaks. The reported success was 93.3% for EVAC and 63.3% for stents (P = 0.05) (16).

Our study is limited by its retrospective look at the data and a small sample of stented patients in the surgical perforation group. This has been the case even when we used esophageal stents to treat perforations.

The reason for this small sample size was, however, secondary to device malfunction. In this patient, the sponge was unable to obtain adequate suction, and no drainage of fluid was recorded for approximately 12 hours. This ultimately led to worsening of the leak and infection across the perforation; the patient ultimately went for surgical repair. We hypothesize that the distal suction holes on the Salem Sump were not properly aligned toward the leak to provide adequate suction in that direction once the sponge collapsed under NPWT. Another potential contribution was in that case a small 10Fr caliber tube was used. This smaller tube may have clogged preventing adequate suction. Since then we have refrained from using the 10Fr size and our minimum diameter tube now used is 12Fr. Another change we made to optimize suction is changing to the round Jackson-Pratt drain, which has its suction holes equally distributed around the tube to provide more uniform suction in all directions under NPWT.

Our study had 1 significant adverse event, which was secondary to device malfunction. In this patient, the sponge was unable to obtain adequate suction, and no drainage of fluid was recorded for approximately 12 hours. This ultimately led to worsening of the leak and infection across the perforation; the patient ultimately went for surgical repair. We hypothesize that the distal suction holes on the Salem Sump were not properly aligned toward the leak to provide adequate suction in that direction once the sponge collapsed under NPWT. Another potential contribution was in that case a small 10Fr caliber tube was used. This smaller tube may have clogged preventing adequate suction. Since then we have refrained from using the 10Fr size and our minimum diameter tube now used is 12Fr. Another change we made to optimize suction is changing to the round Jackson-Pratt drain, which has its suction holes equally distributed around the tube to provide more uniform suction in all directions under NPWT.

Our study is limited by its retrospective look at the data and a small sample of stented patients in the surgical perforation group. The reason for this small sample size was, however, secondary to the poor success rate, which detracted us from doing further stent treatment in this population. Another limitation could be that we did not compare EVAC to traditional conservative treatment. The first patient we tried EVAC on, however, failed traditional therapy for 3 weeks and responded to EVAC. We also had another patient succeed with EVAC who failed traditional therapy for more than 2 weeks. Based on our success we tend to use EVAC as first-line treatment but acknowledge that there has not been any comparative study comparing EVAC to traditional therapy. The authors, however, would argue even if traditional conservative therapy is successful; the length of time to achieve success typically is longer than EVAC which on average was 8 days.
The present study is the first to describe EVAC therapy in a pediatric population. We have demonstrated that this treatment is comparable to esophageal stenting in iatrogenic endoscopic therapy perforations and superior to stenting in surgical anastomotic perforations. Further modifications in EVAC design may better facilitate ease of placement and optimize negative pressure therapy in the esophagus. Further multicenter prospective studies will be needed to truly show superiority of EVAC over stenting and traditional conservative therapy.

REFERENCES


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