



Cost-effective modified endoscopic vacuum therapy for the treatment of gastrointestinal transmural defects: step-by-step process of manufacturing and its advantages

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BACKGROUND

GI transmural defects may be classified into 3 distinct categories: perforations, leaks, and fistulas. Each represents a therapeutic challenge directly affecting morbidity, mortality, and quality of life and is associated with significant healthcare costs.^{1,2} Endoscopic therapy has become the first-line therapy in most cases,^{3,4} with available treatment modalities that include closure techniques such as glues/tissue sealants, cap-mounted clips, and endoscopic suturing; cover techniques such as self-expandable metal stents (SEMS) and cardiac septal defect occluder devices; and endoscopic draining approaches such as septotomy, endoscopic internal drainage with double-pigtail stents, and endoscopic vacuum therapy (EVT).⁵⁻⁸

Unlike other endoscopic techniques, EVT has several mechanisms of action to promote healing, including microdeformation, macrodeformation, changes in perfusion, exudate control, and bacterial clearance.³ Current indications for EVT are broad, including acute, early, late, and chronic GI defects, such as esophageal, gastric, small-bowel, biliopancreatic, and

colorectal defects. For these reasons, EVT has become the preferred technique for management of transmural defects, especially in Europe and Brazil.⁹⁻¹³

Polyurethane foam is traditionally used to perform EVT. However, some challenges have been reported, including difficulty with placement and removal, prolonged procedure times, need for multiple EVT system exchanges, and tissue ingrowth, which may increase the risk of bleeding. To overcome these limitations, the use of an open-pore film was recently reported, providing potential benefits over the polyurethane foam, such as easy placement and longer intervals between EVT systems exchanges.¹⁴ However, the high cost of this novel EVT system may limit the widespread use of this technique.

VIDEO CASE PRESENTATION

In [Video 1](#) (available online at www.giejournal.org), we highlight a cost-effective modified EVT technique for the management of transmural defects and the tools needed

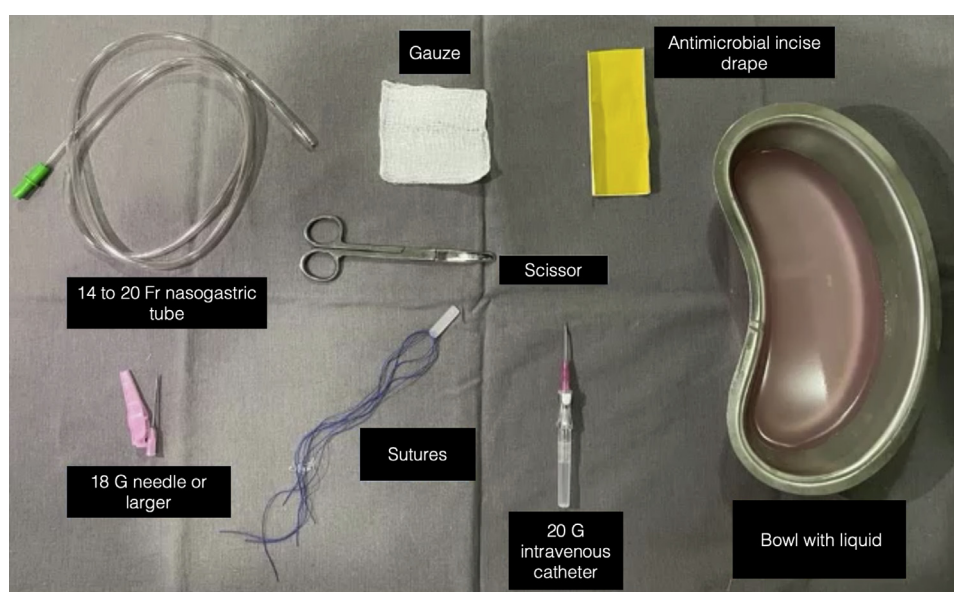


Figure 1. Tools for manufacturing cost-effective modified endoscopic vacuum therapy.

to perform the procedure successfully (Fig. 1).³ With this novel approach, the modified sponge is constructed using a nasogastric tube (NGT), gauze, and antimicrobial incise drape. We demonstrate the step-by-step process of manufacturing the cost-effective modified EVT system in detail (Figs. 2 and 3) and describe this approach's advantages in the management of 3 patients with GI transmural defects, including upper and lower defects.

The first case involved a 60-year-old woman with a history of achalasia, who underwent a Heller myotomy with partial fundoplication. On the third postoperative day, she presented with an esophageal leak, and a surgical suture repair with pleural and mediastinal drainage was performed (Fig. 4). Index EGD was performed with CO₂ insufflation on postoperative day 8 and revealed multiple esophageal transmural defects. At this time, modified EVT was performed using an 18F NGT. Ten days after initial EVT placement, the patient's clinical condition improved and an EVT exchange was performed. During this endoscopy, an external drain was identified and then removed to allow adequate negative pressure. In addition, septotomy was performed to allow for communication of all orifices and improve overall drainage. A nasoenteral feeding tube was then placed to improve nutrition. On postoperative day 28 (10 days after the first EVT exchange), a second EVT exchange was performed after foreign body (suture) removal. Finally, 1 month after the index endoscopy (3 EVT placements and 2 EVT exchanges), the esophageal defect was completely healed.

The second case involved a 56-year-old man with class II obesity who presented to our institution with a leak 3 weeks after laparoscopic conversion from Roux-en-Y gastric bypass to sleeve gastrectomy. There was evidence of a small collection adjacent to the staple line at the proximal stomach (angle of His). EGD was performed using an underwater technique without air or CO₂ insufflation to avoid disruption of the collection because the patient did not have external drainage. For this case, the patient was treated with the modified EVT using a widely available triple-lumen tube to allow for nutrition and drainage via a single tube through the nares, reducing patient discomfort and improving treatment compliance.¹¹ After 2 weeks, there was complete resolution of the leak with no need for EVT system exchange (Fig. 5).

The last case involved a 72-year-old woman with a history of an early colocolic fistula after a left hemicolectomy due to acute diverticulitis. On postoperative day 28, she underwent a colon resection with diverting ileostomy and external drain placement. Colonoscopy was performed approximately 2 weeks after the revisional surgery owing to development of purulent rectal discharge. At this time, a leak was identified adjacent to the colorectal anastomosis with a large infected collection (Fig. 6). The previously placed external drain inside the collection was removed

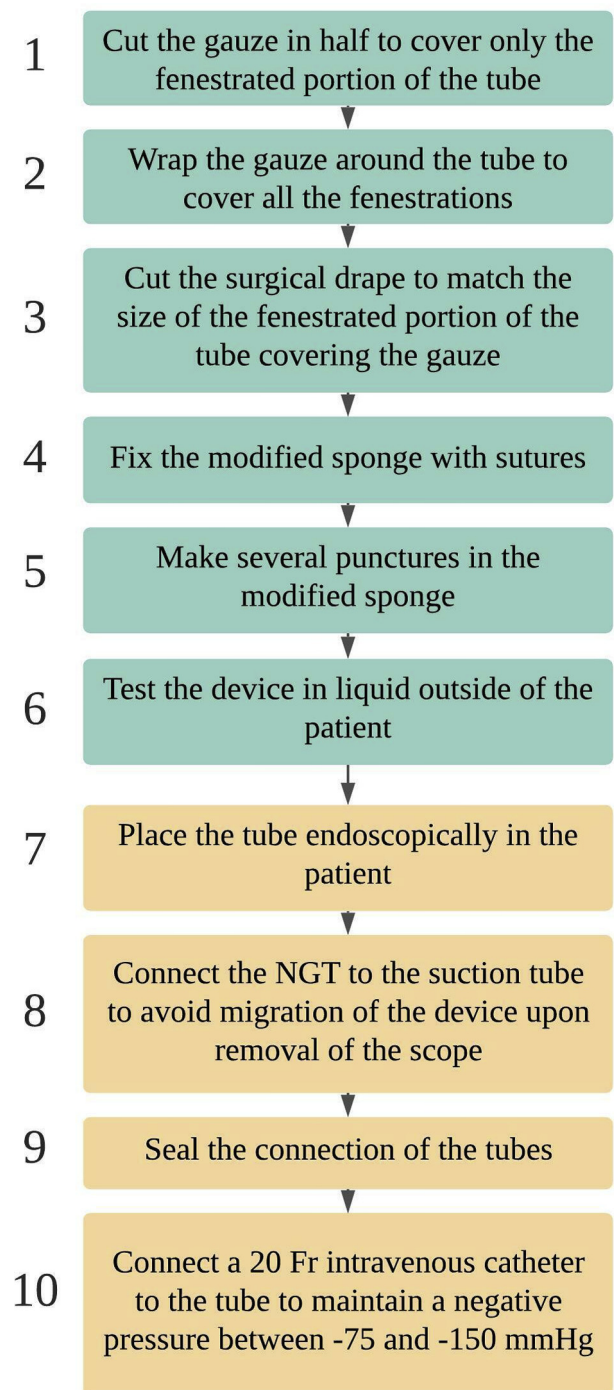


Figure 2. Diagram describing the step-by-step manufacturing of the modified endoscopic vacuum therapy. NGT, Nasogastric tube.

and a compressive dressing was placed to allow for negative pressure promoted by the modified EVT system that was introduced in an intracavitary position during the procedure. Weekly EVT system exchanges were performed to reduce the size of the modified sponge as the collection healed. After 4 weeks of treatment (a total of 4 EVTs), there was significant reduction of the collection and granulation tissue without signs of

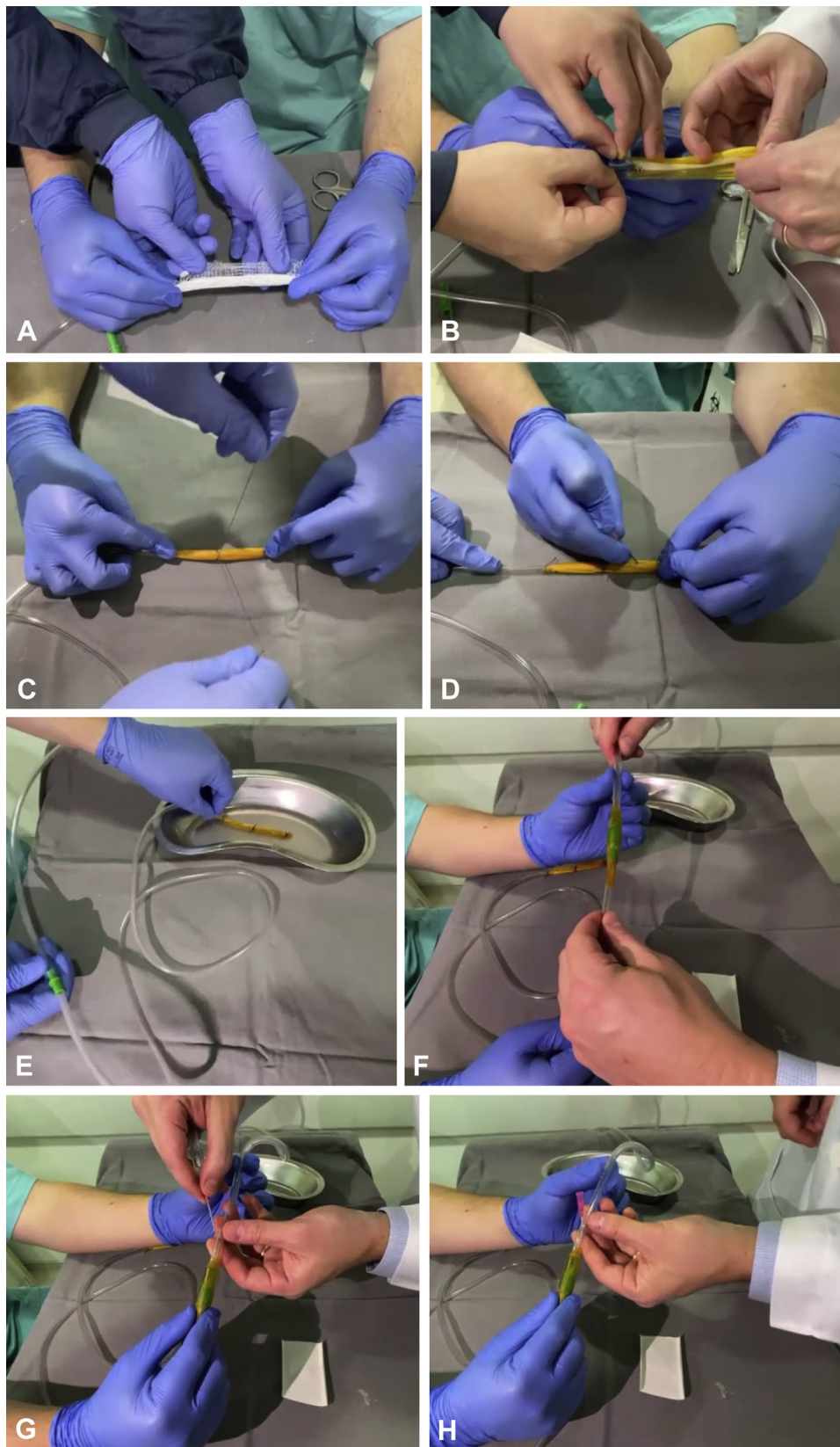


Figure 3. Step-by-step manufacture of the cost-effective modified endoscopic vacuum therapy. **A**, Wrap gauze around the fenestrated portion of the nasogastric tube. **B**, Wrap the antimicrobial incise drape around the fenestrated portion of the nasogastric tube. **C**, Fixation of the modified sponge with sutures. **D**, Perforation of the modified sponge. **E**, Functionality test. **F**, Sealing the connection of the tubes. **G**, A 20-gauge intravenous catheter connected to the tube to maintain a continuous negative pressure between -75 and -150 mmHg. **H**, Final aspect.

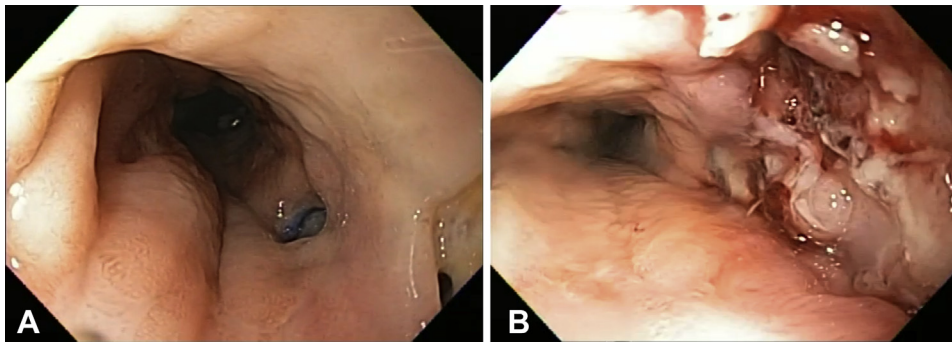


Figure 4. **A**, Esophageal leaks after Heller myotomy. **B**, Final appearance after endoscopic treatment.

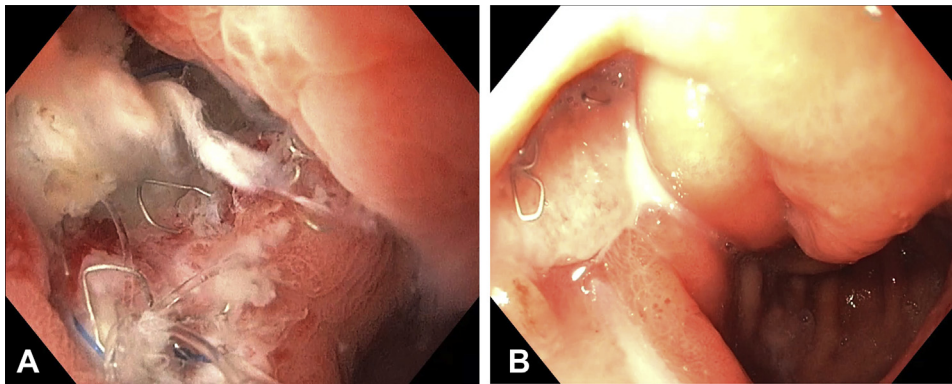


Figure 5. **A**, Postbariatric esophageal leak. **B**, Complete closure after modified endoscopic vacuum therapy treatment.

infection. Therefore, EVT was concluded. The patient remained clinically stable and was discharged 3 days later. At 1-month follow-up, CT scan revealed complete resolution of the collection, and colonoscopy showed complete repair of the wall defect.

DISCUSSION

Among the advantages of this modified EVT device are lower cost, easy insertion through the nares (in upper GI defects) or through the rectum (in lower GI defects), reduced procedure time, longer interval between EVT system exchanges, and less tissue ingrowth, resulting in fewer adverse events such as bleeding.^{11,13} Based on the individual defect characteristics and the presence of an associated collection, the sponge system may be placed intraluminal or intracavitary. It is recommended to place the EVT system inside the cavity when an associated collection is diagnosed.¹ The output volume depends on whether the vacuum therapy is intracavitary or intraluminal, if there is active infection with purulent content, and if the patient is on an oral liquid diet. The decision to conclude therapy should be based on clinical status, endoscopic findings, and imaging studies.

Despite several benefits associated with the EVT approach, other alternatives and possible disadvantages related to EVT use, such as patient discomfort and longer hospital stay, should be discussed before a decision is made. Overall, other modalities such as SEMs are considered a more traditional method with more widespread adoption and clinical experience. Interestingly, in our experience and according to recent studies, the use of conventional esophageal SEMs and specific customized SEMs for sleeve gastrectomy has been associated with a high rate of adverse events such as gastroesophageal reflux symptoms, pain, nausea and vomiting, and stent migration.¹⁵⁻¹⁷ In addition, a recent meta-analysis comparing stent versus EVT in upper GI defects showed higher rates of successful closure, a reduction in treatment duration, and lower mortality rates—all favoring the EVT group.¹⁸

It is critical to understand that patients with transmural defects, especially those with leaks, remain challenging, and an individualized approach is required. All therapies have potential advantages and disadvantages, and treatment decisions must be individualized.¹⁹⁻²⁴ Until now, there has been a relative lack of data to support any technique as a criterion standard method, and often more than 1 intervention is required. Ultimately, a multidisciplinary approach remains essential, and personal and local

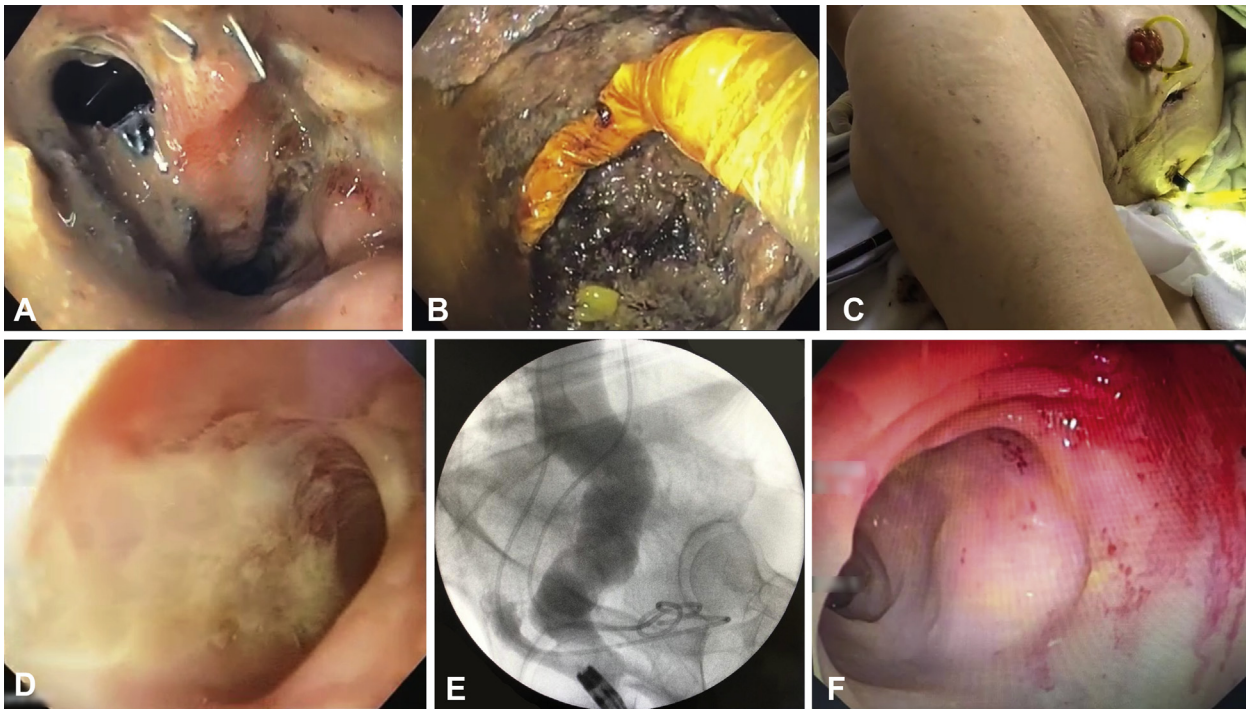


Figure 6. **A,** Leak at the colorectal anastomosis. **B,** Intracavitary modified endoscopic vacuum therapy. **C,** Removal of the external drain. **D,** Reduction of the collection with granulation tissue and no signs of infection. **E,** Fluoroscopy showing reduction of the collection. **F,** Complete repair of the wall defect.

experience should be considered when choosing the best treatment strategy.

CONCLUSION

This modified EVT system appears to be a feasible, safe, and effective alternative for the management of transmural GI defects. In our experience, this technique is associated with high technical and clinical success rates with no adverse events. The modified EVT is easily inserted and increases the interval between the EVT system exchanges. This cost-effective technique may expand EVT use by providing less-invasive treatment to more patients around the world, especially in developing countries.

DISCLOSURE

Dr Thompson is a consultant for USGI Medical, Apollo Endosurgery, Boston Scientific, Covidien/Medtronic, Fractyl, GI Dynamics, and Olympus/Spiration; does research support for USGI Medical, Aspire Bariatrics, Apollo Endosurgery, GI Dynamics, Olympus/Spiration, and Spatz; is a general partner with BlueFlame Healthcare Venture Fund; is a board member of EnVision Endoscopy; is an advisory board member of Fractyl; and has ownership interest in GI Windows. Dr Guimarães Hourneaux de Moura is a consultant for Boston Scientific and Olympus. All other authors disclosed no financial relationships.

Abbreviations: EVT, endoscopic vacuum therapy; NGT, nasogastric tube; SEMS, self-expandable metal stent.

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