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Original Article

Homemade endoscopic vacuum therapy device for the management of transmural gastrointestinal defects

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Objectives: Endoscopic vacuum therapy (EVT) possesses a unique mechanism of action providing a less invasive alternative for the management of transmural gastrointestinal defects (TGID). This study evaluates the efficacy and safety of a novel homemade EVT (H-EVT) for the treatment of TGID.

Methods: Retrospective multicenter study including patients who underwent H-EVT for TGID between January 2019 and January 2022. Main outcomes included technical and clinical success as well as safety outcomes. Subgroup analyses were included by defect location and classification. Logistic regression analyses were performed to determine predictors for successful closure.

Results: A total of 144 patients were included. Technical success was achieved in all patients, with clinical success achieved in 88.89% after a mean of 3.49 H-EVT exchanges over an average of 23.51 days. After excluding 10 cases wherein it was not possible to achieve negative pressure, successful closure occurred in 95.52% of patients. Time to clinical success was less for defects caused by endoscopic (hazard ratio [HR] 0.63; 95% confidence interval [CI] 0.33–1.20) compared to surgical procedures and for patients with simultaneous intracavitary and intraluminal H-EVT placement (HR 0.70; 95% CI 0.55–0.91). Location and classification of defect did not impact clinical success rate. Simultaneous placement of both an intraluminal and intracavitary H-EVT (odds ratio 3.08; 95% CI 1.19–7.95) was a significant predictor of clinical success. Three device-related adverse events (2.08%) occurred.

Conclusions: The use of the H-EVT is feasible, safe, and effective for the management of TGID.

Key words: colonoscopy, endoscopy, fistula, gastrointestinal, postoperative complication

INTRODUCTION

TRANSMURAL GASTROINTESTINAL DEFECTS (TGID) are broadly defined by complete rupture of the gastrointestinal (GI) wall and are characterized into three categories, including perforation, leaks, and fistulas.[1] Management of these defects remains challenging and frequently requires repeated interventions, prolonged hospital stay, and substantial associated health-care costs.[2] Currently available endoscopic therapies are shown in Figure 1.[1–3]

Despite the variety of endoscopic approaches available to date, there are no formal guidelines regarding the optimal management of these conditions. Unlike other endoscopic strategies, endoscopic vacuum therapy (EVT) possesses a unique mechanism of action which promotes defect closure via macro/micro deformation, angiogenesis, exudate control, and bacterial clearance. Furthermore, EVT obviates the need for external drainage.[1–3] Since its first description,[4] EVT has emerged as a promising approach with increased adoption

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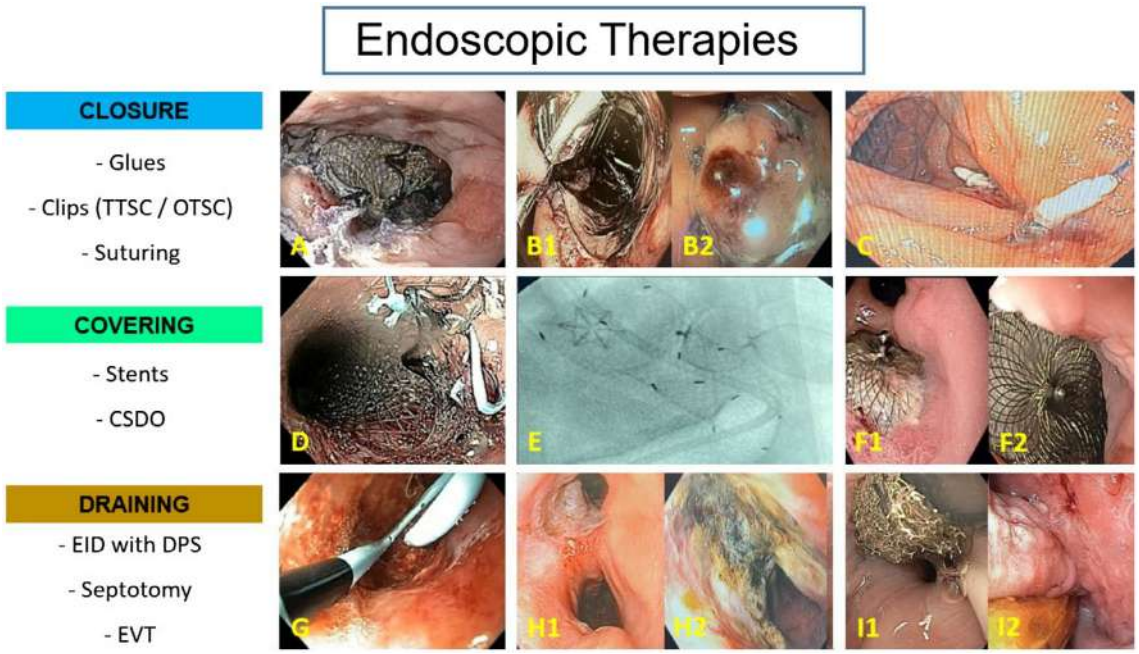

Figure 1 Endoscopic therapies for the management of transmural gastrointestinal defects. (A) Glue (cyanoacrylate) used as an adjunctive therapy after cardiac septal defect occluder (CSDO) placement for the treatment of an esophageal-pleural fistula. (B1) Through-the-scope clip (TTSC) placement for a large gastric perforation closure. (B2) Over-the-scope clip (OTSC) used for the closure of a small gastric leak. (C) Large duodenal perforation closed with endoscopic suturing. (D) Esophageal self-expandable fully covered metal stent fixed with OTSC to avoid migration during the treatment of an esophageal perforation. (E) Customized bariatric stent fixed with OTSC to avoid migration for the management of sleeve stenosis after successful gastric-cutaneous fistula closure using the CSDO. (F1) CSDO placement for the treatment of a distal gastric sleeve-cutaneous fistula. (F2) CSDO placement for the treatment of an esophago-cutaneous fistula. (G) Endoscopic internal drainage (EID) with double pigtail stent (DPS) placement for the treatment of an esophageal leak with an associated contained collection. (H1) Septum between the fistula orifice and the gastric sleeve. (H2) Endoscopic appearance after septotomy. (I1) Intracavitary endoscopic vacuum therapy (EVT) (polyurethane sponge) placement for the treatment of an esophageal leak with an associated infected contained collection. (I2) Intraluminal homemade EVT placement for the treatment of an esophageal leak after successful treatment of an associated infected contained collection.

worldwide for the treatment of TGID including esophageal,[2] gastric,[5] small intestinal,[6] biliopancreatic,[7] and colorectal[8] locations. EVT has been shown to be highly effective, regardless of defect size and presence of an associated collection, compared to traditional endoscopic strategies.[2,3,8–14]

Endoscopic vacuum therapy is traditionally performed using an open-pore polyurethane sponge (OPPS). However, the OPPS may be challenging to place and remove, and is associated with prolonged procedures due to its large diameter, which hinders endoscopic placement through the hypopharynx and small orifices. Additionally, the need for multiple exchanges due to tissue ingrowth increases costs and the potential for adverse events (AEs).[3,15] Based upon these limitations, a smaller diameter open-pore film (OPF) has been utilized to improve placement and allow for longer intervals between EVT system exchanges, with similar results to the original OPPS.[16] Despite these improvements, the high cost and the availability of the OPF remain barriers to use and widespread adoption.

To address these limitations, our group has previously described a homemade EVT (H-EVT) manufactured from widely available material and utilizing wall suction.[3,17–21] This novel design to perform EVT has shown promising results among case series; however, large studies have been lacking to date. Therefore, this large multicenter study aims to evaluate the feasibility, efficacy, and safety of this novel H-EVT for treating TGID.

METHODS

Study design

THIS WAS A retrospective, multicenter analysis of prospectively collected data from seven referral centers (Appendix S1). This study protocol and manuscript preparation were carried out according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (Appendix S2). Institutional Review Board approval for retrospective analyses was obtained for each center prior to data collection. Written informed consent for all patients or health-care proxy was obtained prior to the procedure after a detailed discussion of risks, benefits, and alternatives to H-EVT as this is not a certified medical product.

Patients

Consecutive patients undergoing treatment with the H-EVT for TGID between January 2019 and January 2022 were included in this analysis. Included patients were required to have evidence of TGID diagnosed via clinical history and/or imaging examinations such as computed tomography scan, Omnipaque contrast study, or endoscopic examination. Esophagogastroduodenoscopy (EGD) or colonoscopy was performed for all patients by a trained endoscopist to ensure an appropriate indication for H-EVT. For patients with hemodynamic instability, drainage of infected collections was performed through surgical revision, image-guided percutaneous drainage, or endoscopic internal drainage. After drainage and intensive care management, these patients were managed by endoscopy similarly to patients presenting with hemodynamic stability.

Homemade EVT

The detailed step-by-step process of manufacturing this novel H-EVT approach as well as the use of wall suction has been well described by our group previously[17–21] and are available in Video S1 and Figures 2 and 3.

Procedure

The need for endotracheal intubation or sedation was decided based upon the patient's clinical condition. For patients without external drainage, underwater EGD or careful use of CO_2 insufflation was used to avoid air leakage into the extraluminal compartment and collection disruption. For upper TGID, the H-EVT was inserted directly through the nares. Fluoroscopic assistance was commonly required in the index H-EVT placement; however, use of fluoroscopy was minimal with subsequent H-EVT exchanges.

The type of H-EVT device was at the physician's discretion; however, the nasogastric tube has been primarily used for intracavitary placement, and triple lumen tube for intraluminal position for upper TGID as it allows nutrition and drainage with a single tube.[19,20] The optimal size of the H-EVT system was based upon the estimated size of the defect and/or associated collection during index endoscopy.

When an associated collection was identified, first a lavage under endoscopic visualization was performed. Next, the H-EVT system was placed within the wound cavity (intracavitary). In cases where the orifice of the TGID was smaller than the diameter of the H-EVT system, the orifice was dilated to allow intracavitary access. In instances with an external drain within the wound cavity, the external drain was capped or removed, to ensure a negative pressure with the H-EVT (Fig. 4). Intraluminal placement was indicated when the cavity size was insufficient to accommodate the H-EVT (<3 cm) or in cases without associated collection (Fig. 5). Additionally, when an extraluminal collection was treated by intracavitary H-EVT and the size decreased, the system was changed to an intraluminal position.

Patients with upper GI anastomotic dehiscence and associated collection were treated with two simultaneous H-EVT tubes: one triple lumen tube in intraluminal position and a nasogastric tube in intracavitary position. The goal of this approach was to treat the associated collection (intracavitary), model the anastomosis, reduce aggressive factors such as gastric and biliopancreatic secretions, and allow enteral feeding (intraluminal; Fig. 4). For simultaneous H-EVT tubes, placement of one tube in each nostril was preferable as placement of two tubes through one nostril may increase the risk for pyogenic granuloma and necrosis. During treatment, all patients remained hospitalized. Oral intake with clear liquids were allowed for patients with upper TGID. Patients with lower TGID had no diet restrictions.

Adjunct therapies

Adjunct endoscopic procedures were performed in some cases based upon the endoscopist's discretion (Fig. 4). This typically occurred in the settings described in Table 1.

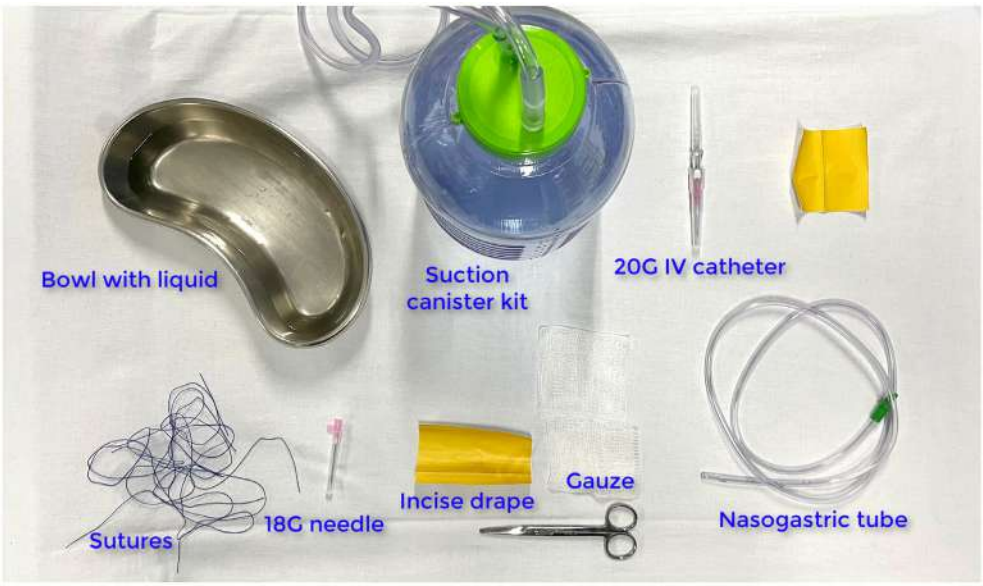

Figure 2 Tools for manufacturing the homemade endoscopic vacuum therapy device.

H-EVT creation	1	Cut the gauze in half to cover the fenestrated portion of the tube
	2	Wrap the gauze around the fenestration portion of the tube (TLT: use the gastric/aspiration fenestrations), covering all the fenestrations
	3	Cut the drape to match the size of the fenestrated portion of the tube covering the gauze
	4	Fix the H-EVT "sponge" with sutures
	5	Make several punctures in the H-EVT "sponge"
Device placement	6	Test the device outside the patient
	7	Place the H-EVT endoscopically
Negative pressure	8	Connect the tube to the suction to avoid migration of the device upon removal of the scope
	9	Seal the connection of the H-EVT tube with the aspiration tube connected to the wall suction using a drape
	10	Connect a 20G IV catheter to the aspiration tube to maintain a negative pressure between 75 and 150 mmHg as described in laboratory tests

Figure 3 Detailed step-by-step process for manufacturing the homemade endoscopic vacuum therapy (H-EVT) device. TLT, triple lumen tube.

EVT exchanges

The H-EVT system was exchanged periodically, usually between 7 and 15 days or earlier in cases of migration or device dysfunction. To exchange the H-EVT system, suction was turned off and the tube was removed with traction.

Data collection, outcomes measures, and definitions

Collected data included patients' sex, age, etiology, location, and classification of the TGID, prior treatment, device type, intraluminal or intracavitary placement,

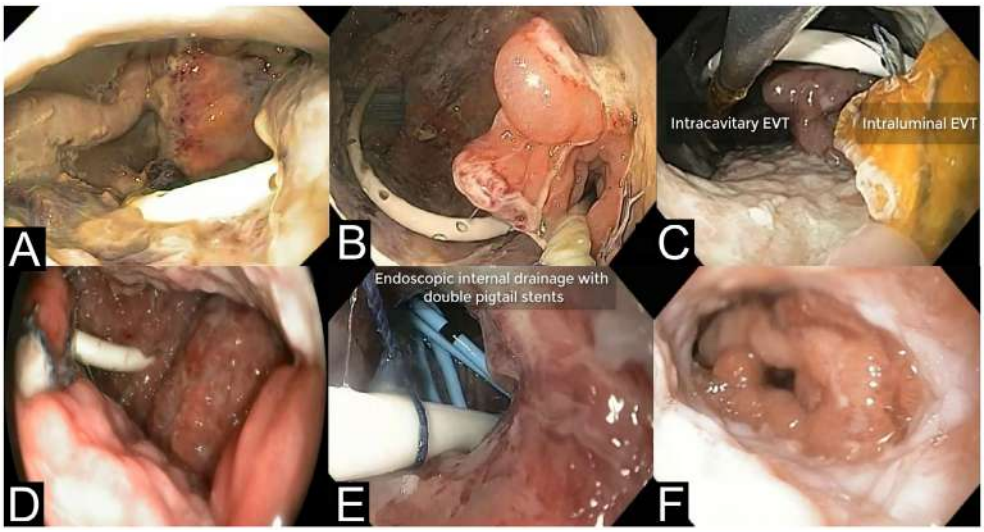

Figure 4 Treatment of a complex esophago-jejunal anastomosis dehiscence. (A) Endoscopic visualization of the abdominal organs (jejunal limb and left kidney) with purulent content due to a large transmural gastrointestinal defect (TGID) with ineffective external drainage. (B) Complete esophago-jejunal anastomosis dehiscence. (C) Simultaneous intraluminal and intracavitary homemade endoscopic vacuum therapy (EVT). (D) Clean residual cavity with granulation tissue and no signs of infection. (E) Endoscopic internal drainage with double pigtail stent (residual cavity-jejunal limb) and nasoenteral feeding tube placement into the jejunal limb. (F) 30-day endoscopic follow-up demonstrating resolution of the TGID with a 1 cm residual cavity without clinical significance.

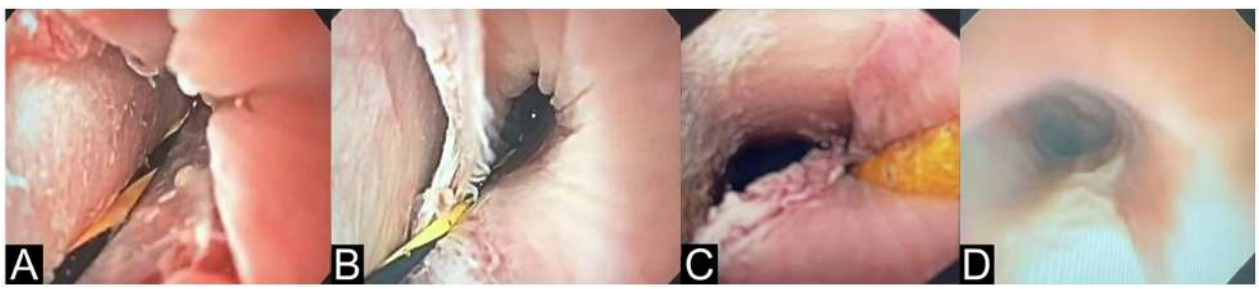

Figure 5 Treatment of an iatrogenic perforation in the proximal esophagus during endoscopic gastrostomy tube placement in a 1-year-old patient. (A) Underwater endoscopic visualization of the extraluminal compartment to avoid pneumomediastinum using a guidewire to facilitate homemade endoscopic vacuum therapy (H-EVT) placement. (B) Endoscopic image showing a large, hemicircumferential perforation (approximately 50% of the lumen). (C) Endoscopic image after H-EVT placement. (D) Endoscopic image 7 days after H-EVT placement showed complete resolution of the transmural gastrointestinal defect.

number of H-EVT sessions, need for device reposition and exchanges, treatment duration, technical and clinical success, need for other therapeutic procedure, AEs, and all-cause mortality.

Main outcomes included technical success, clinical success, and safety of H-EVT in the management of TGID. Technical success was defined as successful H-EVT placement. Clinical success was defined as resolution of the defect without signs of infection as confirmed by imaging exams. Treatment failure was considered if surgical intervention was required at least 1 month after H-EVT placement due to lack of defect resolution, poor healing, or infectious-related complications. AEs were defined as per published ASGE guidelines.[22]

Table 1 Indications for adjunct endoscopic therapies

Indications	Adjunctive therapy
Acute angulation making H-EVT placement challenging	DPS placed as a "bridge stent" followed by intraluminal H-EVT to improve drainage
Iatrogenic perforation during endoscopy	Clip without complete defect closure, followed by intraluminal H-EVT
Development of granulation tissue around a reduced cavity after initial treatment with H-EVT	DPS placement to aid in complete closure, reducing hospital stay
Downstream stenoses	Endoscopic balloon dilation
Septum	Concomitant septotomy during H-EVT exchanges
Epithelized surfaces (chronic defects)	Cytology brushing or ablation via argon plasma coagulation of the epithelized tract to induce granulation

DPS, double pigtail stent; H-EVT, homemade endoscopic vacuum therapy.

Statistical analyses

Means ± standard deviation were used for continuous data and frequencies and proportions for categorical data. Continuous data were compared using the two-sample *t*-test or Wilcoxon rank-sum test and categorical data were compared using the χ^2-test or Fisher's exact test, as appropriate. A subgroup analysis evaluating outcomes in different locations was performed. Classification of the TGID was grouped according to a previous consensus.[23] One-way ANOVA was used to determine any statistically significant differences between the means of two or more independent groups. Time-to-event analyses were assessed using the Kaplan–Meier method and the difference between the groups was calculated using the log-rank test. Cox proportional hazards regression was then used to calculate hazard ratios (HRs). Logistic regression analyses were conducted to determine significant predictors for successful closure of the TGID and were reported as odds ratios (ORs) with corresponding 95% confidence intervals (CI). Statistical significance was defined as a two-tailed P value <0.05. Statistical analyses were performed using the Stata 15.0 software package (StataCorp, College Station, TX, USA).

RESULTS

A TOTAL OF 144 patients treated with H-EVT for TGID were included. Among them, six patients had been included in previous case reports.[17–20] Baseline characteristics are highlighted in Table 2.

Table 2 Patient clinical characteristics and demographic features

Variables	Patients with H-EVT (n = 144)
Mean age in years (SD)	50.39 (18.62)
Male sex (%)	86 (59.72)
Mean days post-surgery to H-EVT (range)	54.77 (0–2920)
Location of TGID (%)	
Esophagus	56 (38.89)
Gastric	47 (32.64)
Small bowel	15 (10.42)
Colorectal	21 (14.58)
Other	5 (3.47)
Cause of the TGID (%)	
Endoscopic	12 (8.33)
Surgical	132 (91.67)
Classification of TGID (%)	
Acute	48 (33.33)
Early	85 (59.03)
Late	7 (4.86)
Chronic	4 (2.78)
Patients with surgical revision prior to H-EVT (%)	74 (51.39)
Patients with endoscopic attempt prior to H-EVT (%)	13 (9.03)
Patients with adjunctive endoscopic procedure (%)	58 (40.28)
Type of H-EVT device (%)	
Nasogastric tube (NGT)	121 (84.02)
Triple lumen tube (TLT)	15 (10.41)
Combination (NGT and TLT)	8 (5.56)
Patients with intraluminal H-EVT (%)	56 (38.88)
Patients with intracavitary H-EVT (%)	62 (43.05)
Patients with both intraluminal and intracavitary H-EVT (%)	26 (18.06)
Mean no. of H-EVT sessions (range)	3.49 (1–14)
Patients requiring H-EVT reposition (%)	8 (5.56)
Duration of H-EVT placement, days (range)	23.51 (3–80)
Duration of H-EVT to achieve clinical success, days (range)	21 (14–35)
Overall clinical success – defect resolution (%)	128 (88.89)
Clinical success after achieving negative pressure (%)	128/134 (95.52)
Adverse events (%)	3 (2.08)
All-cause mortality (%)	13 (9.03)
H-EVT-associated mortality (%)	0 (0.00)

H-EVT, homemade endoscopic vacuum therapy; TGID, transmural gastrointestinal defect.

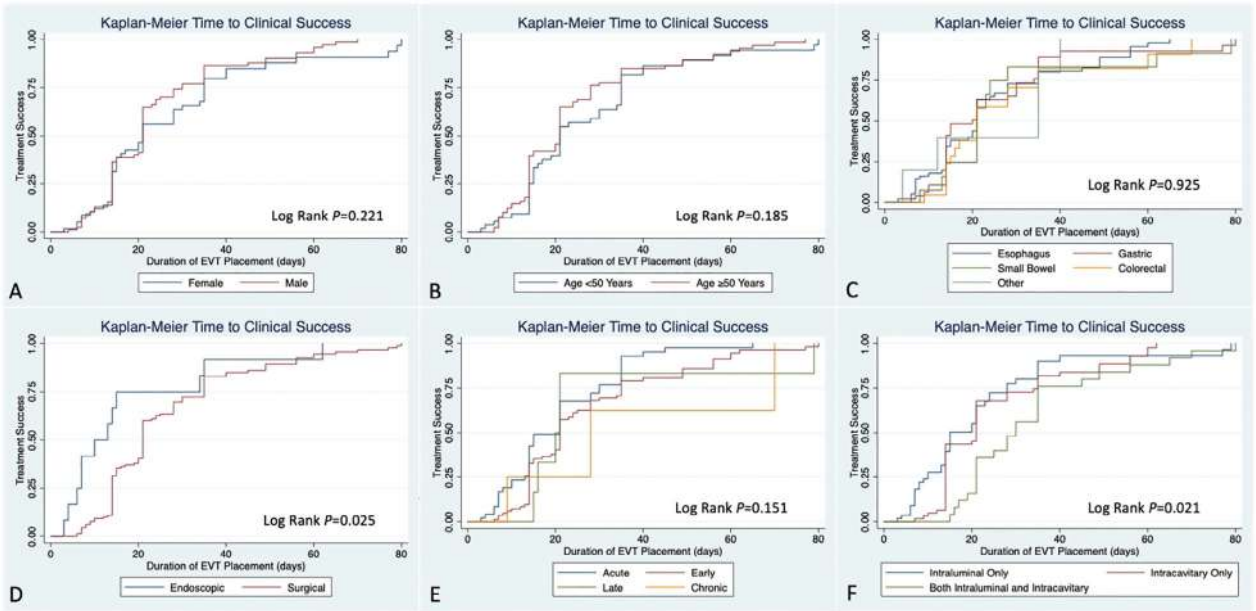

Figure 6 Kaplan–Meier curves demonstrating time to clinical success and homemade endoscopic vacuum therapy (H-EVT)-associated defect resolution. (A) Time to H-EVT clinical success by sex. (B) Time to H-EVT clinical success by age. (C) Time to H-EVT clinical success by transmural gastrointestinal defect (TGID) location. (D) Time to H-EVT clinical success by endoscopic or surgical cause. (E) Time to H-EVT clinical success by TGID classification. (F) Time to H-EVT clinical success by type of H-EVT placement.

Technical and clinical success

Technical success was achieved in all cases, and 128 (88.89%) patients achieved clinical success. When excluding 10 cases in which it was not possible to achieve negative pressure (three GI-cutaneous fistulas, two tracheoesophageal fistulas, three laparostomies, one pleurostomy, and one rectovaginal fistula), the clinical success rate was 95.52%. The additional six H-EVT failures were related to: patient intolerance to nasogastric tube, no diverting ileostomy, gastric tube complete necrosis, sleeve stenosis, and poor clinical and hemodynamic status which resulted in patient death before the H-EVT could act (two patients). Overall, the median number of days to achieve clinical success was 21 (interquartile range 14–35) and the mean number of H-EVT exchanges was 3.49 (1–14; Table 2). There was no difference in time to H-EVT clinical success by sex, age, location, or classification of the TGID. However, time to clinical success was significantly decreased for defects caused by endoscopic procedures (HR 0.63 [95% CI 0.33–1.20]) compared to surgical procedures and for patients with simultaneous intracavitary and intraluminal H-EVT placement (HR 0.70 [95% CI 0.55–0.91]; Fig. 6).

Safety reporting and mortality

A total of three AEs (2.08%) related to the H-EVT occurred. One severe AE (gastric bleeding) was reported in a patient with laparostomy after a perforated gastric ulcer. The patient subsequently underwent partial gastrectomy. One moderate AE was reported in a patient with a colorectal leak after rectosigmoidectomy due to endometriosis. She presented with bleeding which was treated by endoscopic clip placement followed by image-guided embolization. One mild AE (pleural bleeding) occurred due to an accidental dislodgement of the H-EVT tube during treatment of a gastropleural fistula post-Heller myotomy with fundoplication.

Thirteen (9.03%) deaths overall were reported (Table 3). There were no device-associated deaths (Table 2).

Subgroup analyses

Patients with colorectal TGID were older ($P = 0.035$) and more likely to have chronic defects ($P < 0.001$). Type of H-EVT device, mean number of exchanges, treatment duration, clinical success, AEs, and mortality were not significantly different between TGID locations (Table 4).

Table 3 Overall mortality

Causes (*n*)	Author's experience
Related to the H-EVT (8)	
Inability to achieve negative pressure (3): • Laparostomy (2) • Tracheal–esophageal fistula (1)	EVT is not effective when it is not possible to achieve negative pressure and should be considered a contraindication in some conditions such as tracheal–esophageal fistula, rectovaginal fistula, GI-cutaneous fistula, laparostomy, and pleurostomy
Intolerance to the NGT followed by sepsis (1)	Although rare, patient's intolerance to the tube can occur. Additionally, adverse events such as pyogenic granuloma and necrosis require tube removal. In these conditions, other effective drainage techniques are required, such as external drainage (interventional radiology or surgical) or EID-DPS.
Sepsis after surgical revision (2) • Extensive gastric tube necrosis (1) • Gastric sleeve stenosis (complete twist) (1)	Early treatment is key to success. When surgical approach is recommended, adequate time to indicate surgery is essential to achieve satisfactory outcomes. In these two cases, surgery should be performed earlier as endoscopic approaches usually fail in these conditions. Late treatment is related to deterioration of clinical, nutritional, and hemodynamic status, thus, increasing the risk of surgical complications.
Poor clinical and hemodynamic status during the first days of H-EVT (2)	Early treatment is key to success. When treatment (including endoscopic, surgical, or radiological) starts in a patient with poor clinical, nutritional, and hemodynamic conditions, a lower rate of clinical success is expected.
Unrelated to the H-EVT (5)	
Ischemic stroke (1) Advanced cancer stage (2) Sepsis related to urinary tract infection (2)	Multidisciplinary approach is essential to achieve clinical success

EID-DPS, endoscopic internal drainage with double pigtail stent; GI, gastrointestinal; H-EVT, homemade endoscopic vacuum therapy; NGT, nasogastric tube.

Regression analyses

Univariable regression analyses demonstrated no significant difference in clinical success by age, sex, etiology of defect, classification, evidence of prior surgery, associated endoscopic therapy, or type of device (all $P > 0.05$). However, simultaneous placement of both intraluminal and intracavitary H-EVT resulted in a significantly increased clinical success rate compared to intracavitary or intraluminal alone (96.15% vs. 93.55% vs. 80.36%, respectively; $P = 0.032$; Table 5). On multivariable logistic regression analysis, when controlling for age, sex, defect location, classification, type of device, and simultaneous placement of both intraluminal and intracavitary H-EVT remained a significant predictor for clinical success (OR 3.08; 95% CI 1.19–7.95; $P = 0.020$; Table 6).

DISCUSSION

TRANSMURAL GASTROINTESTINAL DEFECTS remain a challenging condition to manage and are associated with significant morbidity and mortality.[2,8] Therefore, a safe, effective, low-cost, reproducible, and minimally invasive therapy is needed. Although data are still limited, EVT has become the most effective endoscopic approach for TGID compared to traditional endoscopic strategies. However, the high cost of the commercial systems and some technical challenges limit its broad adoption.[8–14] The novel H-EVT presents several benefits over other EVT systems, such as shorter intraoperative time, reduced need for EVT system exchange, and lower costs. In addition to the high efficacy and satisfactory safety profile of the H-EVT, this system is affordable and can be easily reproduced.

The high technical success rate (100%) of the H-EVT is similar to the OPF and is related to the smaller distal diameter of the system (between 6 and 8 mm), making it easier to place and facilitating endoscopic manipulation.[16–20] The overall clinical success of 88.89% was similar to more traditional EVT systems despite TGID location.[7,10–12,14,24,25] Importantly, overall clinical success and time to defect resolution were not significantly different based on location or classification of defect. While clinical success was not different between endoscopic vs. surgically based defects, H-EVT appeared to have a shorter time to clinical success in endoscopic based defects.

To achieve clinical success, fundamental principles must be applied, such as adequate drainage and treatment of related factors.[1,2,19,23,26,27] For adequate drainage with EVT, the system needs to function. Compared to OPPS, the

Table 4 Subgroup analyses based on transmural gastrointestinal defect (TGID) locations

Variables	Esophageal (*n* = 56)	Gastric (*n* = 47)	Small bowel (*n* = 15)	Colorectal (*n* = 21)	Other (*n* = 5)	*P*-value
Mean age in years (SD)	52.08 (19.85)	45.72 (16.53)	53.40 (17.50)	57.71 (16.90)	35.60 (21.04)	**0.035**
Male sex (%)	40 (71.42)	18 (38.30)	13 (86.67)	12 (57.14)	3 (60.00)	**0.002**
Mean days post-surgery to H-EVT (range)	12.34 (0–55)	16.09 (0–60)	25.47 (0–150)	283.00 (7–2920)	19.20 (0–45)	**0.003**
Classification of TGID (%)						**<0.001**
Acute (1–7 postoperative days)	24 (42.86)	14 (29.79)	5 (33.33)	3 (14.29)	2 (40.00)	
Early (after 1–6 weeks)	31 (55.36)	32 (68.08)	8 (53.33)	11 (52.38)	3 (60.00)	
Late (after 6–12 weeks)	1 (1.78)	1 (2.13)	1 (6.67)	4 (19.04)	0 (0.00)	
Chronic (>12 weeks)	0 (0.00)	0 (0.00)	1 (6.67)	3 (14.29)	0 (0.00)	
Patients with surgical revision prior to H-EVT (%)	26 (46.42)	21 (44.68)	8 (53.33)	16 (76.19)	3 (60.00)	0.152
Patients with endoscopic attempt prior to H-EVT (%)	4 (7.14)	7 (14.89)	0 (0.00)	2 (9.52)	0 (0.00)	0.387
Patients with adjunctive endoscopic procedure (%)	21 (37.50)	23 (48.94)	5 (33.33)	7 (33.33)	2 (40.00)	0.678
Type of H-EVT device (%)						0.576
Nasogastric tube (NGT)	45 (80.35)	38 (80.85)	11 (73.33)	21 (100.00)	5 (100.00)	
Triple lumen tube (TLT)	5 (8.93)	5 (10.63)	4 (26.67)	0 (0.00)	0 (0.00)	
Simultaneous (NGT and TLT)	6 (10.71)	4 (8.51)	0 (0.00)	0 (0.00)	0 (0.00)	
Patients with intraluminal H-EVT (%)	27 (48.21)	13 (27.65)	8 (53.33)	3 (14.28)	4 (80.00)	**0.034**
Patients with intracavitary H-EVT (%)	19 (33.92)	27 (57.44)	7 (46.66)	7 (33.33)	1 (20.00)	**0.002**
Patients with simultaneous intraluminal and intracavitary H-EVT (%)	10 (17.85)	7 (14.89)	0 (0.00)	11 (52.38)	0 (0.00)	**0.015**
Mean no. of EVT sessions (range)	3.71 (1–14)	2.79 (1–9)	3.73 (1–12)	4.00 (2–12)	4.60 (1–8)	0.232
Patients requiring H-EVT reposition (%)	1 (1.78)	7 (14.89)	1 (6.67)	3 (14.29)	0 (0.00)	0.697
Duration of H-EVT in days (range)	23.71 (6–65)	22.28 (3–80)	23.87 (4–79)	25.10 (9–70)	25.20 (4–40)	0.968
Overall clinical success – defect resolution (%)	52 (92.86)	41 (87.23)	12 (80.00)	18 (85.71)	5 (100.00)	0.556
Clinical success after achieving negative pressure (%)	52 (98.11)	41 (95.34)	12 (92.30)	18 (90.00)	5 (100.00)	0.661
Adverse events (%)	0 (0.00)	2 (4.26)	0 (0.00)	1 (4.76)	0 (0.00)	0.495
All-cause mortality (%)	5 (8.93)	3 (6.38)	2 (13.33)	3 (14.29)	0 (0.00)	0.734
H-EVT-associated mortality (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1.000

Bold value indicates statistical significance.
H-EVT, homemade endoscopic vacuum therapy.

H-EVT has the advantage of the flat suctioning mechanism, which is present along the entire slippery surface of the device, allowing continuous suction even if some of the pores are blocked. Additionally, tissue ingrowth and system obstruction rarely occur, reducing the need for system exchange. Therefore, the time to exchange the H-EVT is based upon each individual patient's clinical condition and defect characteristics. Early exchange is recommended for infected collections, along with lavage of the associated cavity during system exchange. Large defects typically allow for longer intervals between H-EVT exchanges as more time is allotted to ensure proper closure. It remains essential to underscore that downsizing the EVT systems during exchanges is required as the size of the associated cavity is reducing. Cross-sectional imaging is also critically important during this evaluation, to evaluate for changes in size of associated defects and cavities. As a general principle, we aim to keep the H-EVT in place for up to 15 days.

When examining H-EVT-associated failures, the ability to achieve negative pressure was critically important. Therefore, some conditions such as tracheal–esophageal, recto-vaginal, GI-cutaneous fistulas, laparostomy, and pleurostomy should be considered a contraindication for EVT. In our study, 62.5% of defect closure failures were related to inability to achieve negative pressure.

Table 5 Univariable regression analysis for association between homemade endoscopic vacuum therapy (H-EVT) and clinical success

Variables for comparison	Overall clinical success – defect resolution	*P*-value
Age: >50 years vs. ≤50 years	91.11% vs. 85.19%	0.277
Sex: male vs. female	90.70% vs. 86.21%	0.404
Cause of defect: endoscopic vs. surgical	100.00% vs. 87.88%	0.204
Classification: acute vs. early vs. late vs. chronic†	93.75% vs. 87.06% vs. 85.71% vs. 75.00%	0.522
Prior surgery vs. no surgery	89.19% vs. 88.57%	0.907
Prior endoscopic attempt vs. no attempt	92.31% vs. 88.55%	0.683
Associated endoscopic therapy vs. no therapy	89.66% vs. 88.37%	0.812
Device: NGT vs. TLT vs. combination†	87.39% vs. 100.00% vs. 100.00%	0.103
Type of H-EVT: intraluminal vs. intracavitary vs. both†	80.36% vs. 93.55% vs. 96.15%	**0.032**

†ANOVA test used for comparison of >2 categorical independent variables.
Bold value indicates statistical significance.
NGT, nasogastric tube; TLT, triple lumen tube.

Table 6 Multivariable logistic regression analysis for association between homemade endoscopic vacuum therapy (H-EVT) and clinical success

Logistic regression for predictors of clinical success	Odds ratio (95% CI)	*P*-value
Age	1.02 (0.99–1.05)	0.200
Sex	1.42 (0.47–4.29)	0.531
Location of TGID	0.87 (0.55–1.38)	0.553
Classification of TGID	0.54 (0.24–1.23)	0.141
Type of H-EVT device	1.20 (0.39–3.72)	0.755
Placement of both intraluminal and intracavitary H-EVT	3.08 (1.19–7.95)	**0.020**

Bold value indicates statistical significance.
CI, confidence interval; TGID, transmural gastrointestinal defects.

Additionally, both univariable and multivariable regression analyses demonstrated both intracavitary and intraluminal EVT to be a predictor of clinical success and shorter time to defect resolution. These findings are key to determining future treatment algorithms and optimizing patients for EVT.

Interestingly, in our study, similar to a recent meta-analysis,[12] duration of TGID did not impact clinical success or time to resolution – suggesting a broad patient population amenable to treatment. Different from several studies,[5,8,14,28] we reported the use of adjunctive endoscopic approaches in a substantial part of our population. This finding is related to our experience in treating these challenging conditions, as described in Methods.[27,29–34] It is important to state that there is no gold standard method to treat TGID. An individualized approach considering personal/local experience is required. Furthermore, a multidisciplinary team is critical.[3,27,28]

Although procedure time was not registered, the small H-EVT system allows for easy endoscopic insertion and removal, maneuverability, and positioning, reducing intraoperative time. These advantages are proven when comparing our results to studies using other EVT systems.[11,24,34–37] Furthermore, these characteristics may turn it into the best approach for children, avoiding the need for retrograde placement (via gastrostomy).[38]

Cost calculations are complex, and several factors should be considered.[2,39] Although we did not evaluate costs, as placement of the H-EVT is easier and faster than the other EVT systems, it is expected lower room time and reduce the need for general anesthesia. Additionally, it is obvious that the H-EVT using wall suction is cheaper than the commercial EVT systems' accessories.

Safety is a primary concern in the introduction of any novel device. The low rate of AEs reported in our study is similar to other EVT systems.[6,14,37] It is critically important to underscore that a nonworking EVT system may be hazardous for patients. Therefore, physicians and nursing staff need to be carefully trained.[16] Importantly, there was no H-EVT-associated mortality.

Although this is the largest multicenter study regarding the use of a modified EVT system for TGID to date, including a variety of classifications and locations in both upper and lower GI indications, our study is not without limitations. Most importantly, this was a retrospective study allowing for the possibility of selection bias when considering patients for EVT. Additionally, this study was conducted in centers with large experience managing TGID and using H-EVT, which likely affects the generalizability of our results. Ultimately, recognizing that the "MacGyvers bias"[40] can affect our article, comparative studies evaluating

the properties of this device over other EVT systems are needed to validate our findings.

Given the established results of the EVT in the management of TGID, novel indications are being explored, including pre-emptive EVT and treatment of GI hemorrhage, with promising results.[41–43]

In conclusion, this novel H-EVT system was found to be feasible, safe, and effective for the management of TGID, regardless of location or duration of defect. This low-cost device may become a substitute or at least a complement to other EVT devices and has the potential to expand EVT use by providing less invasive treatment to more patients worldwide, especially in resource-scarce settings.

CONFLICT OF INTEREST

AUTHORS DECLARE NO conflict of interest for this article.

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NONE.

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SUPPORTING INFORMATION

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher's web site.

Appendix S1 Participating centers.

Appendix S2 STROBE statement.

Video S1 Step-by-step process of manufacturing the homemade endoscopic vacuum therapy system.