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Indigenously modified endoluminal vacuum-assisted closure therapy for post-operative gastrointestinal leaks: Successful case series

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Abstract

Introduction: Treatment of gastrointestinal perforations and post-operative anastomotic leaks remains a challenge. Endoluminal Vacuum-assisted closure (E-Vac) therapy has positively contributed, in recent years, for the management of gastrointestinal tract perforations and postoperative anastamotic site leaks by using the same principle of vacuum-assisted closure therapy of external wounds. Like traditional E-Vac our Indigenously modified E-VAC provides continuous wound drainage and to promote tissue granulation, decreasing the needed time to heal with a high rate of leakage closure.

Method and results: A series of three different cases with clinical and radiological diagnosis of gastrointestinal postoperative anastomotic site leaks. The first one is a case of anastomotic leak after esophagectomy for mid esophageal cancer complicated by pleuromediastinal abscess, while the second one is a leak of an esophageal gastric anastomotic site after partial gastrectomy done for left Bochdalek hernia and third one is colo-anal anastomotic leak followed by laparoscopic anterior resection for carcinoma rectum. All three cases were successfully treated with E-Vac therapy.

Conclusion: Our experience shows the usefulness of E-Vac therapy in the management of anastomotic and non-anastomotic gastrointestinal perforations and leak. Because of high cost and non availability of traditional E-Vac in INDIA, indigenously modified one appears to be promising therapeutic option in treatment of such cases. Further research is needed to better define its indications, to compare it to traditional treatments and to evaluate its long-term efficacy.

Introduction

A Gastrointestinal (GI) transmural defect refers to the complete rupture of the gastrointestinal wall. These defects can be classified into three primary categories, namely perforation, leaks, and fistulas. The identification of the precise categorization of the defect holds significance in the selection of the optimal therapeutic approach. Historically, numerous endoscopic methods have demonstrated efficacy in managing transmural defects. These techniques encompass clips, cap-mounted clips, Covered Self-Expandable Metal Stents (CSEMS), tissue sealants, endoscopic sutures, cardiac septal defect occluders, septotomies, and internal drainage using pig-tail stents [1,2]. Nevertheless, the efficacy of these therapeutic modalities varies.

Endoscopic Vacuum therapy (E-Vac), alternatively referred to as endoscopic negative pressure therapy or E-Vac therapy, represents a novel endoscopic approach utilised in the management of transmural gastrointestinal defects [3]. The number of indications for Vacuum-Assisted Closure (VAC) therapy has exhibited a consistent upward trend since the 1990s [4,5].

This study presents the effective resolution of three distinct types of gastrointestinal tract transmural defects. The first case involves an esophago-gastric anastomosis performed to address a left Bochdalek hernia, where the stomach completely migrated into the left pleural space resulting in ischemia. This patient subsequently developed a leak at the anastomotic site. The second case pertains to a colo-anal anastomotic leak that occurred following a laparoscopic anterior resection with the addition of a defunctioning descending colostomy. This procedure was conducted to treat rectal cancer. Lastly, the third case involves a gastric leak in a patient who underwent surgery for esophageal carcinoma.

The E-Vac method

The procedure is conducted within the surgical suite, with the patient positioned in a supine position under anaesthesia and an endotracheal tube inserted. The use of general anaesthesia is necessary in order to facilitate the insertion process of the E-Vac device. Initially, the leak cavity is examined and assessed using a flexible endoscope. The leak cavity was debrided using a fistula brush and irrigated with saline solution under direct visualisation. The conventional Eso-SPONGE kit typically includes an open-pored sponge that is connected to a drainage tube, which is then linked to a low-vacuum pump. However, the utilisation of this device is restricted due to its limited availability in various centres and its high cost. The E-vac Endovac device, which has been subject to indigenous modifications, incorporates a vacuum therapy sponge specifically designed for the treatment of leg ulcers. The sponge was trimmed to the appropriate dimensions by measuring the size of the cavity and subsequently cutting it accordingly. The Ryles tube was inserted nasally and taken out orally, with a sponge securely wrapped around the tip of the tube, encompassing all of its openings, using Ethilon sutures. The sponge, under the guidance of an endoscope, was carefully inserted into the cavity along with the RT, and a part of the sponge was allowed to remain in the lumen. A second sponge, of an appropriate size, was affixed by obstructing the cavity located at the distal end of the RT and subsequently positioned on the surface of the skin. RT was connected to an endovac therapy unit, with the pressure being adjusted to 120 mmHg. The process is repeated by substituting the sponge every 72 hours until the formation of granulation tissue results in the complete closure of the cavity (Figures 1,2).

Case capsule 1

A 59-year-old man has complained of pus and mucus discharge from the anal region, as well as intermittent fever episodes, for the past two years. Three years ago, he developed symptoms of per rectal bleeding and was diagnosed with Carcinoma rectum, for which he received three cycles of neoadjuvant radiotherapy followed by laparoscopic anterior resection with a defuncting descending colostomy. He was discharged on post-operative day 8, with no issues reported. Adjuvant Chemotherapy was administered in 13 cycles. After 6 months of surgery, a CT abdomen was performed, which showed post-op changes in the pelvis with Pelvic peritoneal fat stranding and widening of the presacral space. He was having repeated episodes of fever with chills and pus discharge per anus that were resolved with IV antibiotics. After 6 months, an MRI of the pelvis revealed a significant collection of size 9.1 x 5.2 x 8.8 cm with air loculi at the presacral area-most likely a controlled leak (Figure 2). The conservative approach was continued for another six weeks, during which an intermittent fever with mucus and pus discharge from the anal region persisted. A colonoscopy was performed, which showed the cavity and confirmed the findings (Figure 4). Endovac sponges were sutured to RT and placed directly into the cavity with the help of a colonoscope after debriding and irrigating the cavity. After applying post-E-VAC therapy, the patient improved and had no fever after 48 hours. The procedure was repeated on an OPD basis four more times, with the endovac in place for five days each. At each session of endoscopy, there was a reduction in the size of the sponge used and considerable improvement in terms of the size of the cavity and the amount of slough (Figure 5). The cavity completely healed 10 weeks after E-VAC therapy, and the patient has been asymptomatic for the past 4 months. A CT scan showed complete resolution of the leak.

Case capsule 2

A 31-year-old female patient with a Bochdalek hernia with complete stomach migration into the left pleural space and ischaemia. Intraoperatively, after bringing down the stomach, the proximal half was found to be gangrenous with perforation. Upper partial gastrectomy and esophagogastric anastomosis were performed. The surviving stomach was oedematous and ischemic, but not gangrenous. A CT scan with intravenous contrast 48 hours later revealed a severely ischemic stomach, raising concerns about its viability. A recheck laparotomy to test the stomach remnant revealed considerable edoema but looked viable. The anastomotic site looks healthy. On the 12th postoperative day, an oral contrast study revealed a frank leak from the anastomosis, with the infected collection tracking up to the left perinephric space, with endoscopy confirming the results (Figure 6). At this point, management options were limited. The covered stent and reoperation were deemed risky. Endoscopic Vacuum (E-VAC) therapy was considered a safe choice in these conditions.

A UGI endoscopy performed to prepare for the endovac revealed a partial breakdown of the anastomosis with a defect size of 3 cm and a subdiaphragmatic cavity filled with slough. The cavity was entered with a scope, and de-sloughing was accomplished with a brush. Normal saline was used to irrigate the cavity. Endovac was used. Forty-eight hours after beginning endovac therapy, there was a significant decrease in SIRS response as measured by fever, pulse rate, WBC count, and CRP. Endovac was done twice more at 5-day intervals. The therapy lasted two weeks in total. At each endoscopic session, the size of the sponge used was reduced, and the cavity size and amount of slough were significantly improved (Figure 7). After 2 weeks of endovac therapy, a CT oral contrast study revealed a significant reduction in cavity size with a well-formed fistula that closed in about 8 weeks. Endoscopies were performed at 3 and 6 months. Both were normal, and the patient is currently on a complete oral diet.

Case capsule 3

A 65 year lady a case of squamous cell carcinoma of lower end of oesophagus, she has received neoadjuvant chemoradiotherapy and underwent total esophagectomy and gastric pull up, 2 weeks later she presented with fever and shortness of breath after routine work up CECT chest and upper abdomen was done s/o 7mm defect in posterior wall of pulled up stomach at the level of D 6 vertebra with the leak of oral contrast forming a 6.5 x 2.2 x 1.2 cm collection in right paravertebral region from D5 to D8 vertebral level. She was treated with IV antibiotics and other supportive measures. Upper GI endoscopy showed a large fistulous opening with an overlying slough in the posterior wall of the pulled-up stomach along the staple line (Figure 7). She continued to have a fever, so CT-guided pigtailing was done, and pus was sent for Culture sensitivity, and antibiotics were changed according to it. One week after the procedure, a repeat CECT chest and upper abdomen was done. The previously seen right posteromedial collection showed a decrease in size, but a contrast leak persists. She was continued with antibiotics and supportive measures. Her fever subsided, but for persistent fistulous openings, therapeutic options were excision of the stomach, esophagotomy, and covered stents. For the present case, we went ahead with indigenously modified E-Vac therapy, which was performed for a total of 26 days while the sponge was changed four times. During the first three changes, the sponge was placed directly into the cavity. Excellent granulation of the tissues around the leak was achieved, together with a progressive reduction of the cavity size and of the pleuro-mediastinal abscess (Figure 8). Daily output from the collection bag dropped After 6 weeks of initiation of the E-vac therapy, the cavity showed complete healing, a CT scan showed a small pseudodiverticulum but no leak, and she was started on a full oral diet.

Figure 1: E Vac method.

Figure 2: E vac Method.

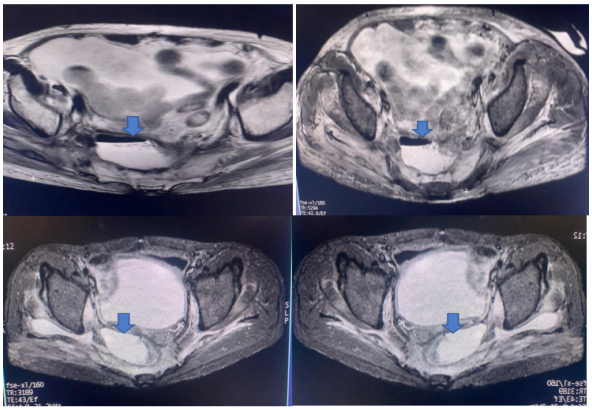

Figure 3: MRI pelvis showing collection in presacral area.

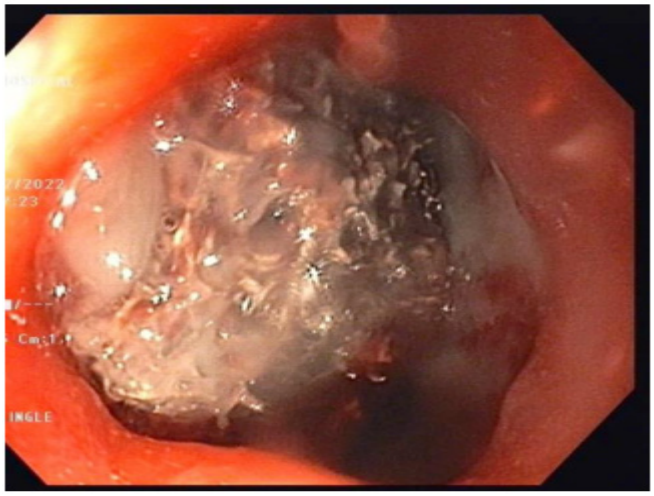

Figure 4: Colonoscopy showing post operative leak after anterior resection of ca rectum and placement of EVAC.

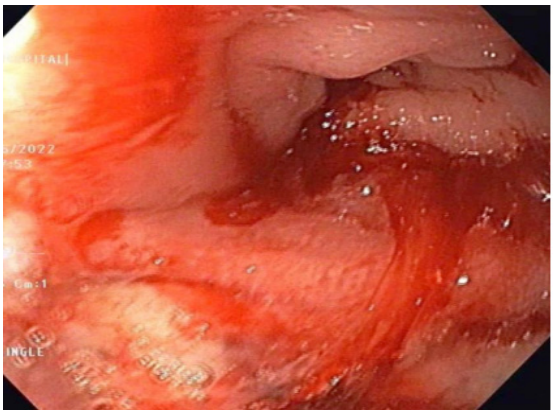

Figure 5: Healing of rectal cavity after E- Vac.

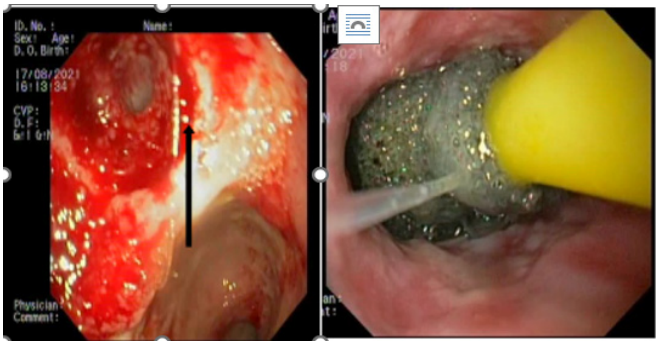

Figure 6: Post operative anastamotic site leak in stomach and placement of E Vac sponge.

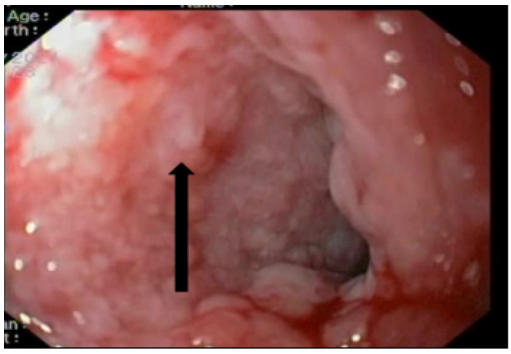

Figure 7: Healed anastamotic leak of stomach after E vac therapy.

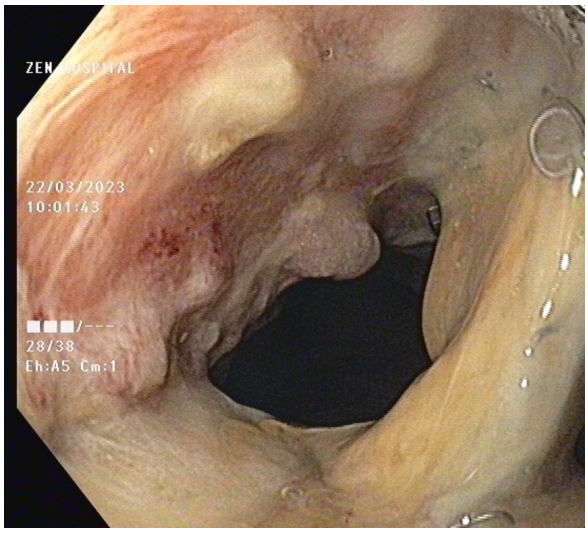

Figure 8: Endoscopic image Anastamotic site leak with overlying slough in cavity after gastric pullup.

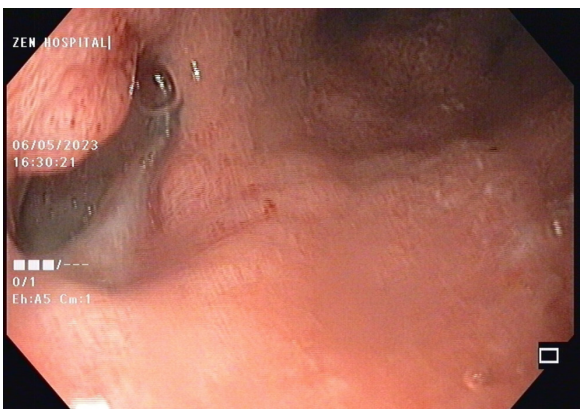

Figure 9: Endoscopic image of Healed cavity of gastric leak after E Vac therapy.

Discussion and literature review

This paper presents a comprehensive analysis of three distinct instances of gastrointestinal fistulas, each characterised by a unique origin and frequency, that were effectively treated through the implementation of E-Vac therapy.

In the first case, postoperative anastamotic leak in the anocolic region is a severe condition that negatively impacts postoperative outcomes. In conventional practise, in cases where a patient exhibits a symptomatic leak, the anastomosis is typically defunct, either as an initial procedure or subsequently. If abscesses are present, they are commonly drained either through percutaneous or transanal methods. Under the application of standard conventional management practises, it is possible that approximately 50% of these leaks may be resolved [6]. However, the development of a chronic presacral sinus occurs in the event that these leaks persist. The treatment for this chronic sinus condition necessitates a significant surgical intervention involving the removal of the leaking anastomosis. Subsequently, either a new anastomosis or an inter-sphincteric proctectomy with omentoplasty and the establishment of a permanent colostomy are performed [7]. Preventing the progression of a leak into a chronic sinus condition is of utmost importance, as it necessitates significant surgical intervention. In this particular case, a treatment approach utilising Vacuum-Assisted Drainage (EVAC) was employed, which involved the gradual reduction of Endosponges to facilitate the desired collapse of the cavity. The application of endovac therapy demonstrated a success rate of 90% in a cohort of 20 patients who experienced a rectal anastomotic leak. Notably, the leaks observed were extra-peritoneal in nature, and no diversion was employed for sepsis control. The therapy exhibited positive outcomes in terms of promoting granulation of the leak cavity and ensuring survival without the need for a stoma. Two patients required balloon dilatation for luminal stenosis [8].

With respect to the second case, Esophageal leaks have been observed to occur in approximately 35% of cases involving esophagectomis. The mortality rate associated with esophagectomy procedures can reach up to 15%. Among these cases, approximately 40% of the mortality is attributed to oesophageal leaks [9]. The available treatment modalities encompass surgical repair, endoscopic stents, endoscopic clips, glue, and Endovac therapy. Surgical intervention is recommended for patients who are in an unstable condition. Endoscopic stenting is frequently employed for the management of patients in stable conditions. The phenomenon of stent migration has been observed in a range of 3-35%, with plastic stents being more frequently associated with this occurrence [10]. The OTSC, or Over-The-Scope Clip, is an emerging device used for the closure of gastrointestinal leaks following endoscopic or surgical procedures. It is increasingly being recognised as a viable treatment option for leaks and fistulas. However, it is important to note that there are certain limitations associated with its use, such as the presence of nonviable tissue surrounding the defect margin, particularly in cases that are detected at a later stage, as well as the requirement for precise tip alignment [11-13].

In the third case, a leakage occurred in the posterior wall along the staple line of the stomach, leading to the infiltration of the mediastinum and pleural cavity. Consequently, the postoperative prognosis was unfavourable, and the patient was at risk of developing complications such as sepsis. The initial publication documenting the effective application of EVT in upper Gastrointestinal (GI) defects was made available in 2008 [14].

In a study conducted by Wedemeyer et al., two instances of intrathoracic anastomotic leaks following esophagectomy and gastrectomy were documented. These leaks were effectively managed through a series of sponge exchanges, with an average of five exchanges performed over a mean duration of 15 days. Notably, no adverse events were observed during the treatment process. Following the completion of this report, various research centres have published studies regarding the application of EVT in the treatment of upper gastrointestinal transmural defects. Until now, the predominant application of EVT in the upper Gastrointestinal (GI) tract has been focused on the closure of esophageal defects [15].

Overall, Evac therapy is considered a safe procedure characterised by a low incidence of adverse events. However, there are significant disadvantages associated with the conventional E-Vacs used for gastrointestinal leaks, including restricted accessibility and exorbitant expenses. The Eso-SPONGE kit consists of an open-pored sponge that is connected to a drainage tube, which is then linked to a low-vacuum pump. However, the utilisation of this device is restricted due to its limited availability in various centres and its high cost. The E-vac Endosponge, which has been modified using indigenous methods, is a vacuum therapy sponge that is specifically designed for the treatment of venous ulcers on the leg. The Ryles tube was inserted through the nasal passage and removed through the oral cavity. A sponge of suitable dimensions was prepared by cutting it to match the size of the cavity. The sponge was then carefully wrapped around the tip of Ryle's tube, ensuring that all the openings were covered, and secured in place using Ethilon sutures. The sponge, under the guidance of an endoscope, was carefully inserted into the cavity along with the RT. A portion of the sponge was intentionally left within the lumen. A second sponge, of an appropriate size, was affixed by obstructing the cavity at the distal end of the RT and positioned on the surface of the skin. The RT was connected to the endovac therapy unit, and the pressure was set at 120 mmHg. The application of continuous negative pressure induces mechanical deformation forces, resulting in both macroscopic and microscopic advantages. The vacuum forces also stimulate local angiogenesis by causing a temporary reduction in blood flow and activating the hypoxia-inducible factor-vascular endothelial growth factor pro-angiogenic pathway. This results in an observable increase in both blood vessel density and blood flow in the specific area.

The primary concern voiced by patients undergoing E-Vac Therapy pertains to the presence of a ryles tube, which can lead to considerable patient discomfort encompassing pain, nausea, and emesis, particularly among individuals with an accompanying nasoenteral tube. Furthermore, it has been observed that patients experience significant distress as a result of having to undergo multiple repetitive procedures for sponge exchanges [16,17]. The most commonly observed adverse events include sponge dislocation, minor bleeding subsequent to sponge exchange caused by the infiltration of granulation tissue into the sponge, and anastomotic strictures. Nevertheless, there have also been documented instances of significant hemorrhagic events. The implementation of endovac therapy is viable even within smaller community hospitals, as the necessary resources for its application are commonly accessible in such healthcare facilities. Furthermore, it is imperative to develop commercially accessible devices in order to enhance technical ease and reduce reliance on operator expertise for the placement of endovacs. Our study demonstrates the feasibility of implementing E-Vac therapy in a community setting, provided that there is an operator with the necessary expertise.

There are several contraindications to endovac therapy, including the presence of massive defects, loculated cavities, cavities with complex shapes, fistulas that do not hold suction and connect to the skin or body cavities, as well as a wide dehiscence of a surgical anastomosis or necrosis of the conduit. Other contraindications include fistulas connecting to the airway, close proximity to blood vessels, and the administration of systemic anticoagulation. In such instances, surgical intervention is frequently necessary. The widespread use of Endovac therapy holds promise for enhancing the outcomes associated with esophageal leaks.

In the year 2017, a study conducted by Kuehn et al [18]. Presented a MEDLINE analysis encompassing 11 case series involving a total of more than 210 patients who had upper Gastrointestinal (GI) tract defects and were treated with E-Vac. This review reports success rates of 90% and 96% for anastomotic leakages and esophageal perforations, respectively. At present, there is a lack of prospective randomised clinical trials that directly compare the efficacy and outcomes of endoscopic stenting, E-Vac therapy, and surgical revisions for upper gastrointestinal leakages or perforations. An additional pivotal aspect pertains to the absence of existing guidelines pertaining to the indication for E-Vac therapy, the minimum diameter of perforations that can be treated, and a standardised duration of treatment.

Conclusion

In difficult situations of GI anastamotic leaks and fistulae there are only limited options for treatment in which E-Vac therapy appears promising. Indigenously modified E-vac is cost effective and made easily. We treated all three cases successfully with our modified E vac.

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