




Assessment of the efficacy of Handmade Vacuum-Assisted Sponge Drain for Treatment of Anastomotic leakage after Low Anterior Rectal Resection

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Received: 20 February 2023 / Accepted: 17 April 2023 / Published online: 22 April 2023
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Abstract

Anastomotic leakage is one of the major complications of colorectal surgery, which might lead to reoperation, increased hospital stays, further intervention and mortality. Vacuum-assisted closure by devices such as Endo-SPONGE® produced by (B-Braun Medical B.V.) is currently being used to treat leakage and fistula. In this study, we aimed to assess the handmade vacuum-assisted sponge drain for anastomotic leakage following low anterior resection. This prospective study included 22 patients who had undergone sponge drain placement to treat anastomotic leakage. All patients had anastomotic leaks or defects after left anterior rectal resection (LAR) without ileostomy. They were treated with neo-adjuvant chemotherapy before the surgery and then subjected to rigid recto-sigmoidoscopy for 30 days following the operation. Any sign of leakage, such as perianal and pelvic pain, was immediately identified and followed up with a CT scan and another recto-sigmoidoscopy. Twenty-two patients were enrolled in this study, 12 men (54.5%) and 10 women (47.4%). All patients had received neo-adjuvant chemotherapy with an average follow-up of 22.30 ± 3.81 . 75% of patients (15 cases) were successfully treated, and 17 patients (85%) underwent successful ostomy closure. Treatment failed in 5 patients (25%), including three men and two women. This study shows that handmade vacuum-assisted sponge drain is a cost-effective method of anastomotic leakage management with efficacy similar to that of Endo-SPONGE®.

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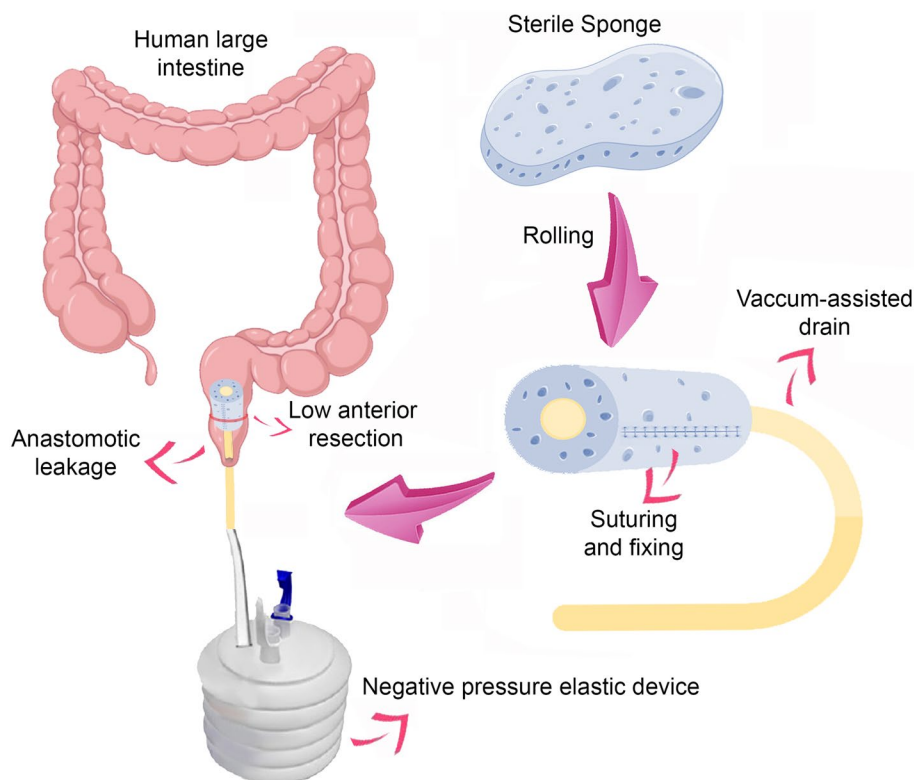
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Graphical abstract



Keywords Colorectal Cancer · Anastomotic leakage · Negative-pressure wound therapy · Colon surgery · Endoscopic treatment · Endo-sponge

Introduction

Colorectal cancers are the second leading cause of cancer-related deaths. Currently, surgical intervention is one of the few curative steps in treating rectum cancer [1–7]. It has been estimated that almost 35% of rectal surgeries get complicated, and around 2.7–11.9% of rectum anastomoses can become complicated with anastomosis leakage (AL) [8–10]. The site of resection affects the incidence rate as leakage happens in 9.4% of rectum resection cases, while only 5.8% of rectum resection cases get complicated with leakage [4, 11–14]. Not only does anastomosis leakage increase mortality rates, but it also disposes patients to severe and life-delipidating consequences as leakage requires reoperation and the creation of a stoma, which significantly reduces life quality in these groups of patients [13, 15–19]. The current literature suggests that invasive methods, including operative surgeries such as Hartmann’s procedure (anastomosis resection and rectal stump closure with end colostomy), should only be used for unstable patients, SIRS-positive or those who show signs of peritonitis [13, 15–23]. More novel methods, such as endoscopic methods using endo-sponges, stents

and clips, have demonstrated promising results in healing acute leaks. A form of commercially available endo-sponge developed by Braun Medical B.V., Melsungen, Germany, is currently being used for the induction of negative pressure in the rectum [8, 13, 17]. Although useful, the high costs and the constant need for changing the device led us to design a handmade vacuum-assisted sponge and evaluate its efficacy in a prospective study.

Materials and methods

Study design

In this prospective clinical, a total of 22 patients, 12 men and ten women, were enrolled in this study from August 2021 to August 2022 at the colorectal surgery ward at imam hospital complex. All patient records and data were examined prospectively, and all were followed up. All patients were diagnosed with either an anastomotic leak or a defect following left anterior resection of the rectum (LAR) with

or without ileostomy. All included cases had received neo-adjuvant chemoradiotherapy before surgery and underwent rigid recto-sigmoidoscopy 30 days after surgery with follow-ups every three months up to at least a year. Any sign of local leakage, including pelvic and perianal pain, anastomosis defect or pus discharge, indicated that the patient underwent another recto-sigmoidoscopy and CT scan. The patients who required immediate interventions, including those who experienced sepsis or recurrences, were excluded from this study (Figs. 1, 2).

Ethical acceptance

Additionally, the Tehran University of Medical Sciences Ethical Committee gave its approval to the study idea (Ethics code: IR.TUMS.THC.REC.1400.070).

Statistical analysis

Continuous variables with a normal distribution were reported using mean and standard deviation (SD) and compared using a student's t-test. The chi-squared or Fisher's exact test was used to compare categorical variables that were expressed as absolute frequencies with percentages.

Statistical analyses were conducted using IBM SPSS Statistics for Windows, version 23.0 (Armonk, NY: IBM Corp.) and Stata Statistical Software, release 15.2 (College Station, TX: Stata Corp LLC.)

Fabrication and method of application

All patients in this study had undergone anterior resection of the rectum with or without ileostomy and had become complicated with anastomosis leakage. All patients whose leakage was specifically confined to local leakage in the perirectal pelvic cavity with no sign of abdominal leakage or peritonitis were included in this study. All patients with abdominal involvement were excluded. To fabricate the handmade vacuum-assisted sponge, the patient was put

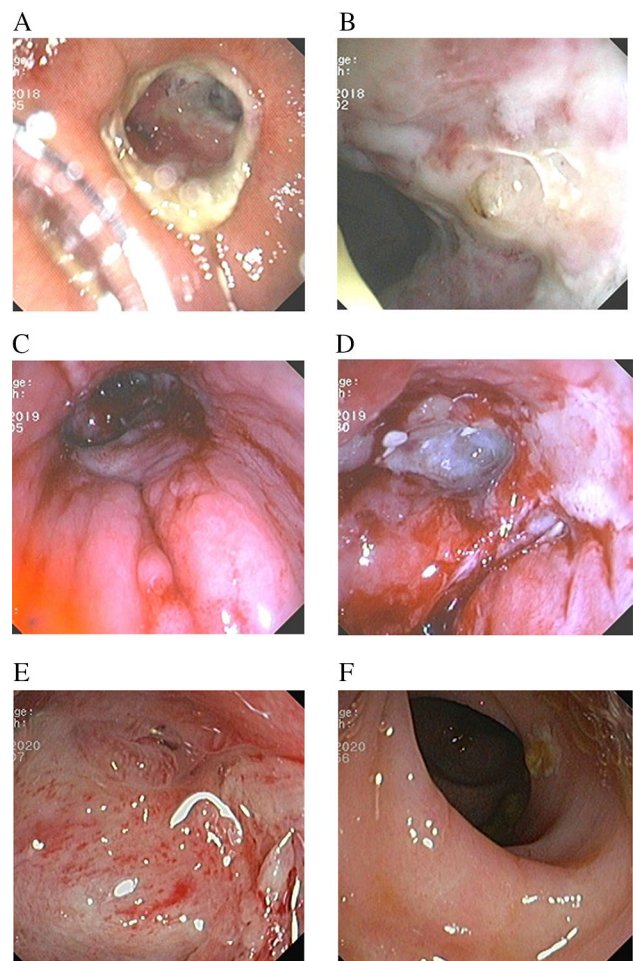
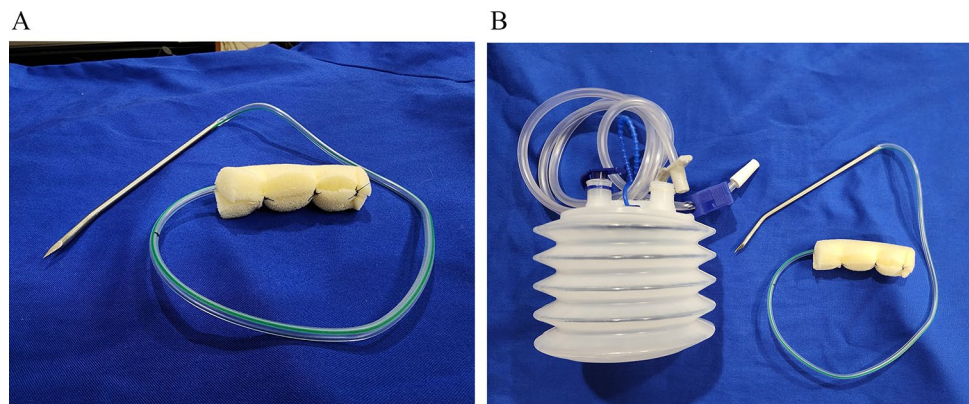


Fig. 2 Serial colonoscopy evaluation of patient number 16. **A, B** The figures showcase anatomic leakage, puss formation and abscess. **C, D** The figures show marked improvement within 6 months after the initial colonoscopy. **E, F** The figures show complete healing and scar formation 18 months after treatment

under general anesthesia or moderate sedation and placed in a lithotomy position in the operating room. The anastomosis was checked using an Eisenhammer Rectal Speculum. The

Fig. 1 **A** Sponge drain. **B** Complete set of vacuum-assisted sponge drain



cavity of the leakage was suctioned, and the size of the cavity was assessed; a piece of sterile polyurethane sponge was cut to the size of an anastomosis leakage cavity (in large cavities, two or more sponges might be needed). (Vaccaro, Tehran, Iran), the sponge was wrapped around a hemovac tube drain and sutured to the drain using a 0 braided silk suture (Supa Medical Devices) 2 or 3 sutures will be needed to fully fix the sponge to the drain (this step is very important because it prevents the sponge from coming off while removing it), the drain is connected to a negative pressure elastic device (e.g., Redivac drain, Supa Medical Devices, Tehran, Iran). The drain was placed gently in the sinus tract using a clamp and was fixated to the perianal skin using tape. The whole system was changed every 2–7 days depending on the daily discharge in the drain; after sponge removal, the defects were evaluated, and if the defect size was more than 1 cm, another sponge would be replaced. Leaving the sponge in the cavity for more than seven days will make it difficult to come out, and a part of the sponge might be left in the cavity. In cases of large amounts of pus accumulation and pelvis sepsis, thorough irrigation and sponge replacement every 24–48 h are needed until sepsis is eliminated.

The patients were also followed up for major device complications such as sponge tear and retainment, foreign body reaction, infection, abscess formation, and rectal stricture. In case the device became defective, and parts of the sponge or drain were retained in the rectum, the retained remnants were either removed manually or via colonoscopy. Similar to other devices, Vacuum-Assisted Sponge Drains can cause foreign body reactions or can become a source of infections and lead to abscess formation; in such instances, the devices were removed, and the patients were treated with medications. If the device leads to stricture, the site of stricture is treated using balloon dilation and in severe cases, the patients undergo re-ostomy.

Results

In total, 22 patients were enrolled in this study; 12 men (54.5%) and ten women (47.4%). The patients were, on average, 58.31 years old (SD: 9.43). All patients were diagnosed with anastomosis leak, with almost one-third of the patients having posterior leakage (36.8%), followed by 31.6% who had a lateral leak. All patients had received neo-adjuvant chemotherapy with an average follow-up of 22.30 ± 3.81 . Seven patients had primary abscesses, two of whom also failed treatment.

In total, two patients out of 22 discontinued participation in the study and refused follow-up. 75% of patients (15 cases) were successfully treated (the leakage was resolved,

and the cavity was closed), and 17 patients (85%) underwent successful ostomy closure. Treatment failed in 5 patients (25%), which included three men and two women.

Regarding failure, one of the cases had disease recurrence and developed sepsis four months after low anterior resection (leakage and sepsis were controlled by sponge drain treatment). One of the patients had a Recto-urethral fistula whose ileostomy was not closed (after multiple sponge replacements, the cavity had not closed, and in a follow-up colonoscopy, a fistula tract was formed). In one patient, the anastomosis leakage was completely healed, but the patient was diagnosed with liver metastasis in the follow-up CT scan and was not a candidate for ostomy closure. One patient had local recurrence in the anastomosis leakage site and underwent pelvic exenteration. In 2 patients, ostomy closure was achieved, but the rectoscopic evaluation four weeks after ostomy closure revealed re-disruption of the anastomosis, subsequently anastomosis take down, and permanent colostomy was done for them.

One of the successful cases was later presented with benign anastomosis stricture, which was successfully managed by dilatation. In our experience, the fibrosis caused after healing of the leakage site was benign and not clinically troublesome; we did not encounter stricture with defects less than 30–40% of the anastomosis circumference.

In this study, we also assessed defect dimensions, including size and depth; our analysis showed, albeit marginally, that defect size and depth are not significantly correlated with failure. Furthermore, none of the patients

Table 1 Comparison of patient characteristics, Risk Factors and outcomes between successful and unsuccessful cases

	Success (n=42)	Failure (n=28)	p value*
Age	56.33 ± 11.78	60.20 ± 2.94	0.48
Gender (female)	53.3%	40.0%	0.606
Leakage site			
Anterior	1 (6.7%)	1 (20.0%)	
Posterior	7 (46.7%)	3 (60.0%)	
Lateral	3 (20%)	1 (20.0%)	
Anterolateral	4 (26.7%)	0 (0.0%)	
Ostomy closure	2 (13.3%)	2 (40.0%)	0.197
Anastomotic stricture	0 (0.0%)	1 (6.7%)	0.554
Fistula formation	1 (20.0%)	0 (0.0%)	0.076
Defect size	31.26	36.40	0.518
Defect depth	3.76	3.20	0.598
Neoadjuvant therapy length	2.26	2.00	0.473

*p values report the significance of differences between the two groups. Fisher's Exact test was used for the analysis and p values < 0.05 were considered significant

Table 2 Clinical and demographic characteristics

Number	Sex	Age	Outcome	Follow-up time (month)	Defect size (mm)	Defect depth (cm)	Position	Fistulation	Stoma closure	Sepsis	Abscess formation	Neoadjuvant time (month)
1	Male	61	Unsuccess	25	15	3	Posterior	Yes	No	No	Yes	3
2	Male	60	Unsuccess	19	37	2	Posterior	No	Yes	Yes	No	2
3	Male	85	Success	21	30	4	Posterior	No	Yes	No	No	3
4	Female	59	Success	22	50	4	Anterior	No	Yes	No	Yes	3
5	Female	49	Success	27	25	3	Anterolateral	No	Yes	No	No	3
6	Female	41	Success	20	27	4	Posterior	No	Yes	No	No	2
7	Male	65	Success	16	15	3	Lateral	No	No	No	No	2
8	Male	58	Success	28	40	6	Anterolateral	No	Yes	No	No	3
9	Female	63	Success	26	40	5	Posterior	No	Yes	No	Yes	3
10	Male	45	Unsuccess	16	75	3	Lateral	No	Yes	No	No	1
11	Female	64	Success	21	17	2	Anterior	No	Yes	No	Yes	2
12	Male	64	Unsuccess	26	50	5	Posterior	No	Yes	No	No	1
13	Male	57	Success	23	25	7	Anterolateral	No	No	No	Yes	2
14	Male	58	Success	19	35	2	Posterior	No	Yes	No	No	2
15	Female	64	Success	24	30	9	Anterolateral	No	Yes	No	No	3
16	Female	49	Success	16	30	3	Lateral	No	Yes	No	Yes	2
17	Female	51	Success	25	25	1.5	Posterior	No	Yes	No	No	2
18	Female	56	Unsuccess	24	30	2	Lateral	No	No	No	No	1
19	Male	59	Success	27	30	1.5	Posterior	No	Yes	No	Yes	2
20	Female	37	Success	21	25	2.5	Posterior	No	Yes	No	No	2

developed any kind of complications, such as device retainment or foreign body reactions (Table 1).

Discussion

Anastomotic leakage has always been regarded as the primary challenge in colorectal surgeries, and it has always been associated with high mortality rates as subsequent complications, sepsis and peritonitis in particular, can lead to life-threatening consequences [19–21, 23–28]. Several causes have been identified to have effects on the development of anastomotic leakage, including radiotherapy, tension, and poor perfusion due to mesorectal excision [9, 11, 14, 29, 30]. Current literature indicates that all refractory cases that do not resolve with less invasive methods should undergo permanent colostomy [4, 26, 27, 31]. Meanwhile, other novel methods, such as endoscopic methods using endospores, stents and clips, have demonstrated promising results in healing acute leaks [22]. While Hartmann's procedure (anastomosis resection and rectal stump closure with end colostomy) has been suggested as the definitive treatment that should only be implemented for cases that are severely affected or have become unstable and SIRS positive [13, 14, 21, 24]. The literature has also demonstrated that laparoscopic intervention has similar survival rates; hence it is better to resort to less invasive laparoscopic and endoscopic methods for the management of such complications [2]. A recent literature review by Guida et al. regarding the management of anastomotic fistula and leaks has demonstrated that transrectal vacuum-assisted closure (VAC), the Over-The-Scope clipping system (OTSC) and the Overstitch suturing system are the most effective method; however, this study also indicates that early detection significantly decreases the chances of success and decreases healing time and hospital stay [15].

Conventional VACs are mainly used for two reasons; (1) the cleansing and draining, which results in the preparation of the rectum for closure (2) the creation of negative pressure in the rectal cavity, which results in the formation of granulation tissue and closure of anastomosis. There are several methods for the application of VACs; while the means of endoscopic procedures are the most common and less invasive, other methods, such as digital insertion and transanal minimally invasive surgery (TAMIS), the approach can be as effective [13, 27].

Our hand-made device has two main advantages in comparison to commercially accessible Endo-SPONGEs. The first one is the relative cost of fabrication. A single set of Endo-SPONGE is 195€, while it costs less than 5€ to fabricate the handmade set. On the other hand, sponge placement requires recto sigmoidoscopy, while low rectum leaks, which constitute most of the cases, can easily

be accessed with speculums and retractors. This, in turn, results in lower operating costs and more patient compliance (Table 2).

Early detection and acute management of leakage can lessen the need for invasive therapy. Moreover, it might also prevent abscesses and sinus formation, which can precipitate the chances of sepsis in these patients [20, 32]. Due to the limited sample size, this study could not establish that there was significance in the early detection of leakage; however, similar studies have suggested that early VAC therapy prevents complications and failures [8, 13–15, 17, 18, 21]. The ideal interval for replacing a sponge is usually between 2 and 7 days. This procedure can be performed when sufficient granulation tissue has been developed to prevent a difficult removal [8, 13–15, 17, 18, 21, 22, 24]. Moreover, irrigation should be carried out with saline solution before the sponge is taken out. In this study we tried to further evaluate the efficacy of handmade vacuum-assisted sponge drain; we followed the patients for an average of 22 months and assessed failures. The results from failed cases indicate that sepsis and abscess formation can minimize the effects of drainage on controlling leakage and the healing process; however, the device can also help surgeons to provide better care and might limit the need for an ostomy. On the other hand, other indications for ostomy placement (e.g., recto prostatic fistula) led to ostomy even with successful leakage control and healing [20, 23, 26–28, 32]. Although the long-term success of the procedure is not known, this procedure is considered promising in treating rectal cancer [20–22, 24, 25]. A study conducted by Riss and colleagues revealed that 20 out of 20 patients who were treated with Endo-SPONGE were successfully treated in a follow-up of 17 months [3]. Regarding the superiority of the handmade VAC regarding operational costs and ease of application, we assume that it could be used as a standard procedure in controlling anastomotic leakage.

Acknowledgements We would like to express our gratitude for the contributions of the colorectal surgery ward at Imam Khomeini Hospital, Tehran University of Medical Sciences.

Author contributions AK conceived and designed the investigation conducted surgery and participated in data gathering and manuscript composition. LM participated in data gathering and manuscript composition. MK conceived and designed the investigation and participated in data gathering and manuscript composition. BB participated in surgical intervention, coordinated tasks and participated in drafting and revising the manuscript. MSF participated in surgical intervention, coordinated tasks and participated in drafting. AK participated in surgical intervention, coordinated tasks and participated in drafting. AN performed surgical intervention. ES participated in manuscript drafting. LF participated in manuscript drafting and figure creation. ZS participated in manuscript drafting. AT participated in data gathering. AA participated in data gathering. AH conceived and designed the study. Participated in data gathering, manuscript drafting and revision. SMA conceived and designed the study conducted surgeries and also contributed to patient follow-up.

Funding This study was self-funded by its authors and received no funding from any government/non-governmental organization.

Data availability Data are available on request due to privacy/ethical restrictions.

Declarations

Conflict of interest The authors declare no conflicts of interest.

Ethics statement This study was submitted to and ethically approved by the Research Deputy and the Ethics Committee of the Tehran University of Medical Sciences (Reference number: IR.TUMS.TH.C.REC.1400.070) and was carried out per the ethical standards outlined in the 1964 Declaration of Helsinki and all subsequent revisions. All participants signed a written informed consent form.

Consent for publication All patients signed informed consent forms.

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