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Long-term efficacy of vacuum-assisted therapy (Endo-SPONGE®) in large anastomotic leakages following anterior rectal resection

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Abstract

Background The aim of our study was to test the long-term efficacy of Endo-SPONGE® therapy in a group of patients treated in our center with vacuum-assisted therapy because of anastomotic leakages after colorectal surgery.

Methods Eleven patients [male: 6; mean age: 71 (range: 44-82) years] who had anastomotic leakage treated with Endo-SPONGE® placement were included in the study. Patient records were examined retrospectively. All patients with documented anastomotic leakage on abdominal computed tomography following an anterior resection of the rectum for rectal cancer underwent sigmoidoscopy to determine the extent of the anastomotic defect and the size of the presacral abscess.

Results Ten of the 11 patients (90.9%) showed closure of the anastomotic leakage after a mean of 16 sponge changes. During follow up [mean: 29 (range: 6-64) months], we observed two cases of anastomotic stricture. Treatment failure was observed in one patient who presented an increased size of dehiscence after 23 sessions of endoscopic treatment, despite an initial good response.

Conclusions Our study substantially confirms previous conclusions and reaffirms that Endo-SPONGE® treatment for colorectal anastomotic leakages, performed in suitable patients, represents a successful and safe approach. The reduction in wound closure time, mild-to-moderate discomfort and possibly shorter hospitalization suggest that Endo-SPONGE® treatment can be a prominent therapeutic regimen with adequate patient acceptance.

Keywords Endo-SPONGE® therapy, anastomotic leakage, colorectal surgery, rectal cancer

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Introduction

The safety of surgery performed in patients with colorectal cancer has substantially improved over the last 50 years, as a result of advances in preoperative preparation, antibiotic prophylaxis, surgical technique and postoperative management. Nevertheless, the adverse event rate is not negligible [1]. In particular, anastomotic leakage is a serious and frequent complication after anterior rectal resection, occurring in 1-24% of patients [2-5]. This complication is associated with increased morbidity and mortality rates during the postoperative phase and can result in a permanent stoma in up to 25% of cases [6-8].

After partial or total mesorectal resection a presacral cavity that is not completely filled by neorectum could represent a complication of surgery. In the presence of anastomotic leakage, mucus and fluids accumulate in the presacral cavity, bridging to the development of an abscess that can evolve over time into a chronic presacral cavity; in such cases closure of the ileostomy is difficult and a permanent stoma may be required. In addition, if closure of the stoma is attempted, the functionality of the neorectum might be compromised. Thus, the key is prevention of the presacral cavity with concomitant sepsis [9].

Treatment choices available for anastomotic leakage can be conservative, such as broad-spectrum antibiotic coverage, parenteral nutrition, or nasogastric aspiration. The surgical approach includes simple drainage or loop colostomy,

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Conflict of Interest: None

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resection of the anastomosis with proximal colostomy and closure of the distal stump (Hartmann procedure), or, finally, abdominoperineal resection [6]. Alternative treatment options for low anastomotic leaks are defunctioning and percutaneous or trans-anastomotic drainage, often requiring a long recovery. The outcome is uncertain, including the closure of the para-anastomotic abscesses or the development of a chronic presacral cavity [5].

The use of local vacuum sponge treatment (Endo-SPONGE®; B. Braun Medical B.V., Melsungen, Germany) represents a minimally invasive and well-tolerated alternative for treating patients with anastomotic leakage after rectal resection [10]. The aim of this study was to test the long-term efficacy of Endo-SPONGE® therapy in a group of patients treated in our center with vacuum-assisted therapy because of anastomotic leakage after colorectal surgery.

Patients and methods

Patients

Between March 2010 and February 2015, 11 patients [male: 6; mean age: 71 (range: 55-82) years] with anastomotic leakage treated with Endo-SPONGE® placement at the S. Maria delle Croci Hospital (Ravenna, Italy) were included in the study. Patient records were examined retrospectively and the study was approved by the local ethics committee.

All patients underwent a colorectal anastomosis, using the Knight-Griffen technique, following anterior resection of the rectum for rectal cancer. Five of the 11 patients underwent neoadjuvant radio/chemotherapy. The anastomosis was constructed at a median height of 4.5 (range: 2-8) cm from the anal verge.

After surgery, in patients with signs and/or symptoms consistent with an anastomotic leakage, such as sepsis, fever, elevated white cell count and C-reactive protein, perineal or pelvic pain, localized or generalized peritonitis, and discharge of blood or pus per rectum, the diagnosis of anastomotic leakage was made by computed tomography (CT) with intravenous contrast or with double-contrast barium enema. All patients with documented anastomotic leakage on abdominal CT underwent sigmoidoscopy to determine the extent of the anastomotic defect and the size of the presacral abscess.

Endoscopic procedure

The Endo-SPONGE® is an open-pored polyurethane sponge connected to an evacuation tube that is applied endoscopically via an introducer device. This therapy was performed under conscious sedation by the administration of meperidine (0.5-1 mg/kg i.v.) and midazolam (2.5-5 mg i.v.).

The technique includes several steps. Firstly, aspiration of the enteric and purulent content and rinsing with saline solution were performed with a flexible gastroscope (EG 201 FP Gastroscope for the first 5 cases, EG 590 WR Gastroscope for the remaining six cases, Fujinon, 9.8 mm diameter). The length and size of the abscess cavity were estimated and the Endo-SPONGE® was then cut accordingly. Secondly, after the introduction of the gastroscope into the cavity, a plastic tube, positioned over the scope, was advanced into the deepest point of the cavity. After lavage and withdrawal of the gastroscope, the Endo-SPONGE® was compressed into the lubricated introducer and inserted into the cavity using a pushing probe, while retracting the plastic tube. Finally, the evacuation tube, coming out of the patient's anus, was connected to a vacuum suction device that created a constant negative pressure, between 100 and 120 mmHg, in the sponge and collected the effluent fluid. In the case of large leakage, two sponges were inserted (Fig. 1) and two devices connected. The correct positioning of the sponge was checked endoscopically. The Endo-SPONGE® was changed every 48-72 h to prevent the granulation tissue from growing into the sponge and according to the endoscopic result. After two or three days, saline solution (0.9%) was introduced into the sponge just before removal to facilitate its painless extraction. Granulation and closure of the cavity was confirmed by flexible endoscopy and water-soluble contrast enema. Closure was defined as a decreased cavity covered with granulation tissue that did not allow the insertion of a new sponge. An endoscopic example of an outcome is shown in Fig. 2.

Each patient had a follow-up colonoscopy and a contrast barium enema at least 2 months after complete closure of the abscess cavity (Fig. 3, before and after treatment). Moreover, every patient had a one-year colonoscopy as part of the oncological follow up and all underwent a clinical assessment every six months.

Results

The clinical data of the 11 patients studied are shown in Table 1. Data are presented as mean (range). Ten out 11 patients (90.9%) showed closure of the anastomotic leakage after a mean

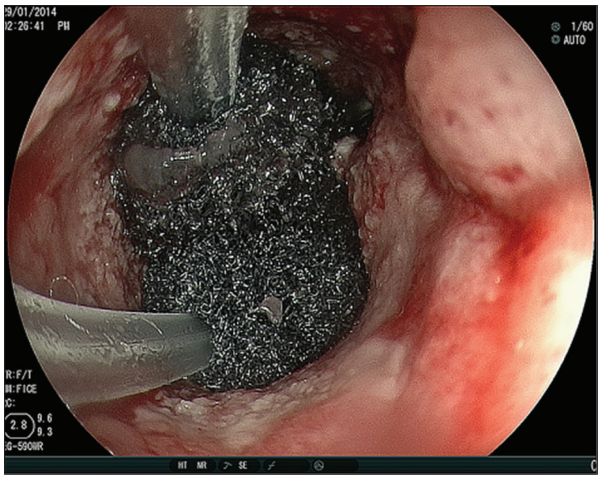

Figure 1 Two Endo-SPONGEs® were inserted because of the large size of the leakage

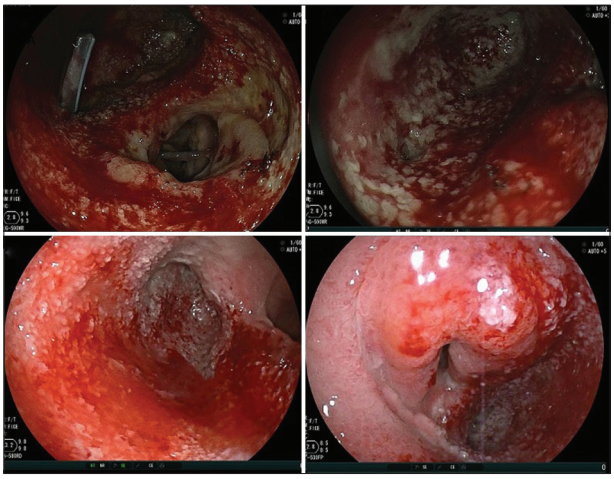

Figure 2 Example of Endo-SPONGE®-supported closure of the anastomotic leakage

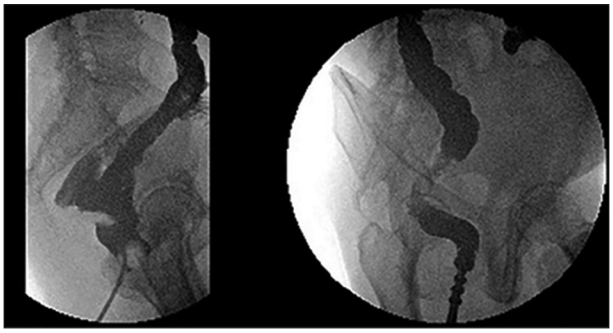

Figure 3 Barium enema before Endo-SPONGE® treatment and one month after

of 16 (range: 9-23) sponge changes performed over a mean of 37 (range: 18-65) days. The ileostomy was subsequently closed in all the 10 patients with a closed abscess cavity.

During follow up [mean 29 (range: 6-64) months], we observed two cases of anastomotic stricture: the first patient developed a stenosis eight months after the removal of the Endo-SPONGE® and was treated with endoscopic dilation. The second patient showed a stenosis after five months and was then successfully treated by placement of a fully covered stent that was removed after 5 weeks.

Two patients died during follow up from unrelated causes (i.e. prostate and metastatic rectal cancer) after one and two years of follow up. Treatment failure was observed in one patient, who presented an increased size of dehiscence after 23 sessions of endoscopic treatment, despite an initial good response. This patient underwent reoperation with breakdown of the anastomosis and was converted to Hartmann's procedure.

Discussion

Anastomotic leakage is a serious complication following colorectal surgery. This postoperative event still represents a major complication with high morbidity and mortality. Different factors have been associated with anastomotic leakage, including low rectal anastomosis, malnutrition, preoperative radiation, stoma placement, and male sex [11-14]. Furthermore, patients often recover with sequelae, especially fibrosis of the anastomosis and the surrounding tissue. Prolonged pelvic sepsis and fibrosis are responsible for impaired long-term neorectal function after ileostomy closure in many of these patients [15-17]. When anastomotic leakage is associated with generalized peritonitis, a surgical approach is mandatory. However, if the patient is clinically less affected, other approaches can be considered.

Treatment with a vacuum sponge represents one of the minimally invasive methods of facilitating the restoration of intestinal continuity, especially if it is applied within 6 weeks following the initial surgery [18]. Early closure is an attractive option, because it might shorten the duration of defunctioning and increase the ileostomy closure rate.

Few studies have evaluated whether the anastomotic leakage is associated with changes in the physiology and clinical function of the neorectum, concluding that leakage and the concomitant chronic inflammatory process in the pelvic region affect the long-term functional outcome. Neorectal function is evaluated excluding alterations in anorectal manometry, manovolumetry and defecatory function (urgency of defecation, pain during defecation, continence, ability to expel stool and feeling of complete evacuation) [19-20]. Therefore, Endo-SPONGE® therapy can improve the function of the neorectum by reducing the pelvic chronic inflammatory process.

In 2008, Weidenhagen *et al* first reported the efficacy of Endo-SPONGE® treatment in 29 patients, achieving resolution of the leakage in all but one patient over a median of 34 days of treatment. In 9 cases, a combination therapy with fibrin glue was used. The authors reported 10 anastomotic stenosis and 2 fistulas during the follow up. In our series we had a success rate of 10/11 (90.9%) with regard to healing of the peri-anastomotic abscess cavity using endoscopic vacuum treatment. The ileostomy was closed in all patients who had a closed abscess cavity.

The number of operations performed depends mainly on the size of the cavities. Our series differs slightly from others, having a longer duration of treatment and a larger number of sessions (37 days and 16 Endo-SPONGE® treatments), possibly due to the rather larger median size of leakage (7.5 cm). We continued the treatment until the cavity was well covered with granulation and did not allow the insertion of another sponge.

In a more recent publication, Strangio *et al* [21] reported a success rate of 88% in their series, with a median of nine sessions and 28 days for healing, and a 12% complication rate (two fistulas and an abscess). They also performed a literature review, with a total of 174 patients including their series. By considering only data of the studies enrolling >10 cases, a complete healing of the cavity was achieved in 131 (94.3%) of 149 patients, with a success rate ranging from 56.6% to 100%, over a treatment duration of 34 (range: 1-221) days and with a median of 11 (range: 1-41) sessions. The overall complication

Table 1 Patient characteristics and clinical data

Patient N°	Age	No. of Endo-SPONGE® treatments	Endo-SPONGE® treatment to closure (days)	Distance of anastomosis from anal verge (cm)	Size of leakage (cm)	Closure of anastomotic leakage	Relapse of leakage	Complication	Follow up (months)
1	81	19	41	6	8	Yes	No	No	40
2	68	9	18	6	5	Yes	No	No	64
3	74	21	47	3	10	Yes	No	No	12
4	51	10	22	3	8	Yes	No	No	19
5	76	15	65	5	8	Yes	No	Stenosis	51
6	66	20	33	5	6	Yes	No	No	46
7	55	23	51	2	5	No	-	-	-
8	70	13	28	8	4	Yes	No	No	18
9	79	9	24	4	12	Ye s	No	No	9
10	82	20	44	3	8	Yes	No	Stenosis	21
11	82	18	37	4	9	Yes	No	No	6
Total	71	16	37.3	4.5	7.5	10/11 (90.9%)	None	2/11 (18%)	28.6

Summary Box

What is already known:

- Endo-SPONGE® therapy is a helpful therapy for rectal anastomotic leakages
- The complications of vacuum therapy are very few
- Nowadays, dismantling of the anastomosis with Hartmann's procedure for a rectal leakage is less common

What the new findings are:

- The Endo-SPONGE® treatment seems to be effective, even for large rectal leakages
- A long-term follow up of Endo-SPONGE® therapy showed stable results
- Randomized comparative studies with other treatment choices are still lacking

rate was around 20%, mainly consisting of anastomosis stenosis, recurrent abscess, and fistula.

The complications of endoscopic vacuum treatment are few. Complications reported in the literature include pain, bleeding from the cavity when changing the sponge, and stenosis at the anastomotic site. Furthermore, there have been reports of patients with recurrent abscesses and development of large systems of enteroenteric fistulas [22]. In our study, we observed two cases of anastomotic stenosis (18%) during a long-term period of follow up (mean: 28.6, range: 6-64 months). Furthermore, a clinical and endoscopic follow up was offered to all patients; we observed one case of recurrent abscess that healed with conservative treatment eight months after the completion of therapy. The rate of complications was then similar to that reported previously.

Our study substantially confirms previous conclusions and reaffirms that Endo-SPONGE® treatment for colorectal anastomotic leakages, performed in suitable patients, represents a successful and safe approach, even for large leakages. In particular, it represents a minimally invasive tool that can avoid dismantling of the anastomosis with Hartmann's procedure, which may thus become less common. Only the potential long duration of therapy can represent a limitation of this technique.

In conclusion, Endo-SPONGE® placement can be helpful in the treatment of large anastomotic leakages after colorectal surgery. The reduction in wound closure time, the mild-to-moderate discomfort, and possibly shorter hospitalization suggest that Endo-SPONGE® treatment can be a prominent therapeutic regimen with adequate patient acceptance.

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