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ARTÍCULO ORIGINAL

Endoscopic vacuum therapy for treatment of large distal anastomotic dehiscence after colorectal surgery

Terapia de vacío endoluminal para el tratamiento de dehiscencias anastomóticas distales posterior a cirugía colorrectal

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ABSTRACT

Background: Management of anastomotic dehiscences following colorectal surgery is a topic of debate. In this context, endoluminal vacuum therapy offers promising results. **Objective:** To analyze the efficacy and feasibility of endoluminal vacuum therapy in distal anastomotic dehiscences after colorectal surgery. **Materials and methods:** This study is a descriptive case series that evaluates patients with anastomotic dehiscences over a period of 18 months. All patients were treated with Endo-sponge™ (Braun Medical, Hessen, Germany). **Results:** Fourteen patients were included in the final analysis. The indications for endoluminal vacuum therapy were Hartmann's stump insufficency (n=6), anastomotic leakage after laparoscopic total mesorectal excision (n=4), and anastomotic dehiscence after transanal total mesorectal excision (n=4). A total of 204 sponges were placed per patient (median 12.5, range 1-33). Complete resolution was achieved in 9 patients (57.1%) in a mean time of 108 days (range 15-160 days). In the sub-analysis, patients with acute dehiscence (<3 months) achieved complete resolution in 80% (8/10), whereas no patient with chronic defects reached resolution (0/4). A low complication rate (7%) was recorded. **Conclusion:** Endoluminal vacuum therapy appears to be a feasible and safe treatment with a high success rate in patients with large acute colorectal anastomotic defects.

Keywords: *Anastomotic leak; Surgical wound dehiscence; Colorectal surgery; Endoscopy (source: MeSH NLM).*

RESUMEN

Introducción: El manejo de las dehiscencias anastomóticas después de una cirugía colorrectal es un tema de debate. Frente a esto, la terapia de vacío endoluminal ofrece resultados prometedores. **Objetivos:** Analizar la eficacia y viabilidad de la terapia de vacío endoluminal en dehiscencias anastomóticas distales posteriores a cirugía colorrectal. **Materiales y métodos:** El presente estudio es una serie de casos descriptiva, que evalúa a pacientes con dehiscencias anastomóticas durante un periodo de 18 meses. Todos los pacientes fueron tratados con Endo-sponge™ (Braun Medical, Hessen, Alemania). **Resultados:** Catorce pacientes fueron incluidos en el análisis final. Las indicaciones para la terapia de vacío endoluminal fueron la insuficiencia del muñón de Hartmann (n=6), la filtración anastomótica posterior a la escisión mesorrectal total laparoscópica (n=4) y la dehiscencia anastomótica después de la escisión mesorrectal total transanal (n=4). Se colocaron un total de 204 esponjas por paciente (mediana 12,5, rango 1-33). La resolución completa se logró en 9 pacientes (57,1%) en un tiempo medio de 108 días (rango 15-160 días). En el subanálisis, los pacientes con dehiscencia aguda (<3 meses) lograron una resolución completa en un 80% (8/10), mientras que ningún paciente con defectos crónicos lo alcanzó (0/4). Se registró una baja tasa de complicaciones (7%). **Conclusión:** La terapia de vacío endoluminal parece ser un tratamiento factible y seguro con una alta tasa de éxito en pacientes con grandes defectos anastomóticos colorrectales agudos.

Palabras clave: *Fuga anastomótica; Dehiscencia de la herida operatoria; Cirugía colorrectal; Endoscopía (fuente: DeCS Bireme).*

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INTRODUCTION

Gastrointestinal anastomotic defects are defined as a communication between intra-luminal and extra-luminal space due to anastomotic failure. They represent a significant cause of morbidity and mortality and a relevant burden in terms of costs and length of hospital stay [1]. Despite advances in surgical techniques and perioperative management, risk of colorectal anastomotic leaks still varies from 1.5% to 23% [2-4] and it can lead to a permanent stoma in up to a quarter of the patients [5-7].

Management of such complication has not been standardized yet, especially in case of very-low colorectal anastomoses [8]. Treatment includes a variety of options, ranging from endoscopic and/or radiologic techniques to surgical re-intervention. In case of anastomotic defects, fluids accumulated in the pre-sacral cavity result in the formation of an abscess which preclude any treatment aiming to restore the GI continuity. In these cases, is mandatory to evacuate the extraluminal fluids collected in order to avoid sepsis [9].

Endoscopic vacuum therapy (EVT) represents a novel and promising minimally invasive and well-tolerated technique, able to obtain a progressive external drainage and a reduction of the cavity. It is based on the concept of a sponge which is endoscopically placed and then connected to a suction bottle with negative vacuum pressure [4,10,11]. The material of the sponge (polyurethane foam), the open-pored structure and the negative pressure are intended to induce granulation of the tissues, in order to achieve closure of the leak.

The aim of this study was to analyze efficacy, feasibility and safety of EVT in the management of anastomotic defects after colorectal surgery.

MATERIALS AND METHODS

This is a single center retrospective evaluation of prospectively collected consecutive patients with colorectal anastomotic leak referred to the Endoscopic Unit for EVT from October 2017 to April 2019. Patients were considered eligible for the procedure in case of anastomotic defect with extraluminal collection. Exclusion criteria were small (i.e., <1 cm) or circumferential anastomotic defects. Patients with small defects were treated by plastic double pig-tail placement [12], while patients with circumferential anastomotic defect underwent re-surgery.

EVT therapy was performed under conscious sedation, in an outpatient setting. All patients were treated with the same type of sponge (Endo-SPONGE™; Braun Medical, Hessen, Germany).

A preliminary endoscopic evaluation was performed in order to define size and shape of dehiscence (Figure 1), using standard gastroscopes (OLYMPUS 180 series) with a diameter of 9.8 mm or slim trans-nasal endoscopes (OLYMPUS 180 series) with a diameter of 5,5 mm in case of small defects. Insufflation was always performed using CO_2. Removal of necrotic debris was achieved with biopsy forceps, when indicated. The cleaned cavity was subsequently irrigated with Iodopovidone (7.5%) solution and saline solution (1:3 diluition). Finally, Endo-sponge™ was modeled to fit the cavity and advanced through a 12 mm overtube into the dehiscence (Figure 2). After removal of the overtube, the sponge was connected to a suction bottle at a 150-mmHg negative vacuum.

After a mean 3-days interval, the sponge was removed and replaced until healing process was achieved (i.e., cavity <1 cm covered by granulation tissue). To maintain the healing process, further endoscopic curettages and lavages (Figure 3) were performed until full resolution of the cavity, which was defined as the disappearance of anastomotic defect at endoscopy (Figure 4). Treatment failure was defined as persistence of cavity during follow up and/or no sign of tissue granulation and/or occurrence of infectious complications.

For the sub-analysis, patients were divided into 2 groups according to the interval between dehiscence diagnosis and EVT-treatment. For this purpose, the dehiscence was considered acute if treated within 3 months and chronic if treated later.

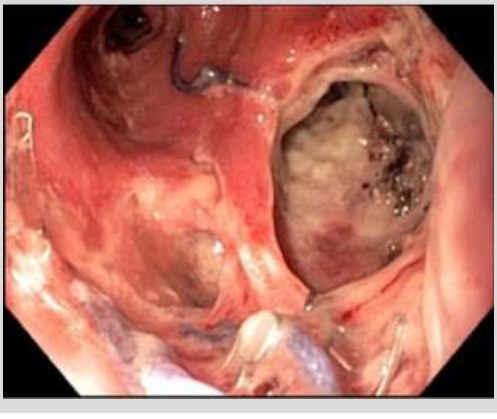

Figure 1. Preliminary endoscopic evaluation of dehiscence.

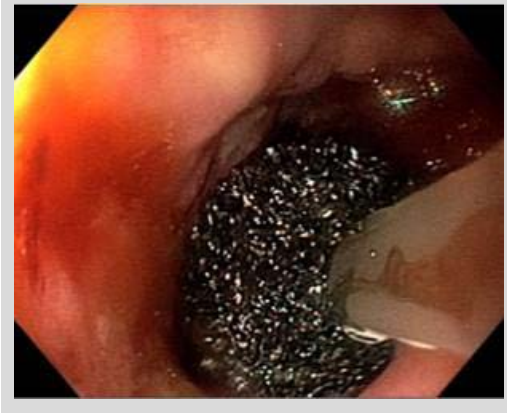

Figure 2. Endo-sponge™ placed into the dehiscence.

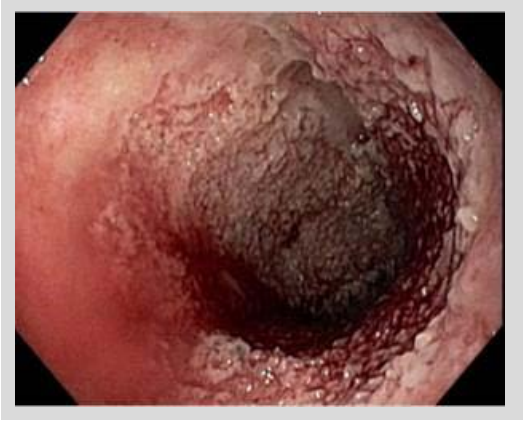

Figure 3. Curettages and lavages performed endoscopically until full resolution of the cavity.

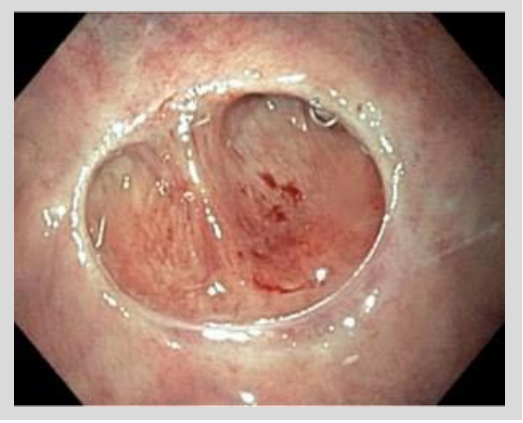

Figure 4. Healing of dehiscence after treatment with Endoscopic Vacuum Therapy.

Continuous data are presented as median values with range, unless otherwise specified. Categorical data are presented as frequencies or percentages. For the comparison of categorical variables, the chi-square test was used. A p-value <0.05 was considered statistically significant. For statistical analysis data were analyzed using MedCalc Statistical Software version 14.8.1 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2014).

Ethical considerations

This study was conducted at a tertiary care center, adhering to all ethical standards and ensuring the confidentiality of patient information. The research was performed in accordance with the Declaration of Helsinki and established guidelines for scientific research. The study was approved by the ethics committee of Fondazione Poliambulanza in Brescia, Italy, and all data collected were anonymized, with no information that could potentially identify individual patients.

RESULTS

Sixteen patients were enrolled. Two patients were excluded due to the small size of the defect (< 1 cm) and were treated with pig-tail drainage. Fourteen patients (M:F = 11:3) with a mean age of 65 years (sd ± 12.8) were included in the final analysis (Table 1). Indications for EVT are listed in Table 1. Eleven patients (78.5%) of our series had previously received neoadjuvant radiotherapy.

Table 1. Demographic data and clinical characteristics from patients treated with endoscopic vacuum therapy.

No	Gender	Age (years)	Surgery	Radiotherapy	Acute/chronic	Retreatment	Complete healing	No of sessions
1	M	74	Hartmann	Yes	Chronic	No	No	28
2	M	70	TATME	Yes	Acute	No	Yes	27
3	M	40	TATME	Yes	Acute	No	Yes	3
4	M	48	Hartmann	Yes	Chronic	Yes	No	6
5	M	70	Hartmann	Yes	Acute	No	Yes	16
6	F	71	Hartmann	No	Acute	No	Yes	5
7	M	86	Hartmann	No	Chronic	Yes	No	13
8	M	74	TME	Yes	Acute	No	Yes	8
9	M	63	TME	Yes	Acute	Yes	Yes	17
10	M	78	Hartmann	Yes	Chronic	Yes	No	31
11	M	66	TME	No	Acute	No	No	12
12	M	56	TATME	Yes	Acute	No	Yes	4
13	F	66	TME	Yes	Acute	No	No	33
14	F	49	TATME	Yes	Acute	No	Yes	1

M, male; F, female; TATME, trans anal total mesorectal excision; TME, total mesorectal excision; Acute, <3 months; Chronic, >3 months.

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Table 2. Results obtained with Endoscopic Vacuum Therapy comparing acute and chronic dehiscence.

	Acute	Chronic	*p* value
Number of sponges, median (range)	10 (1-33)	20.5 (6-31)	0.3
Treatment time (days), median	47 (1-126)	68.5 (30-262)	0.4
Full resolution rate, % (rate)	80 (8/10)	0 (0/4)	0.015

Overall, 204 sponges were placed in 14 patients with a mean number of 14.6 (sd ± 11) sponges per patient. After the achievement of the healing process, defined as reduction of the cavity to < 1 cm, sponges were removed and patients underwent a median of 9 sessions (sd ± 13) of endoscopic curettages and lavages to maintain the healing process by formation of granulation tissue. Four patients had defect recurrence, requiring a subsequent EVT-retreatment due to insufficient healing progression. Among these patients: one underwent 3 more EVT treatments and at the end reached a full resolution; another patient was finally considered a treatment failure despite 2 more EVT treatments; two patients died during range EVT retreatments for neoplastic progression (1) and septic complications (1), respectively. Relapses occurred after a mean of 30 days (sd ± 26) from the previous treatment and 3/4 (75%) of the patients affected had a Hartmann procedure plus radiotherapy. Overall, full resolution was achieved in 8 patients (57.1%) in a mean time of 99 days (sd ± 50). Of those who achieved a full resolution, 87.5% (7/8) were pre-operatively treated with radiotherapy.

To note, when considering the interval between the dehiscence diagnosis and EVT treatment inception, the full resolution rate was significantly higher in patients with acute dehiscence compared to chronic defects [80% (8/10) vs 0% (0/4), p<0.05]. Moreover, in patients with chronic dehiscence, the number of sponges placed was higher [median: 20.5 (range 6-31) versus 10 (range 1-33)] and the treatment time (days) was longer [median: 68.5 (range 30-262) versus 47 (range 1-126)] compared to acute dehiscence. In both cases, the difference is not statistically significant (Table 2).

Two patients (14%) experienced complications. One patient developed urethral fistula and was treated by placement of urinary catheter, but still achieved full resolution of the cavity. Another patient developed fever after EVT session and was successfully treated with antibiotics. This mild adverse event was due to suction bottle malfunction and not directly related to EVT treatment.

DISCUSSION

The results of the present study suggest that EVT is an effective approach for the management of patients with large and distal defects after colorectal surgery, especially if applied in acute dehiscence.

EVT was firstly used for treatment of upper GI leaks [13] and it was originally created with self-constructed drainage devices and off-label use of electronic vacuum pumps. It works by intraluminal and intracavitary apposition of wound edges and provides simultaneous internal drainage. To be effective, two basic requirements must be met: intact or at least compensated blood perfusion and the presence of a closed compartment, allowing for the build-up of negative pressure [14].

Following the first promising results in treatment of upper leaks, EVT was also used for the management of lower anastomotic leaks. Anastomotic leakage is a serious complication following colorectal surgery. Endoscopic vacuum therapy has been proposed as a minimally invasive alternative to surgical re-intervention in clinically stable patients without generalized peritonitis. The benefit of the EVT over other endoscopic interventions is the ability to maintain control of the site of infection while also performing serial debridement of the leak cavity, thereby promoting healing by secondary intention [15].

In the last decade, several studies have demonstrated the efficacy of EVT in management of anastomotic leaks [8,10,16-19], with reported healing rates ranging between 56% and 97%. In the present series, closure of the abscess cavity was achieved in 8 out of 14 patients (57.1%), which is lower than the rate reported in the majority of the studies. However, stratifying patients according to time between dehiscence diagnosis and EVT inception, patients with an acute defect (≤ 3 months) were statistically more likely to achieve full resolution of the cavity compared to chronic defects [80% (8/10) vs 0% (0/4), p=0,03]. This can be explained by the development of fibrosis which can negatively affect the healing process of chronic dehiscence.

In a similar study conducted in Colombia, 6 patients were successfully treated with EVT. Among these patients, 2 had upper gastrointestinal tract dehiscence [20]. These lesions have mortality rates going from 25-60%, so EVT shows up as a promising alternative with an efficacy rate of 84%, compared to stents that only has 54% [20].

Some relevant risk factors for both dehiscence after surgery and EVT treatment failure are chemo/radiotherapy, nutritional status and smoking [20,21]. In the present series, a negative role of radiotherapy cannot be demonstrated since the vast majority (87.5%) of the patients who achieved a full resolution had previously undergone radiotherapy. Even though nutritional status is a common risk factor among endoscopic and surgical procedures, Latin-American reports have not found complications associated to this [20,22]. In this context, more studies are needed to report efficacy, risk factors and complications in Latin-American population.

Complication rate, in the present series, is about 14%, in agreement with literature [23], confirming the safety profile of EVT, without post-procedural adverse events directly related to treatment. Furthermore, all patients included in the present series underwent treatment in an outpatient setting, confirming that Endo-SPONGE™ therapy may be safely performed in this setting, with a considerable reduction of both cost of procedures and discomfort for the patients.

Closure of large cavities by means of Endo-SPONGE™ may require several sessions (in our series until 33) and last a long period (up to 4 months). To reduce the timing of dehiscence closure either suture or Over-the-Scope-Clip application following Endo-SPONGE™ treatment has been proposed [9], with promising results. Larger studies or comparative studies (EVT + OTSC vs EVT alone) are needed to confirm these results.

This study has certainly some limitations. The retrospective design can negatively affect the level of evidence obtained and may be associated with selection bias. Nevertheless, a careful prospective collection of data recorded in the electronic dossier was systematically performed, mitigating this issue. Another main limit is represented by the small sample size, which is anyway in line with series already published in literature and is burdened by the low incidence of the disease. Finally, the heterogeneity of surgical procedures performed and the lack of study protocol, including time between diagnosis and endoscopic treatment, could have affected the results. Larger prospective series could better address this point.

In conclusion, this study confirms that endoscopic vacuum therapy is a promising alternative to surgery in the management of large and distal acute dehiscence and supports its efficacy, tolerability and low complication rate.

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