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This is the author's manuscript

Original Citation:

Availability:

This version is available <http://hdl.handle.net/2318/155812> since

Published version:

DOI:10.1016/j.dld.2014.12.003

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Long-term efficacy of endoscopic vacuum therapy for the treatment of colorectal anastomotic leaks

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Abstract

Background

Anastomotic leaks are a severe complication after colorectal surgery. We aimed to evaluate the long-term efficacy of endoscopic vacuum therapy for their treatment.

Methods

Retrospective review of a series of post-surgical colorectal leaks treated with endoscopic vacuum therapy, with minimum follow-up of 1 year. Generalized peritonitis or haemodynamic instability was considered contraindication to endoscopic treatment.

Results

Endoscopic vacuum therapy was applied in 14 patients with colorectal leak, in 2 cases complicated by recto-vaginal fistula. Overall success rate was 79%, favoured by early beginning of treatment (90%) and presence of a stoma (100%) and no preoperative radiotherapy (86%). Median duration of treatment was 12.5 sessions (range 4–40). Median time for complete healing was 40.5 days (range 8–114), for a median cost of treatment of 3125 Euros. No complication related to endoscopic vacuum therapy was observed. Further surgery was required in 3 cases.

Conclusion

Endoscopic vacuum therapy is a safe treatment for post-surgical leaks, with high success rates.

Keywords

- Anastomotic leak;
- Colorectal surgery;
- Endoscopic vacuum;
- Postoperative complications

1. Introduction

Anastomotic leak is a relatively frequent postoperative complication after colorectal surgery owing to an increase morbidity and mortality. Anastomotic leak management depends on clinical manifestation, on clinical stability of the patient and on the distance of the anastomosis from the

anal verge, particularly if the anastomotic leak is extra-peritoneal, rather than intra-peritoneal. In selected cases endoscopic management has been demonstrated to be a safe and effective alternative to surgical management.

Different kinds of endoscopic devices can be used for this purpose. Synthesis and suturing devices allow a direct closure of gastrointestinal defect and are indicated in small leaks up to 20 mm of diameter [1] and [2]. Temporally application and periodical substitution of covered stents adopt the principle of excluding the wall defect from contamination of gastrointestinal lumen and require drained or clean extra-luminal tissues in order not to create bacterial proliferation and abscess formation [3]. The endoscopic vacuum system (Endosponge[®], B.Braun, Melsungen AG, Tuttlingen, Germany) is based on the application of topic negative pressure on tissues in order to drain, and favour granulation and secondary closure of large defects. It is indicated in large anastomotic leaks in presence of an extra-luminal cavity.

Most relevant literature on endoscopic vacuum therapy reports small case series with mismatched overall success rate in the treatment of anastomotic leaks following anterior resection of the rectum [4], [5] and [6].

2. Materials and methods

We reviewed our series of post-surgical colorectal leaks treated with endoscopic vacuum therapy. Indications were all cases of acute or chronic leak in the presence of extraluminal abscess. The presence of generalized peritonitis or haemodynamically unstable patient was considered a contraindication to endoscopic treatment. Diagnosis was in all cases confirmed by contrast CT scanning and by direct endoscopic exploration showing the anastomotic defect in communication with an extraluminal cavity.

Anastomotic leaks were considered healed when direct endoscopic examination with the aid in all cases of direct water soluble contrast infection during endoscopy, showed a complete restoration of the wall epithelium. Unsuccessful treatment was defined as the need for surgery for the onset of peritonitis, the lack of patient's compliance or the lack of improvement for at least 4 weeks. Leaks and fistulas were considered acute if endoscopic treatment was attempted within 60 days after surgery, and chronic if treated later.

The endoscopic vacuum system is composed by an open-cell polyurethane sponge of 7 cm × 3 cm, which can be cut down until minimum size, depending on the size of the cavity. The dimension of the cavity is defined by endoscopic inspection. The sponge is connected to an evacuation tube advanced by a pusher tube with handle into the over-tube once removed the scope. We connected the tube to a vacuum system producing continuum negative pressure up to 700 mmHg when in hospital, and a portable system (Renasy Go, Smith and Nephew, London, UK) producing continuum negative pressure up to 200 mmHg when discharged. The sponge is kept in place by the negative pressure applied to the sponge.

Patients' characteristics were tested by the Fisher's exact test for categorical variables and by the Mann–Whitney and Kruskal–Wallis tests for continuous ones. The continuous variables are reported as median (range). All reported *P*-values were obtained at the conventional 5% significance level. Data were analyzed as of October 2014 by R 3.1.1 (R Foundation for Statistical Computing, Vienna-A, <http://www.R-project.org>).

3. Case series

Between November 2008 and June 2013, 14 consecutive patients (7 males and 7 females; median age 68 years old, range 55–85) with a leak of a colorectal anastomosis who met the inclusion criteria were treated with endoscopic vacuum therapy. We present here their results with more than 1-year follow-up.

As shown in Table 1, we included 12 anastomotic leaks following rectum anterior resection (RAR), 1 leak after Transanal Endoscopic Microsurgery (TEM) and 1 recto-vaginal fistula following a Stapled Transanal Resection of the Rectum (STARR) procedure. The median distance from the anal verge was 5 cm (range 3–9 cm).

Table 1.

Demographic and clinical data including follow-up for patients undergoing endoscopic vacuum therapy.

No.	Gender	Age (years)	Surgery	Neoadjuvant RT ^a	Derivative stoma	Chronic/acute	Length of the cavity (cm)	Circumference leak amplitude (%)	Com healing
1	M	76	AR	Yes	Yes	Chronic	3	25%	Yes
2	F	62	STARR	No	No	Acute	6	25%	Yes
3	F	57	AR	Yes	No	Chronic	5	25%	No
4	M	57	AR	Yes	Yes	Chronic	7	50%	Yes
5	F	55	AR	Yes	Yes	Acute	2	25%	Yes
6	F	64	AR	Yes	Yes	Acute	3	25%	Yes
7	F	64	AR	Yes	Yes	Acute	4	25%	Yes
8	M	75	AR	No	No	Acute	3	25%	Yes
9	M	72	AR	Yes	No	Chronic	9	75%	No
10	F	74	AR	No	Yes	Acute	7	75%	Yes
11	M	68	AR	No	Yes	Acute	7	75%	Yes
12	F	78	TEM	No	No	Acute	2.5	25%	Yes
13	F	69	AR	No	Yes	Acute	3.5	25%	Yes
14	F	85	AR	No	No	Acute	4	25%	No

M, male; F, female; AR, anterior resection; STARR, Stapled Transanal Resection of the Rectum; TEM, Transanal Endoscopic Microsurgery.

a

RT: radiotherapy; OTSC, over-the-scope-clip.

Table options

The main patient characteristics are reported in Table 2, overall and by achievement of complete healing.

Table 2.

Univariate analysis of data correlating with complete healing.

	Overall	Stratified for healing		P	Test
		No	Yes		
<i>n</i>	14	3	11		
Age, years (median [range])	68.5 [55.0, 85.0]	72.0 [57.0, 85.0]	68.0 [55.0, 78.0]	0.64	Nonnorm
Length of the cavity, days (median [range])	4.0 [2.0, 9.0]	5.0 [4.0, 9.0]	3.5 [2.0, 7.0]	0.20	Nonnorm
No. of sessions (median [range])	12.5 [4.0, 40.0]	28.0 [8.0, 40.0]	11.0 [4.0, 37.0]	0.14	Nonnorm

	Overall	Stratified for healing		P	Test
		No	Yes		
Time to complete healing, days (median [range])	40.5 [8.0, 114.0]	102.0 [20.0, 102.0]	33.0 [8.0, 114.0]	0.24	Nonnorm
Male gender (%)	5 (35.7)	1 (33.3)	4 (36.4)	1.00	Exact
Surgery (%)				1.00	Exact
AR	12 (85.7)	3 (100.0)	9 (81.8)		
STARR	1 (7.1)	0 (0.0)	1 (9.1)		
TEM	1 (7.1)	0 (0.0)	1 (9.1)		
RT (%)	7 (50.0)	2 (66.7)	5 (45.5)	1.00	Exact
Derivative stoma (%)	8 (57.1)	0 (0.0)	8 (72.7)	0.05	Exact
Chronic/acute (%)	4 (28.6)	2 (66.7)	2 (18.2)	0.18	Exact
Leak (%)				1.00	Exact
25%	10 (71.4)	2 (66.7)	8 (72.7)		
50%	1 (7.1)	0 (0.0)	1 (9.1)		
75%	3 (21.4)	1 (33.3)	2 (18.2)		
Additional endoscopic treatment	3 (21.4)	0 (0.0)	3 (27.3)	1.00	Exact
Need of further surgery	3 (21.4)	3 (100.0)	0 (0.0)	0.003	Exact

AR, anterior resection; STARR, Stapled Transanal Resection of the Rectum; TEM, Transanal Endoscopic Microsurgery; RT: radiotherapy.

Table options

Ten cases of acute leaks and 4 cases of chronic leaks were treated; endoscopic vacuum treatment was started in a range between 5 and 485 days after surgery. All but two patients were operated for oncologic reason; 1 patient underwent TEM for a circumferential rectal adenoma with high grade dysplasia and 11 patients underwent anterior resection of the rectum for rectal adenocarcinoma. Out of them, 7 patients underwent neoadjuvant long term radiotherapy and 8 had a loop ileostomy at the time of diagnosis of the anastomotic leak.

After informed consent, the anastomosis suspected of a leak was explored by flexible endoscopy, with a PCF-Q180AL Video Colonoscope (Olympus Endoscopy, Tokyo, Japan) with 11.3 mm diameter. No lavage or debridement was performed except in one case at the beginning of our experience, in whom a subsequent peritonitis was generated. If a leak was confirmed, the size of it was measured by trying to access it with the endoscope. In 2 cases of chronic leaks it was necessary to dilate the leak to have access to the external cavity and position the sponge. Once into the extraluminal cavity only suction was applied to clean the cavity as much as possible in order to measure its maximum length. An endoscopic vacuum sponge, cut down according to the size of the cavity, was advanced in the cavity through the anastomotic leak, by means of the dedicated introduction overtube. The device was replaced two or three times a week until complete healing of the dehiscence was achieved. The procedure was performed on an outpatient basis in all chronic cases, and was initiated on an inpatient basis in all acute cases, who were discharged within 1 week from the beginning of the treatment if the general clinical conditions were favourable and proceeded on an outpatient basis.

Video 1 illustrates the technique of positioning including indications and contraindications, and tips and tricks.

Video 2 illustrates the most complex case we have treated which required up to 7 months to heal completely and to allow closure of the loop ileostomy in a patient who underwent a Total Mesorectal Excision for rectal cancer.

The median duration of treatment was 12.5 sessions (range 4–40). The median time for complete healing was 40.5 days (range 8–114).

Overall success rate of endoscopic vacuum therapy was 79% (11/14): 89% (9/10) in acute leaks (<60 days) and 50% (2/4) in chronic leaks (>60 days) ($P = 0.176$). Reasons for failure was the onset of peritonitis in the acute case, due to persistence of communication between the extraluminal cavity and the peritoneal cavity, while in the two chronic cases it was due to the lack of patient's compliance and the lack of improvement for at least 4 weeks, respectively. Among patients with diverting stoma, clinical success was 100% (8/8) while it was 50% (3/6) among patients without stoma ($P = 0.055$). After neoadjuvant radiotherapy, success rate was 71% (5/7), while it was 86% (6/7) among untreated patients ($P = 1.000$). Both recto-vaginal fistulas healed completely. A median of 12.5 sessions per treatment was needed. No complication related to endoscopic vacuum therapy was observed. The procedure was well accepted by all patients. The system was connected in all cases to a Renasys Go suction device (Smith and Nephew, London, UK), which allowed a normal life during the day due to its batteries lasting about 20 h, which were recharged overnight. Therefore quality of life of patients with the device in place was acceptable in all cases and no patient suspended the treatment for lack of compliance. No patient reported symptoms possibly related to the treatment.

Three patients required further endoscopic treatment: an “over-the-scope-clip” was applied in two cases and fibrin-glue injection was performed in one case. Further surgery with the creation of a diverting stoma was required in the 3 cases of endoscopic treatment failure.

The cost of the device is 180 Euros, all included, except cost of the use of the endoscopic unit, where the procedure lasts about 15 min every session, including 1 doctor and 2 nurses, so that each session can be calculated to cost about 70 Euros. Consequently a complete treatment cost in our experience in a range between 1000 and 10,000 Euros. Considering the median number of sessions was 12.5 sessions in our series, the median cost of a treatment was 3125 Euros.

4. Discussion

Anastomotic leak management depends on clinical manifestation, on clinical stability of the patient and on the distance of the anastomosis from the anal verge, particularly if the anastomotic leak is cervical or extra-peritoneal, rather than mediastinal or intra-peritoneal.

Conventional operative management of a colorectal anastomosis leak includes explorative laparotomy, peritoneal lavage and, in at least 80% of cases, the creation of a diverting stoma. This reduces complications such as peritonitis and sepsis and mortality rate, but surgical management leads to a relatively high morbidity rate. On the other side, morbidity rate of radical surgery associated with primary temporary stoma creation is as high as 30%, but then reversal rate in patients who experience anastomotic leak is <50% [7] and [8].

Endoscopic treatment of anastomotic leaks has been proposed as an alternative to operative management in clinically stable patients with non-generalized peritonitis. In general, patients who present with generalized peritonitis, free intra-peritoneal leak or severe sepsis with hypotension should be first resuscitated and surgery is mandatory. Complementary to endoscopic clips which are indicated for small leaks up to 20 mm and covered stents which are indicated in presence of stenosis, endoscopic vacuum therapy has a role in the management of anastomotic leak with concomitant extraluminal abscess.

This is one of the largest series reported in literature. Our experience is that endoscopic vacuum therapy is a safe and effective technique. Although the relatively small case series we could observe a significant difference in success rate in favour of the presence of a diverting stoma, and a slight tendency also in favour of acute cases compared to chronic ones. On the contrary, we could not

confirm a negative role for neoadjuvant radiotherapy as patients preoperatively treated showed a complete healing in >70% of cases. We did not experience procedure related complication although in literature few cases of subsequent stenosis or minor bleeding due to vessels erosion, all successfully treated by endoscopy, were reported.

Endoscopic vacuum therapy seems a useful endoscopic alternative to surgery in the management of colorectal post-surgical leaks. Further prospective clinical studies are needed to confirm the value and the efficacy of this newly available technique in the disputed treatment of these patients.

Appendix A. Supplementary data

The following are the supplementary data to this article:

Video 1.

This video illustrates the technique of positioning including indications and contraindications, and tips and tricks.

Video 2.

This video illustrates the most complex case we have treated which required up to 7 months to heal completely and to allow closure of the loop ileostomy in a patient who underwent a Total Mesorectal Excision for rectal cancer.

References

- [1]
- M.J. Grupka, J. Benson
- Endoscopic clipping
- [2]
- A. Arezzo, M. Verra, R. Reddavid, *et al.*
- Efficacy of the over-the-scope clip (OTSC) for treatment of colorectal postsurgical leaks and fistulas
- Surgical Endoscopy, 26 (2012), pp. 3330–3333
- [3]
- E.A. Bonin, T.H. Baron
- Update on the indications and use of colonic stents
- Current Gastroenterology Reports, 12 (2010), pp. 374–382
- [4]
- P.J. van Koperen, M.I. van Berge Henegouwen, C. Rosman, *et al.*
- The Dutch multicenter experience of the endo-sponge treatment for anastomotic leak after colorectal surgery
- Surgical Endoscopy, 23 (2009), pp. 1379–1383
- [5]
- R. Weidenhagen, K.U. Gruetzner, T. Wiecken, *et al.*
- Endoluminal vacuum therapy for the treatment of anastomotic leak after anterior rectal resection
- Rozhledy V Chirurgii, 87 (2008), pp. 397–402
- [6]
- S.T. Mees, D. Palmes, R. Mennigen, *et al.*
- Endo-vacuum assisted closure treatment for rectal anastomotic insufficiency
- Diseases of the Colon and Rectum, 51 (2008), pp. 404–410
- [7]
- A.A. Khan, J.M. Wheeler, C. Cunningham, *et al.*
- The management and outcome of anastomotic leaks in colorectal surgery
- Colorectal Disease, 10 (2007), pp. 587–592

- [8]
- T. Mala, A. Nesbakken
- Morbidity related to the use of a protective stoma in anterior resection for rectal cancer
- *Colorectal Disease*, 10 (2008), pp. 785–788