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Efficacy of the over-the-scope clip (OTSC) for treatment of colorectal postsurgical leaks and fistulas

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Abstract

Background

Colorectal postsurgical leaks and fistulas are severe complications that dramatically increase morbidity and mortality. The aim of this study was to evaluate the clinical impact of over-the-scope clip (OTSC) closure to seal the visceral wall in the management of acute and chronic colorectal postsurgical leaks and fistulas.

Methods

We reviewed our prospective series of acute and chronic colorectal postsurgical leaks and fistulas observed between April 2008 and September 2011 and treated by OTSC. Indications were all cases with an orifice <15 mm in maximum diameter with no extraluminal abscess and luminal stenosis.

Results

Endoscopic OTSC closure was performed in 14 consecutive patients (mean defect = 9.1 mm in diameter) by means of 10.5- or 12-mm clips, depending on the wall defect diameter. In eight cases, the indication was an acute leak and in six cases a chronic leak, mainly after anterior rectal resection; two cases were complicated by a rectovaginal fistula and in two other cases by a colocutaneous fistula. OTSC treatment was used to complete endoscopic vacuum-assisted closure of a large defect in three cases. The overall success rate was 86 % (12/14): 87 % (7/8) in acute and 83 % (5/6) in chronic cases. No OTSC-related complications occurred. Further surgery was required in one case.

Conclusion

Endoscopic OTSC closure of colorectal postsurgical leaks and fistulas is a safe technique, with a high success rate in both acute and chronic cases, including rectovaginal and colocutaneous fistulas.

Keywords

Colorectal surgery Postoperative complications Anastomotic leak Endoscopic clips Over-the-scope clip

Anastomotic leakage, the most feared complication of colorectal surgery, is associated with increased morbidity and mortality, prolonged hospital stay, and additional health-care costs. Its reported prevalence varies widely from 1 to 39 %, but clinically relevant leaks probably occur in 3–6 % of cases, depending on the definition and the type of resection [1]. There is no universally accepted definition of a dehiscence colorectal anastomosis. It may present as a generalized peritonitis or as fecal discharge from the wound and/or drain requiring abdominal reoperation [2]. Where indicated, operative endoscopy to achieve wound healing may be a viable alternative. For example, a localized abscess may be amenable to endoscopic vacuum-assisted closure, also known as endo-VAC therapy [3], and anastomotic stenosis may be adequately managed by endoluminal stenting [4] with covered stents in cases of associated fistulas or leakage. Extravasation of radiological contrast in an otherwise mildly symptomatic or asymptomatic patient poses a strategic challenge. Except for instances requiring only surveillance, the need for a loop ileostomy or colostomy constitutes an indication for secondary surgery which will not necessarily guarantee healing in all cases. Unlike repair of colonic perforations during diagnostic or therapeutic endoscopy [5], endoscopic clipping on scarred anastomotic tissue, even at an early stage, is often unsuccessful.

A new over-the-scope clip system, called OTSC (Ovesco Endoscopy, Tübingen, Germany) [6], appeared on the market about 3 years ago. The system consists of a nitinol clip loaded at the tip of the endoscope that can capture a large amount of tissue and compress the lesion until healed. Results from animal models and initial clinical use support the efficacy of OTSC closure in the treatment of gastrointestinal bleeding; its role in the management of iatrogenic perforations in humans is less defined, and reports on its use in treating colorectal postsurgical leaks and fistulas are anecdotal [7–9]. Here we report on the use of OTSC in the endoscopic treatment of colorectal postsurgical leaks and fistulas.

Case series

From April 2008 to September 2011, 14 consecutive patients (8 females and 6 males; mean age = 64 years, range = 41–82) underwent OTSC placement for closure of a postsurgical leak or fistula of the colon or rectum. Table 1 lists the patients' characteristics. The mean diameter of the perforation was 9.1 mm (range = 5–12 mm) as measured by comparison with a foreign body retrieval grasper (maximum opening = 6 mm). Leaks and fistulas were considered acute if endoscopic treatment was attempted within 60 days after surgery and chronic if treated later. Depending on the diameter of the wall defect, two clip configurations (10.5 or 12 mm) were employed.

Table 1

Demographic and clinical data including follow-up for patients who underwent over-the-scope clip (OTSC) placement

No.	Sex	Age (years)	No. of orifices	Defect size (mm)	Neoadjuvant RT	Surgery	Leak/fistula location	Indication	Additional treatment	Complete healing	Need of further surgery
1	M	73	1	10	Y	AR	Colorectal anastomosis	Chronic leak	ENDOVAC	Y	N
2	F	58	2	8, 5	Y	AR	Colorectal anastomosis	Chronic leak	ENDOVAC	N	N
3	F	76	1	10	Y	AR	Colorectal anastomosis	Acute leak	Covered SEMS	Y	N
4	M	41	1	6	Y	AR	Colorectal anastomosis	Chronic leak	N	Y	N
5	F	59	1	5	Y	AR	Colorectal anastomosis	Acute leak with rectovaginal fistula	N	Y	N
6	F	65	1	10	N	AR	Colorectal anastomosis	Acute leak with rectovaginal fistula	N	N	Y
7	F	73	1	10	Y	AR	Colorectal anastomosis	Acute leak	N	Y	N
8	M	56	1	10	Y	AR	Colorectal anastomosis	Acute leak	N	Y	N
9	F	74	1	12	Y	AR	Colorectal anastomosis	Chronic leak	ENDOVAC	Y	N

No.	Sex	Age (years)	No. of orifices	Defect size (mm)	Neoadjuvant RT	Surgery	Leak/fistula location	Indication	Additional treatment	Complete healing	Need of further surgery
10	F	66	1	8	Y	AR	Colorectal anastomosis	Acute leak	N	Y	N
11	M	69	1	9	N	AR	Colorectal anastomosis	Acute leak	N	Y	N
12	F	76	1	12	N	AR	Colorectal anastomosis	Acute leak	N	Y	N
13	M	68	1	12	N	Colostomy closure	Colocolonic anastomosis	Chronic colocutaneous fistula	N	Y	N
14	M	82	2	10, 5	N	Right colectomy	Ileocolonic anastomosis	Chronic double colocutaneous fistula	N	Y	N

AR anterior resection, RT radiotherapy, ENDOVAC endoscopic vacuum-assisted closure, SEMS self-expanding metallic stents

Two patients with chronic lower rectal defects who reported pain when the fistula orifice tissue was handled with alligator forceps were excluded because clip placement might have caused persistent discomfort. In eight cases the indication was an acute leak and in six cases a chronic leak, mainly after rectal anterior resection and colorectal anastomosis. Two patients had a diverting lateral ileostomy at the time of endoscopic treatment. In two cases the leak was complicated by a rectovaginal fistula and in two other cases by a colocutaneous fistula. Nine (64 %) patients had undergone neoadjuvant radiotherapy for rectal cancer.

After obtaining informed consent, the procedures were performed either without sedation or under conscious sedation with intravenous midazolam. Endoscopic repair of wall leaks was done using an Olympus PCF-Q180AL pediatric colonoscope (Olympus Endoscopy, Tokyo, Japan) with a working channel 3.2 mm in diameter. The endoscope, equipped with a dedicated transparent cap mounted on it and the clip loaded at the tip of the scope, was positioned in front of the wall defect. Initially, we used an alligator jaw or a rat tooth grasper to grasp the leak borders or fistulous orifices; later in the study period we used a dedicated OTSC twin grasper in acute cases and an anchor tripod in chronic cases. As far as practical, the tissue was retracted into the applicator cap under air suction and closed by deploying the OTSCs. The traumatic version of the clip, with sharp, pointed teeth, was used in all cases. After OTSC deployment, the defect closure was assessed by soluble contrast enema injection through the working channel of the scope and by tentative guide-wire cannulation.

A single OTSC was applied in all cases, except for the last one where two orifices were present. This patient experienced a recurrence of the colocutaneous fistula after 2 months and was retreated successfully by an additional OTSC.

Endoscopy was repeated when indicated by clinical follow-up assessment. The minimum follow-up period was 4 months. The overall success rate was 86 % (12/14): 87 % (7/8) in acute and 83 % (5/6) in chronic cases (Table 1). There were no OTSC-related complications. Redo surgery was required in one case. In the second case of failure, the patient refused further surgery, preferring to leave the chronic abscess untreated.

Discussion

Colorectal postsurgical leaks and fistulas pose a clinical dilemma: whether to create a temporary or a definitive stoma, both burdened by high morbidity and mortality. Today, flexible endoscopy

offers a valid alternative to surgery for treating solitary extraluminal abscesses or when associated with luminal stenosis with either Endo-VAC therapy or covered stenting, respectively. Treatment for a simple leak or fistula with no extraluminal collection or stenosis remains controversial.

Standard clips are widely used for mechanical hemostasis, and their role in endoscopic closure of perforations has been explored [10–12]. Four different designs of clips to be released through the scope are available: QuickClip2 (Olympus Corp., Melville, NY, USA), Resolution Clip (Boston Scientific, Natick, MA, USA), TriClip (Cook Medical Inc., Winston-Salem, NC, USA) and InScope Multiclip Applier (Ethicon Endo-Surgery, Cincinnati, OH, USA). While their effectiveness in achieving hemostasis and endoscopic closure of perforations is well described [9], successful treatment of postsurgical leaks and fistulas is anecdotal. One of the limitations to commercially available clips is a low closure force that is suboptimal for compressing scarred and hardened tissues [12]. Often encountered in patients undergoing neoadjuvant therapy, this clinical situation not only represents a well-known risk factor for leakage, it also impairs healing of the bowel tissue once retreated. New and more effective compression clip techniques are therefore needed to obtain more satisfactory and less invasive nonsurgical repair.

In this scenario, the over-the-scope clip system (Ovesco Endoscopy, Tübingen, Germany) offers the advantage of capturing a large amount of tissue and applying compression at approximately 8–9 N once released. Moreover, it allows for a surgery-like serosa-to-serosa tissue approximation. The nitinol clip loaded at the tip of the endoscope can capture leaks and fistula orifices and compress them constantly until healed [6].

To our knowledge, this series is the largest ever reported to date on the specific, and disputed, indication of colorectal postsurgical leaks and fistulas. In fact, larger series on the application of OTSC have been reported, but among them colorectal postsurgical leaks and fistulas are anecdotal [7–9]. In our hands, endoscopic closure with OTSC is a relatively simple and safe technique. In the two unsuccessful cases, the technical difficulty was in aligning the endoscope tip with the lesion since foreign body retrieval forceps were erroneously employed. This did not reoccur when dedicated twin graspers and anchors were used for treating the acute and chronic cases, respectively. Furthermore, having gained experience in how to remove an OTSC once deployed, first by cooling it and then pulling it out with a foreign body retrieval forceps, even application in potentially painful areas such as the lower rectum need no longer represent an absolute contraindication.

Applying two clips close to each other, as in the patient who had two orifices of a colocutaneous fistula, is somewhat difficult. This was probably the cause of the early drop of the clips and consequent recurrence of one of the orifices which was retreated successfully 2 months later with the application of another OTSC.

Unlike previous reports [7, 9], in our series, though small, treatment of acute and chronic cases was highly successful, including those involving rectovaginal and colocutaneous fistulas. Despite the high cost of the device and accessories, the high success rate with endoscopic OTSC closure justifies its routine use, unless evidence demonstrates greater morbidity and mortality compared to a second surgery, which, in any case, is still more expensive than OTSC.

In conclusion, application of OTSC appears to be useful in the endoscopic management of colorectal postsurgical leaks and fistulas. Further prospective clinical studies are needed to confirm the value and the efficacy of this newly available clipping device in the disputed treatment of these patients.

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