Endoscopic treatment of gastrointestinal fistulas using an over-the-scope clip (OTSC) device: Case series from a tertiary referral center

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Gastrointestinal perforations and post-surgical fistulas are dreaded complications that dramatically increase morbidity and mortality. A new endoscopic over-the-scope clip (OTSC) system may be potentially useful for sealing visceral perforations in several clinical settings. We evaluated the advantages and clinical impact of the placement of OTSCs on the management of non-malignant gut leaks in 12 consecutive patients. OTSCs of 9.5 or 10.5 mm were used, according to the diameter of the defect within the wall. The indications for treatment were mainly related to post-surgical fistulas. Healing of the fistula was assessed by endoscopic or radiological means, and failed only once. No OTSC-related complications occurred. Endoscopic closure of perforations and post-surgical fistulas with the OTSC system is a simple and minimally invasive technique. This approach, when feasible, may be less expensive and more advantageous than a surgical approach.

Introduction

Gastrointestinal perforations and post-surgical fistulas are complications that may increase morbidity and mortality to as high as 60% [1,2]. The recent introduction into clinical practice of more invasive endoscopic procedures, such as endoscopic mucosal resection, endoscopic submucosal dissection, and novel laparoscopic approaches to the treatment of gastrointestinal tract diseases, has increased the risk of these complications. Until recently, surgery was the mainstay of therapy for gastrointestinal tract leaks, but it could lead to an increased length of hospital stay and higher costs.

Perforations that occur in the gastrointestinal tract can be closed by means of commercially available endoscopic clips deployed through the working channel of an endoscope [3]. In addition, other endoscopic techniques have been proposed, such as endoscopic stenting [4] and endoscopic gluing with fibrin and Histoacryl or Vicryl plugs [5,6]; however, clipping is a simpler method.

Several varieties of clip device are available, including rotatable devices, single-shot systems, and clips that can be reopened [7]. Initially introduced for the treatment of upper gastrointestinal tract bleeding [8,9], indications for clip application have rapidly expanded to include the closure of perforations and fistulas, and the securing of tubes or catheters to the gastrointestinal wall [10]. However, commercially available clips have some limitations, such as a low closure force that is suboptimal for compressing scarred and hardened tissues, and only partial success in closing large and circular full-thickness wall perforations [11,12].Therefore, because a high number of clips is often required to treat GI tract wall defects and large full-thickness wall lesions are difficult to treat endoscopically with currently available systems, new and more effective compression clip techniques are required in order to obtain more satisfactory and less invasive non-surgical repair.

The new endoscopic OTSC system (Ovesco AG, Tübingen, Germany), an alternative device for closing leaks with an intraluminal procedure that avoids surgical repair, has recently been introduced into clinical practice. It is biocompatible for long-term implantation, can capture a large amount of tissue, deliver a compression force of approximately 8–9 N when released, and compress the lesions until the wall defects have healed [13].

The application of the OTSC, as a "serosa to serosa" suture, was first tested in animal models [13–16]. Although an excellent device in fresh incisions, such as perforations that might occur during endoscopic mucosal resection or endoscopic submucosal dissection, it is more difficult to apply successfully in fibrous tissues, such as the edges of chronic fistulas, where the use of anchor or twin-type graspers is vitally important in ob-

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Table 1 Demographic and clinical data for patients undergoing over-the-scope clip (OTSC) placement.

Patient number (sex; age)	Size of defect, mm	Number of clips	Location of leak	Indications	Additional treatment
1 (M; 53)	25	2	Duodenal suture	Dehiscence after surgical repair of endoscopic perforation leakage	None
2 (F; 31)	8	2	Longitudinal gastric suture*	Post surgical anastomotic fistula	Metallic stent
3 (M; 70)	10	1	Gastric suture in duodenocephalopancreatectomy	Post surgical anastomotic fistula	None
4 (M; 46)	6	1	Duodenojejunal anastomosis	Post-surgical anastomotic fistula	None
5 (F; 79)	8 and 6	2	Gastrojejunal Roux-en-Y anastomosis	Post-surgical anastomotic fistula†	None
6 (F; 65)	7	1	Colo-rectal anastomosis	Post surgical anastomotic dehiscence	None
7 (M; 67)	7	2	Colo-colic anastomosis	Post surgical anastomotic dehiscence	None
8 (F; 71)	8 and 4	1	Esophagojejunal Roux-en-Y anastomosis	Decubitus by surgical drainage on jejunal wall	Standard clips × 3‡
9 (M; 46)	15	1	Ileum	Post traumatic fistula	None
10 (F; 51)	22	1	Rectum	Post surgical fistula (after cystectomy)	None
11 (M; 71)	10	1	Rectum	Post surgical fistula (after prostatectomy)	None
12 (F; 73)	6	1	Duodenojejunal anastomosis	Post surgical fistula	Metallic stent

F, female; M, male; DCP.
* in sleeve gastrectomy; † after partial gastrectomy; ‡ applied to the smaller defect.

taining a definitive closure of the fistula [17]. More recently, the OTSC system has shown its efficacy in some small preliminary studies in humans [18–22].

The present study, performed within the endoscopy unit of a tertiary referral center, evaluated the advantages and clinical impact of the OTSC system in the management of nonmalignant gastrointestinal tract wall leaks.

Case series

The OTSC system

A standard endoscope is used with twin or anchor-type graspers and OTSCs (Ovesco).

The Ovesco twin grasper has two jaws that move separately to approximate the edges of the gastrointestinal tract wall before applying suction. The anchor grasper has three retractable hooks, which facilitate approximation of the margins of the tissue before suctioning. Two different types of OTSC are commercially available: the atraumatic version with blunt teeth for clipping fresh borders or vessels in gastrointestinal bleeding, and the traumatic version with sharp teeth for more fibrotic tissues.

The clip is mounted onto a silicone cap (similar to a band ligation device), placed onto the tip of an endoscope, and applied by stretching a wire by means of a hand-wheel installed on the entrance of the working channel. When the clip was released from the applicator, it closes because of the "shape-memory" effect and the high elasticity of the nitinol alloy. This is similar to a bear-claw closure mechanism, and applies a permanent force to the tissues.

Patients and procedures

In the period April 2009–August 2010, 12 consecutive patients (six women/six men; mean age 60, range 31–70) underwent OTSC placement (**Table 1**). Indications for treatment were post-surgical or traumatic fistulas of the gastrointestinal tract; the nonmalignant visceral leaks had defect diameters of 6–25 mm, measured by comparison with a standard biopsy forceps (maximum opening 6 mm), and were resistant to conservative or surgical treatment (defect diameters). All patients had nutritional support and intensive care when needed.

Following informed consent from each patient, all procedures were performed under conscious sedation with intravenous meperidine and midazolam, or deep sedation with intravenous propofol. Endoscopic repair of wall leaks was done using a standard endoscope (operative gastroscope or pediatric colonoscope) with a working channel of 3.8-mm diameter. The endoscope, with the mounted and loaded clipping devices, was positioned in front of the mucosal leak, the fistulous tract was grasped by the OTSC grasper, invaginated into the applicator cap, and closed by deploying the OTSCs. We used the traumatic version of the clip, which has sharp, pointed teeth (**Fig. 1**).

Patient outcomes are shown in **Table 2**. Endoscopy was repeated according to the needs of clinical follow-up. Water-soluble contrast radiographs were taken to assess the sealing of the leaks immediately after clipping with the OTSC, and repeated 1 month later in selected cases when the success of the procedure needed to be confirmed.

Discussion

The treatment of gastrointestinal leaks caused by fistulas, perforations, or anastomotic dehiscence usually requires surgery, but such surgery carries a significant risk of morbidity/mortality [1]. In addition, surgical procedures need general anesthesia, often prolong hospitalization and, therefore, increase costs; thus, an endoscopic approach to this problem, such as the OTSC system, may represent a good alternative.

Our experience in a limited number of cases within a single center has confirmed the preliminary observations reported in the smaller series, and shown favorable results for both outcomes and side effects. No complications occurred, and the leaks were all healed at follow-up 1–3 months later. It is worth noting that in 9 of the 11 patients, the leak was sealed within 4 days by a single application.

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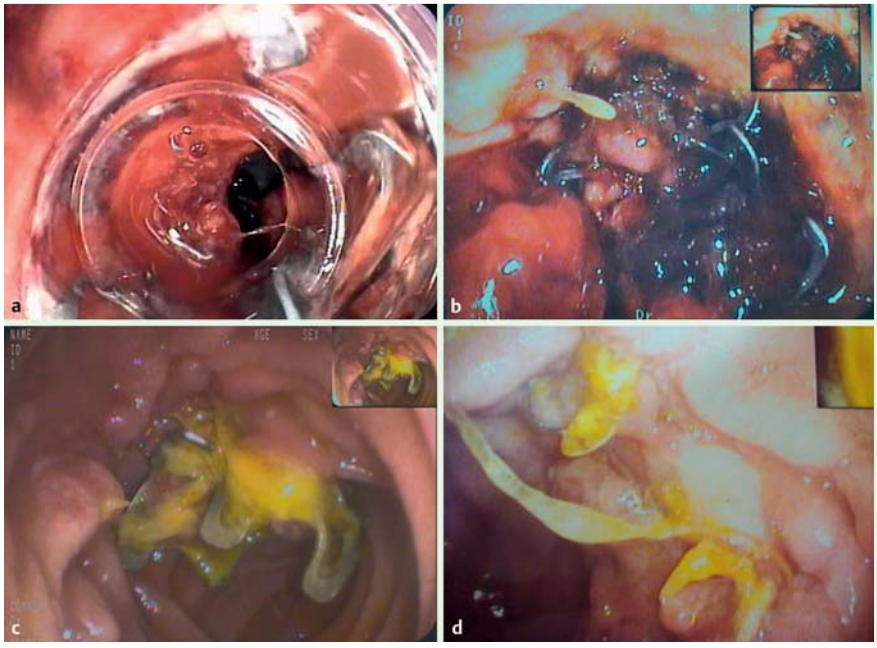

Fig. 1 Duodenal leakage. **a** Endoscopic view of the defect causing leakage, which was 2.5 × 4 cm. **b** The two clips immediately after placement. **c** The two clips 2 weeks after placement. **d** Final follow-up 45 days after the placement of the clips.

Table 2 Patient outcomes after over-the-scope clip (OTSC) positioning.

Patient number	Outcome	Follow-up		
		Time, months	Scar	Clip
1	Complete sealing	1.5	Normal	Detached
2	Complete sealing	1	Normal	Detached
3	Complete sealing	1	Normal	Detached
4	Complete sealing of fistula but patient died 2 weeks later (unrelated sepsis)			
5	Complete sealing	1	Normal	Still attached
6	Complete sealing	3	Normal	Detached
7	Early clip detachment, repositioned with complete sealing	1	Normal	Detached
8	Complete sealing	1	Normal	Still attached
9	Complete sealing	1	Normal	Detached
10	Complete sealing	1	Normal	Still attached
11	Complete sealing	1	Normal	Still attached
12	Failure to seal the fistula			

The data from ourselves and others, therefore support the use of OTSC to close perforations, anastomotic dehiscence, and fistulas in the upper and lower gastrointestinal tract [18 – 22]. This method seems to be more effective in deep wall leaks with respect to other devices, such as clips, endoloops, and T-tags [23]. The main limitation of the OTSC technique is its inability to treat a leak larger than 2.5 cm, although sometimes it may be possible to apply two clips, depending on the anatomical location of the defect.

In our experience, the failure of this technique was more frequent when the leak edges were fibrotic, and in patients who had undergone several surgical approaches; in such instances, endoscopic suturing may be a better first approach.

In conclusion, OTSC positioning represents a potentially beneficial procedure for this difficult to treat patient group with gut leakage. The technique is less expensive than a conventional surgical approach: in our hospital the OTSC procedure carries a cost of about US$ 1050, whereas a surgical reintervention would cost US$ 3800. Further prospective clinical studies are needed to confirm the value and the efficacy of this newly available clipping device in the treatment of wall lesions, perforations, or challenging bleeding.

Competing interests: None

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