

ORIGINAL ARTICLE

Endoscopic management of digestive leaks with the Over-The-Scope Clip: A retrospective study



Tito Correia^{a,*}, Pedro Amaro^a, Ana Oliveira^a, Alexandra Fernandes^a,
Diogo Branquinho^a, Ana Nunes^b, Francisco Portela^a, Carlos Sofia^a

^a Gastroenterology Department – Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal

^b Gastroenterology Department – Hospital Garcia de Horta, Almada, Portugal

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Abstract

Introduction: The Over-The-Scope Clip (OTSC[®]) is a device with promising applications in endoscopic closure of perforations/dehiscence/fistulas, endoscopic hemostasis and NOTES.

Aims: To evaluate the clinical effectiveness and safety of OTSC.

Methods: Between September 2011 and September 2013, 6 consecutive patients underwent OTSC placement by two experienced endoscopists. In three patients OTSC was used in the closure of surgical dehiscences, both in upper digestive tract (after esofagojejunostomy and gastric sleeve) and in lower digestive tract (blind loop dehiscence after colorectal anastomosis). Two patients had esophageal fistulas with several weeks' duration (one to the bronchial tree and other to the pleura). Furthermore, OTSC was used to close an iatrogenic perforation following colonic polypectomy.

Results: All procedures experienced technically immediate success and there were no complications related to the placement of the OTSC (1 clip). It was well tolerated and patients were hospitalized on average 15 days (5–53 days). However, during follow-up (mean = 12.4; 5–22 months) permanent closure of chronic esophageal-bronchial fistula could not be achieved in one patient.

Conclusion: In our experience, OTSC shows efficacy in solving gastrointestinal leaks.

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* Corresponding author.

E-mail address: Titocorreia@gmail.com (T. Correia).

PALAVRAS-CHAVE

Over-The-Scope clip;
Deiscência
gastrointestinal;
Fístula;
Perfuração

Resolução de fugas digestivas com Over-The-Scope Clip: análise retrospectiva**Resumo**

Introdução: O endoclip Over-The-Scope (OTSC) é um acessório com possíveis aplicações no encerramento de perfurações/deiscências/fístulas, hemostase endoscópica e em NOTES.

Objectivo: Avaliar a eficácia clínica e segurança do OTSC.

Métodos: Entre Setembro de 2011 e Setembro de 2013, seis pacientes consecutivos foram submetidos à colocação OTSC por dois endoscopistas com experiência em modelos animais. Em três pacientes o OTSC foi utilizado no encerramento de deiscências cirúrgicas, tanto no tracto digestivo superior (após esofagojejunosomia e sleeve gástrico) como no tracto digestivo inferior (deiscência de ansa cega após anastomose colorretal). Dois pacientes apresentaram fístulas esofágicas com duração de várias semanas (um para a árvore brônquica e outro para a pleura) que dificultou a colocação do OTSC. O OTSC foi usado, igualmente, para fechar uma perfuração iatrogénica após polipectomia do cólon.

Resultados: Todos os procedimentos obtiveram sucesso técnico imediato e não se observaram complicações relacionadas com a colocação do OTSC (1 clip). O procedimento foi bem tolerado e os pacientes permaneceram internados, em média, 15 dias (5–53 dias). No entanto, durante o acompanhamento (média=12,4; 5–22 meses) o encerramento definitivo de fístula esôfago-brônquica crônica não foi possível em um dos pacientes.

Conclusão: O OTSC provou a sua aplicabilidade na resolução de soluções de continuidade gastrointestinal.

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Introduction

Post-surgical complications such as fistula and anastomotic leaks are conventionally submitted to surgical repair (open, laparoscopic or external drainage). However, surgical reintervention has a significant morbidity and mortality, prolongs hospital stay and increases the costs.¹ Several endoscopic techniques have been described for closure of gastrointestinal leaks (perforations, leaks, and fistulas) by using various devices and methods such as clipping with multiple metallic endoclips,^{2–4} ligating with endoloops and rubber bands,⁵ fibrin glue sealing,⁶ prolene mesh plugging and application of cyanoacrylate,⁷ clips and endoloop together by using a double channel endoscope.⁸ In 2007, Kirschniak et al. described the first cases of small mural leaks closure with a new endoclip system, the over-the-scope clip – OTSC® (Ovesco Endoscopy, Tuebingen, Germany).⁹ This endoclip is made of super-elastic shape memory nitinol alloy (MRI-safe material), which resumes its former unbent shape after the clip is released and exerts a more sturdy closure compared to conventional endoclips due to its capacity to grasp more visceral tissue and apply a greater compressive force. The system consists of a clip that is preloaded on a transparent applicator cap mounted on the endoscope tip, which can be released by pulling a taut wire threaded through the working channel to the hand-wheel of the scope, similar to band-ligation systems. Recently, case series and reviews have been published describing its success in treatment of gastrointestinal bleeding, fistula, and perforations.^{10–18}

The present retrospective study, performed within the endoscopy unit of a tertiary referral center, evaluated the clinical effectiveness and safety of the OTSC system in the management of non-malignant gastrointestinal tract wall leaks.

Patients and procedures

Clinical cases of six consecutive patients that underwent OTSC placement between September 2011 and September 2013 were reviewed. Patient characteristics are summarized in Table 1. The OTSC system was mounted onto the tip of a gastroscope (Olympus GIF-1T Q160; diameter of 9.8 mm; working channel of 2.8 mm; Olympus, Tokyo, Japan) in the same manner as a band ligation device. “Traumatic” version (t type) of OTSC, medium sized caps twin type graspers (OTSC Twin Grasper® Ovesco Endoscopy, Tuebingen, Germany) and anchor (OTSC Anchor®, Ovesco Endoscopy GmbH, Tuebingen, Germany) were used. Two endoscopists with previous experience in animal models performed the application of the device. All procedures took place under conscious sedation with intravenous midazolam or deep sedation with intravenous propofol.

All procedures were performed by two advanced endoscopists with experience of OTSC placement in animal models.

To all patients had been previously explained the therapeutic procedure and all signed the respective informed consent.

Results

A systematic approach of the data, including patient procedure details, technical and clinical outcomes, is represented in Table 1.

Patient 1: A 71-year-old man underwent total gastrectomy and Roux-en-Y esophagojejunostomy for gastric adenocarcinoma. A blind loop jejunal dehiscence and complex fistula occurred 10 days later. After a couple of weeks under antibiotherapy and external drainage, he suddenly developed dyspnea and hemoptysis. New CT and barium

Table 1 Patient characteristics, procedure details and long-term clinical outcome. AB – antibiotherapy; ED – External drainage; M–W – Mallory–Weiss; M – male; F – female; S – successful; d – days; m – months.

Characteristics	Patient number					
	1	2	3	4	5	6
Age/Gender	71/M	84/M	36/F	66/F	71/F	63/M
Location of the leak	Blind loop jejunal dehiscence	Blind loop colorectal anastomosis	Longitudinal gastric suture – sleeve	Esophago-bronchial fistula	Esophago-pleural fistula	Sigmoid colon
Indication	Post surgical fistula	Post surgical fistula	gastrectomy Post surgical fistula	Spontaneous esophageal rupture	Post M–W perforation	Post polipectomy perforation
Time from diagnosis to OTSC placement (d)	54	78	40	153	33	0
Maximum lesion size (mm)	12	9	11	7	9	10
Additional treatment	ED + AB	ED + AB	Relaparoscopy + ED + AB	Surgery + AB + Esophageal stent	ED + AB	AB
Hospital stay after OTSC placement (d)	7	7	5	53	14	6
Technical immediate outcome	S	S	S	S	S	S
Duration of follow-up (m)	22	15	13	Lost at follow-up	7	5
Clinical outcome	Asymptomatic	Asymptomatic	Asymptomatic	Persistence of fistulous track	Asymptomatic	Asymptomatic

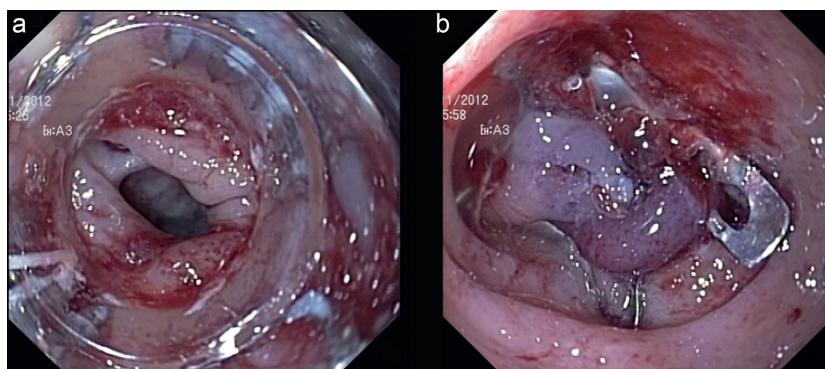


Figure 1 Patient 2 – Colon blind loop dehiscence in a colorectal anastomosis before (a) and after (b) treatment with OTSC.

transit described a transdiaphragmatic tract linking the abdominal collections to a lung abscess with fistula to the bronchial tree. Despite broad-spectrum antibiotics and external drainage, there was progressive clinical deterioration due to severe septic shock, not allowing surgical approach. Endoscopy was then performed which revealed a 12 mm dehiscence of the Roux-en-Y blind loop closure. As it has not been possible to aspirate the fistula hole into the device it was decided to suck the entire circumference of normal mucosa upstream the orifice, creating a new closure of the loop by the placement of the OTSC. The immediate clinical response was extremely favorable, as evidenced by the swift recovery from the septic state and resolution of the suppurated abdominal fistula to the bronchial tree. The patient remains asymptomatic after 17 months of follow up.¹⁹

Patient 2: An 84-year-old man underwent anterior rectal resection for rectal cancer, with protective ileostomy and colorectal anastomosis. Two weeks after the surgery, an anastomotic dehiscence was diagnosed by CT, which identified a pre-sacral abscess (12 cm × 6 cm), close to surgical anastomosis, as well as air in the retroperitoneum. After pelvic drainage and antibiotic therapy there was clinical improvement. However, soon after, he developed pelvic pain and fever, and CT and barium transit confirmed persistence of colorectal anastomosis dehiscence and pelvic abscess. Endoscopy, revealed a fistulous orifice in the colon blind loop (Fig. 1a). Leak margins were easily grasped with the OTSC anchor and invaginated into the applicator cap and the wall was closed by a OTSC with occlusion of the fistula lumen (Fig. 1b). The patient fully recovered and was discharged after seven days.

Patient 3: A 36-year-old woman underwent laparoscopic sleeve gastrectomy for obesity. She presented on the fifteenth postoperative day with abdominal pain, fever and vomiting. CT revealed a postoperative leak in the proximal third of the gastric sleeve. Initially, a new laparoscopic approach was performed, with abdominal abscess drainage, fistula resection and abdominal drains were placed. Symptoms persisted and an esophagogastroduodenoscopy confirmed the maintenance of the gastric fistula. Subsequent placement of fully covered esophageal stent (Poliflex®, 12 cm long, 20 mm diameter) was possible and assisted to clinical improvement. However, shortly thereafter, the patient developed obstructive symptoms and maintained purulent material by surgical drains. Endoscopically, prior esophageal

stent was removed (medium part was damaged) upkeeping the gastric fistula and a OTSC was deployed. The patient presented clinical (purulent drainage stopped) and imagiological improvement (no contrast leak). At follow-up, the patient continued to tolerate oral intake, maintaining a stable weight, without abdominal pain or fever.

Patient 4: A 66-year-old woman underwent surgical esophagorraphy after spontaneous rupture of the esophagus. Three months later she developed symptoms of esophago-bronchial fistula, confirmed by endoscopy and barium transit. Medical and endoscopic treatments were performed with placement of three partially covered self-expandable stents, which presented distal migration. The patient showed clinical improvement with resolution of fistula in the barium transit. Six months after she presented with fever and a respiratory infection was diagnosed. Esophagogastrosocopy was performed and two small holes compatible with esophageal-bronchial fistula were identified in the mid esophagus. She was referred to our department and an OTSC was deployed after traction with an anchor with apparent closure of the fistulous orifice, confirmed by contrast study (Fig. 2 a–c). A few days after, the patient developed a respiratory exacerbation and it was verified the absence of the esophageal OTSC. The persistence of the fistulous track (Fig. 2d) led to a new surgical approach, also without success.

Patient 5: A 71-year-old woman presented with hematemesis due to Mallory–Weiss tear. A few days later she developed sepsis consequent to respiratory infection, with right pleural effusion. Placement of chest drain identified purulent liquid. After resumption of oral feeding, it was observed food content in pleural drainage, confirmed by contrast examination with identification of fistulous track with about 5 cm from the distal esophagus to the right pleural space (Fig. 3a and b). Persistence of pleural effusion led to endoscopic attempt to closure the fistulous orifice using endoclip OTS with anchor (Fig. 3c). During the procedure methylene blue was instilled in the lumen, and no drainage by the chest tube was identified. New contrasted study took place 15 days after OTSC placement, which showed no leakage of the contrast product (Fig. 3d). Clinically, the patient resumed oral feeding, without evidence of recurrence of the fistula or other complications.

Patient 6: A 63-year-old man previously healthy underwent elective colonoscopy in our department to perform polypectomy. At 45 cm from the anal margin, there was a

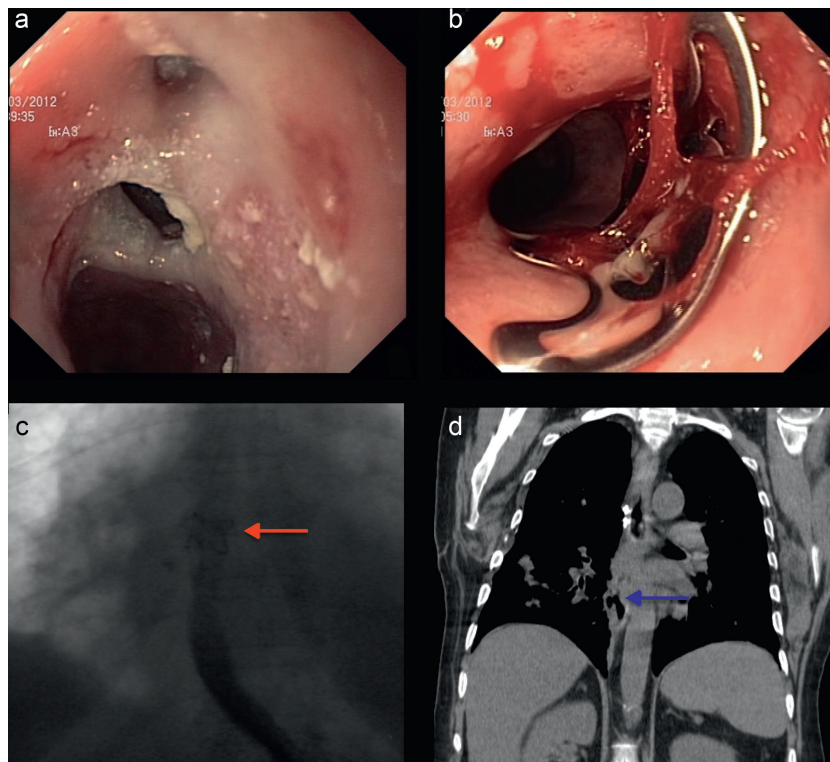


Figure 2 Patient 4 – Esophageal-bronchial fistula: endoscopic view before (a) and after (b) OTSC placement; (c) contrasted study one day after OTSC (red arrow) placement; (d) persistence of the fistulous track (blue arrow) in CT.

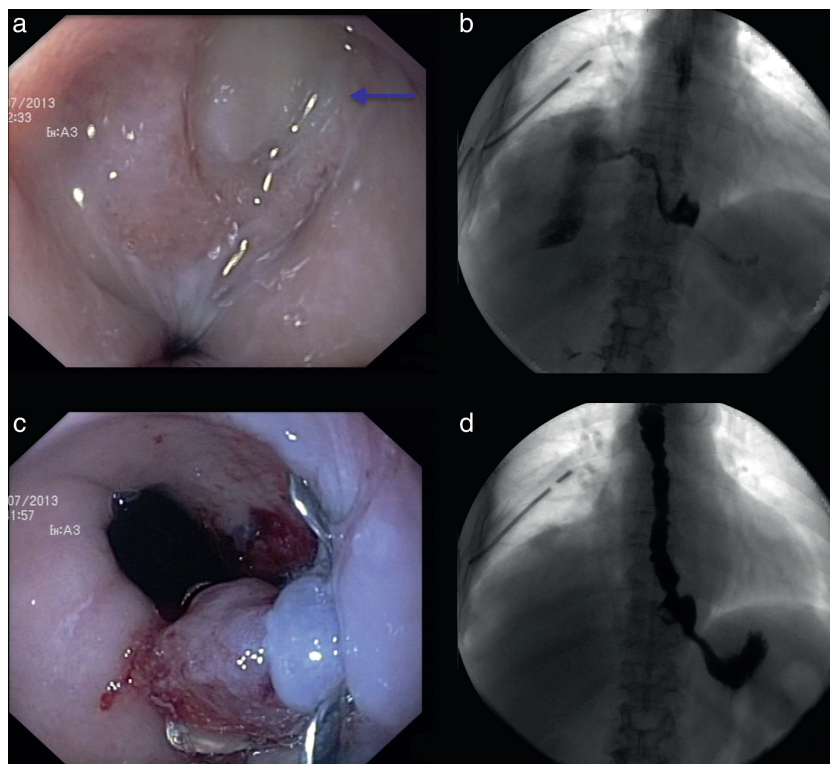


Figure 3 Patient 5 – Esophageal-pleural fistula after perforation of a Mallory-Weiss tear: (a) fistulous orifice with pus (blue arrow); (b) esophageal-pleural fistula in contrast study; (c) endoscopic view after OTSC placement; (d) contrast image after treatment with OTSC.

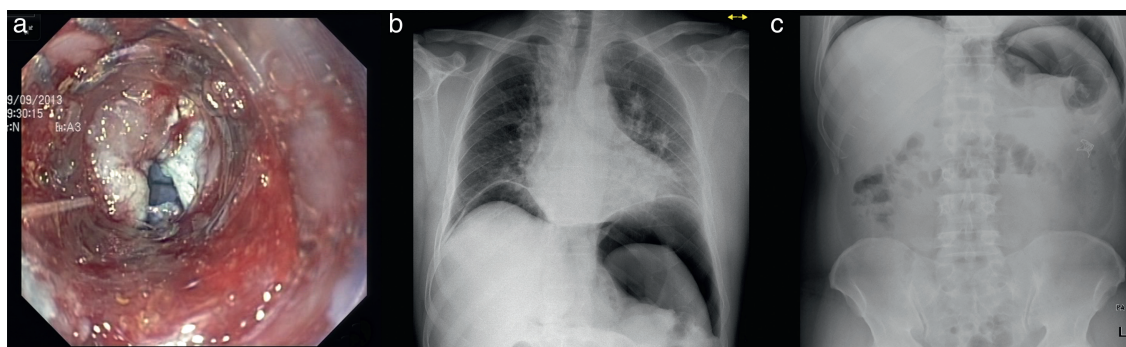


Figure 4 Patient 6 – (a) Endoscopic view before OTSC placement; (b) pneumoperitoneum immediately after perforation closure; (c) pneumoperitoneum 3 days after OTSC placement.

large and bulky sessile polyp, with a multilobulated surface, measuring about 5 cm in diameter. After mucosal elevation with diluted epinephrine and methylene blue, the polyp was removed with a snare. Upon verification of the scar, there was a perforation of 10 mm (Fig. 4b). Using a therapeutic gastroscope, the colic perforation was closed using an OTSC, with apparent success. The residual polypoid tissue was also removed with a snare. The patient was admitted under broad-spectrum antibiotics and no oral intake. He showed positive clinical, analytical and radiological evolution (Fig. 4c), and three days after the event liquid diet was introduced. He was discharged asymptomatic, seven days after admission.

Discussion

Spontaneous or iatrogenic perforation of the gastrointestinal tract wall may cause a variety of clinical settings, ranging from an asymptomatic course up to severe (and even lethal) complications, requiring prompt closure and control of extraluminal fluid collections and sepsis. Anastomotic leaks are probably the most dreaded complications of intestinal surgery, with mortality rate often reported to be up to 10–15%.²⁰ The incidence of intestinal anastomotic leaks ranges from 1 to 19% depending on the location of the anastomosis. However, small bowel anastomosis tends to be associated with a lower risk of anastomotic disruption than large bowel anastomosis, particularly when compared to the distal rectum or anal canal.²⁰ Anastomotic leakages following esophagectomy occur in about 10% of cases. Anterior rectal resections lead to anastomotic leakages in 9.6% if a diverting ileostomy is used, with even higher rates if an ileostomy is omitted.²⁰

In endoscopic procedures, the risk of perforation depends essentially on the purpose of the exam. Perforation occurs by accident in 0.06–0.12% of diagnostic colonoscopies.^{21,22} However, reported perforation rates are 0.3–0.5% after endoscopic mucosal resection and 4–10% in endoscopic submucosal dissection, and hence substantially higher than conventional endoscopic procedures.²³

Until recently, iatrogenic or surgical leaks were surgically managed, using a diversity of procedures (proximal diversion, omentoplasty) combined with percutaneous drainage and intravenous antibiotics. Nonetheless, direct surgical

repair is difficult, hazardous and often not feasible. Recent advances in endoscopic techniques have improved the treatment of this severe event using endoclips and self-expandable stents. The choice to treat a perforation endoscopically is made on the basis of the cause, location, duration and severity of the perforation, patient's age and general health and, finally, on the endoscopist and surgeon's experience. Furthermore, endoscopic treatment allows shorter hospitalization, a negligible morbidity and mortality, prompt resumption of an oral diet and reduced costs.²⁴

Since 1993 several series of endoscopic closure using endoclips have been described in literature, involving the esophagus, stomach, duodenum-jejunum and colon-rectum.^{2–7} Conventional endoclips (metallic double-pronged clips introduced through the operative channel of the scope) are used for the management of bleeding and perforations. However, they have limitations, namely restricted opening distance between the jaws and low closure force, which hamper its use in the presence of scarred and hardened tissue or inflammatory mucosa. It is common experience that a high number of clips are necessary to treat gastrointestinal leaks. The use of self-expandable stents is effective for sealing and healing chronic gastrointestinal dehiscence. Yet, removal of partially covered stents may be difficult due to ingrowth at uncovered ends with the risk of mucosal tears, whereas fully covered stents show a migration rate up to 50% and often require replacement.²⁵ Although the success rate is satisfactory, healing can sometimes take months to occur, and many patients experience a slew of added morbidities while they wait: alkaline and acid reflux, epigastric pain, downright intolerance.

The choice of OTSC technique in the cases presented was based not only on the nature of the injury but also because of the unique characteristics of the clip itself. Indeed, this new approach has proved to be useful in similar situations, in which alternative options were lacking.^{11,12,15–17,26} Proper application of OTSC requires perfect coaptation with the injury and aspiration of tissues into the “cap” so that they can be captured on release of the clip. Alternatively, the tissues can be pulled using the devices handled through the working channel and marketed specifically for this purpose (OTSC *Twin Grasper*® or OTSC *Anchor*®). Made of highly elastic nitinol, biocompatible and easily delivered, this new device is remarkable and its full potential to help

endoscopists and surgeons get out of a jam and has yet to be realized. The success described in the closure of acute perforations is explained by the fact that margins of the defect are commonly flexible and elastic to allow approximation by simply sucking them in the cup or, in larger leaks, by grasping them, avoiding laceration.⁹ On the other hand, difficulties may arise in the treatment of chronic leaks, which are surrounded by hardened and inelastic tissues unfit to be approached. Indeed, Kirschniak¹⁵ and Albert²⁶ have reported that the success rate of OTSC is inversely proportional to the time from diagnosis of the clinical leakage to the application of the clip, ranging from 100% after 1 week to less than 60% with increasing time.

Our series demonstrates the capacities and limitations of OTSC system. Although OTSC application was technically successful in all patients, we experienced one patient with fistula recurrence within a few days (patient 4). However, when referred to our department, this patient had a chronic esophago-bronchial fistula, with two small holes identified in the middle esophagus. The attempt to place the OTS clip was hampered by the presence of fibrotic tissue, inelastic, and unfit to be sucked to the cup. Despite immediate clinical success with apparent fistula closure after the OTSC release (clip was present, but with no contrast leak), ten days after the patient presented with recurrent respiratory symptoms, no visualization of the clip and fistula maintenance. This long-term clinical failure is probably explainable by the small amount of tissue between the OTSC jaws, consequence of tissue fibrosis. In patient 5, while there was esophageal-pleural fistula, better margins traction was achieved allowing the correct release of the OTSC and consequent closure of fistula. Closure of the blind jejunal loop dehiscence was performed by a particular technique not yet described. Due to inability to directly access the fistulous orifice, we held circumferential aspiration of healthy tissue (without traction) located about 2 cm upstream of the orifice, with subsequent release of the OTSC.¹⁹ The aim of this approach was to create an endoscopic closure of the loop, using healthy tissue proximal to dehiscence and thereby excluding it from luminal contact. The possibility of complete luminal closure used deliberately in this case has been described as an adverse effect in two cases of a series published in 2012.¹⁸ In two other cases, success was achieved by releasing the clip on the surgical leak, with consequent clinical improvement and completely resolution of the wall defect. In the last patient OTSC placement was achieved in an iatrogenic perforation of the colon in the context of a mucosal resection, thus avoiding surgical approach. The five successfully treated patients had fast recovery and started oral ingestion with no further treatment.

In our series there were no immediate or late complications associated with OTSC placement, but is clear that there was a learning curve when using this device and associated accessories. Some severe adverse events are described in the literature, such as complete lumen closure secondary to clip misplacement.¹⁸ Other possible complications include mucosal damage caused by the teeth of the OTSC protruding out of the hood top during insertion. Therefore, special care should be taken when the OTSC is inserted into physiologically narrow sites, such as the esophageal entrance, pyloric or anal ring.²⁷

Although it has not been used so far in our center, OTSC has been described to be effective as hemostatic therapy. It may be of particular benefit in some cases of ulcer hemorrhage refractory to conventional therapy and in surgical anastomotic bleeding lesions.²⁷

In conclusion, OTSC can be useful in the management of gastrointestinal leaks. OTSC has several advantages over through-the-scope clips, allowing the closure of orifices of larger size using a single clip. The cost of this clip is not negligible, though earlier hospital discharge is expected when compared to surgery. Management of small iatrogenic or spontaneous GI perforations or leaks should involve multidisciplinary collaboration including surgeons and endoscopists. In our opinion, endoscopic treatment should be considered earlier in course of the disease, thus trying to prevent tissue fibrosis which hampers this approach.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data and that all the patients included in the study received sufficient information and gave their written informed consent to participate in the study.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

Conflicts of interest

The authors have no conflicts of interest to declare.

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