Closure of gastrointestinal defects with Ovesco clip: long-term results and clinical implications

Gianfranco Donatelli, Fabrizio Cereatti, Parag Dhumane, Bertrand Marie Vergeau, Thierry Tuszynski, Christian Marie, Jean-Loup Dumont and Bruno Meduri

Abstract

Background: The Over-The-Scope Clip (OTSC®, Ovesco Endoscopy GmbH, Tübingen, Germany) is an innovative clipping device that provides a strong tissue grasp and compression without provoking ischemia or laceration. In this retrospective study we evaluated immediate and long-term success rates of OTSC deployment in various pathologies of the gastrointestinal (GI) tract.

Methods: A total of 45 patients (35 female, 10 male) with an average age of 56 years old (range, 24–90 years) were treated with an OTSC for GI defects resulting from a diagnostic or interventional endoscopic procedure (acute setting group) or for fistula following abdominal surgery (chronic setting group). All procedures were performed with CO_2 insufflation. **Results:** From January 2012 to December 2015 a total of 51 OTSCs were delivered in 45 patients for different kinds of GI defects. Technical success was always achieved in the acute setting group with an excellent clip adherence and a clinical long-term success rate of 100% (15/15). Meanwhile, considering the chronic setting group, technical success was achieved in 50% of patients with a long-term clinical success of 37% (11/30); two minor complications occurred. A total of three patients died due to causes not directly related to clip deployment. Overall clinical success rate was achieved in 58% cases (26/45 patients). A mean follow-up period of 17 months was accomplished (range, 1–36 months).

Conclusion: OTSC deployment is an effective and minimally-invasive procedure for GI defects in acute settings. It avoids emergency surgical repair and it allows, in most cases, completion of the primary endoscopic procedure. OTSC should be incorporated as an essential technique of today's modern endoscopic armamentarium in the management of GI defects in acute settings. OTSCs were less effective in cases of chronic defects.

Keywords: ERCP, EUS, GI fistula, GI leak, GI perforation, OTSC, Ovesco clip

Introduction

Standard endoclips were introduced in the 1980s and have been successfully used to treat bleeding, GI tract perforation, leak and fistula closure [Raju and Gajula, 2004]. However, they are less efficient for closure of GI perforations larger than 10 mm due to the limited size of the jaws and insufficient grasping force [Jovanovic *et al.* 2011; Weiland *et al.* 2013]. The advent of Natural Orifice Transluminal Endoscopic Surgery [Kalloo *et al.* 2004] highlighted the limitations of standard endoclips in full thickness closure of GI tract defects. However, clips may in some cases induce mucosal approximation with subsequent full thickness transmural healing [Dray *et al.* 2010].

Recently, new devices have been introduced to reach watertight closure [Pinho et al. 2015].

The Over-The-Scope Clip (OTSC®, Ovesco Endoscopy GmbH, Tübingen, Germany) is an innovative clipping device that provides a strong

Original Research

Ther Adv Gastroenterol

2016, Vol. 9(5) 713-721 DOI: 10.1177/

1756283X16652325



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Parag Dhumane, MD Department of General and Laparoscopic Surgery, Lilavati Hospital and Research Center, Bandra (w), Mumbai, India tissue grasp and compression without inducing ischemia or laceration.

The OTSC has been widely used for closure of gastrointestinal iatrogenic defects, visceral perforation and bleeding. Once applied, the OTSC remains attached to the mucosa and its removal requires cumbersome procedures with ND-YAG laser, argon plasma coagulation or dedicated devices [Schmidt et al. 2014]. However, like other types of endoscopic clips, OTSCs sometimes may fall off with reappearance of symptoms. Several studies have been published evaluating the effectiveness of OTSCs in managing bleeding, GI perforation, fistula and leak both in acute settings and as a rescue therapy [Wedi et al. 2016; Sulz et al. 2014]. Review of current literature showed an immediate success rate varying from 57-100% and a low complication rate [Haito-Chavez et al. 2014; Keren et al. 2015; Manno et al. 2015; Fischer and Richter-Schrag, 2015; Rahmi et al. 2015; Baron et al. 2012].

In this retrospective study we evaluated immediate (technical and clinical) and long-term success rates of OTSC deployment. All procedures were carried out in a private endoscopic service.

Materials and methods

Since 2012, OTSC has been integrated in the endoscopic arsenal of our endoscopic unit. Its use is considered in cases of bleeding, GI leak, fistula and GI perforation. Data were collected in a prospectively-maintained database. We retrospectively reviewed and analyzed all our consecutive cases of OTSC deployment. From January 2012 to December 2015 a total of 45 patients (36 females and 10 males) with an average age of 56 years old (range, 24-90) were treated with t-type OTSC (pointed teeth) for perforation resulting from diagnostic or interventional endoscopic procedure and for leak/fistula following abdominal surgery. All patients with a defect up to 20 mm in diameter were included in the study. Perforations larger than 20 mm were excluded because OTSC deployment was not considered the appropriate treatment. Informed consent, including need for multiple endoscopic sessions, was obtained from all patients. The study was approved by the Institutional Review Board for Human Research.

The following procedural data were collected: location and size of the defect (<10 mm, 10-20 mm, >20 mm), type of clip, type of endoscope

used, delay from the first surgical/endoscopic procedure (days), previous radiological or surgical drainage, immediate/short-term and longterm outcomes and complications rate. Patients were clinically followed up *via* their attending physician or primary caregiver. If radiological investigations were performed during follow up, clip indwelling time was evaluated. However, no radiological exams were specifically planned to assess overall clip indwelling time.

A total of 15 patients (acute setting group) underwent OTSC deployment for the treatment of: 4 colonic perforations occurred during diagnostic colonoscopy, 8 duodenal perforations (7 during biliopancreatic endoscopic ultrasonography and 1 during endoscopic retrograde cholangio pancreatography [ERCP]), 2 gastric perforations during endoscopic submucosal dissection (ESD) and 1 rectal perforation during endoscopic mucosal resection (EMR).

In 30 patients OTSC was used as a rescue therapy (chronic setting group) for postsurgical fistula. We treated 1 duodenal fistula following biliopancreatic surgery, 25 leaks following bariatric surgery (22 sleeve gastrectomy, 3 gastric bypass), 1 colocolic anastomotic dehiscence after low rectal anterior resection, 2 duodenal stump fistulas following Billroth II reconstruction and 1 persistent gastrocutaneous fistula following percutaneous endoscopic gastrostomy (PEG) tube removal. Features of the study population are listed in Table 1.

In the chronic setting group argon plasma coagulation (APC) was used prior to OTSC deployment in order to ablate mucosal edges and surrounding areas. A cytology brush was then used to scrape the fistula opening with the aim to increase the grasp of the clip on the tissue [Willingham and Buscaglia, 2015]. All OTSCS were applied by suction technique [Donatelli et al. 2013]. After defect visualization the cap was gently applied on the edges of the defect and a constant soft suction was applied to suck in the edges. The OTSC was applied over sucked-in mucosa to achieve watertight closure. Whenever possible a small amount of omentum was sucked inside the GI wall defect in order to achieve epiploplasty (Figure 1). We chose a cap (16.5 mm, 17 mm or 21 mm) slightly bigger than the defect in order to easily suck in all edges.

All procedures were carried out under general anesthesia and antibiotics were administered. All

	Patients (<i>n</i>)	Ratio female (F)/male (M)	Median age (years)	Technical success rate	Clinical success rate
Acute setting group	15	12F/3M	71.5	100%	100%
Chronic setting group	30	23F/7M	46.5	50%	36.6%
Total	45	35F/10M	54.9	75%	58%

Table 1. Study population.



Figure 1. a: latrogenic sigmoid colon perforation with visualization of perivisceral fat through the defect. b: Watertight closure by OTSC epiploplasty. OTSC, Over-The-Scope Clip.

procedures were performed under fluoroscopic guidance with CO_2 insufflation. In the acute setting group, air insufflation was switched to CO_2 insufflation as soon as a perforation was recognized. Patients were kept nil by mouth for the first 24 hours. Oral diet was restarted as early as possible according to patient's clinical condition after an average of 3 days (range, 1–7 days)

Definitions

The acute setting group included subjects in whom OTSC was deployed due to perforation following diagnostic or therapeutic endoscopic procedures. Perforation was defined as an unintentional acute iatrogenic full-thickness defect in the GI tract.

The chronic setting group included patients in whom OTSC was deployed for fistula or leaks following GI surgery. Anastomotic leak was defined as disruption at surgical anastomosis or staple line resulting in fluid collection with or without evidence of extravasation of medium contrast medium on radiological evaluation. Clinical success was defined as persistent closure of the GI defect after full oral diet resumption (no peritonitis, no sepsis, no spillage of enteral liquid in the surgical drain). Technical success was defined as successful deployment of OTSC, confirmed endoscopically by correct clip adherence to the mucosa and radiologically showing no medium contrast extravasation from the GI defect. Immediate clinical success was defined as improvement of overall clinical condition or cessation of drain output. Overall long-term clinical success was defined as complete resolution of the GI defect after a minimum follow up of 2 weeks.

Results

A total of 51 OTSCs were delivered in 45 patients for various types of GI defects. All clips were the sharp teeth 'traumatic' t-type model. Different defect sizes were treated: 29 patients presented a defect <10 mm, 15 patients had a defect between 10-20 mm and 1 subject presented a defect >20 mm (this last patient needed 2 OTSCs to achieve closure with epiploplasty) [Donatelli *et al.* 2014].

The choice of clip size and type of endoscope used was at the endoscopists discretion (G.D., J-L.D., T.T., B.M.V., B.M.) as per the size and location of the defect.

A total of 38 OTSCs size 11/6t were deployed with a standard gastroscope, 9 OTSCs size 12/6t were deployed with a pediatric colonoscope, meanwhile in 4 patients the biggest size 14/6t clip was deployed with a standard colonoscope.



Figure 2. a: Large duodenal defect. b: OTSC in place achieving watertight closure of the defect. c: No contrast extravasation confirms watertight closure. OTSC, Over-The-Scope Clip.

Out of 51 OTSCs, 45 clips were deployed in the upper GI (36 of 11/6t, 7 of 12/6t and 2 of 14/6t), while 6 OTSCs were used in the lower GI tract (2 of 11/6t, 2 of 12/6t and 2 of 14/6t).

A 14/6t clip was delivered in the upper GI for a gastro-gastric fistula following gastric by-pass. Another one was deployed for a large duodenal defect following ERCP.

The acute setting group consisted of 15 patients who underwent OTSC deployment due to endoscopic-induced GI perforation (5, colon-rectum; 8, duodenum; 2, stomach). A total of 16 clips were delivered in 15 patients.

Technical, short term and long-term success rate was 100% with a median follow up of 9 months (range, 1–24 months).

Successful deployment and watertight closure of the defect was demonstrated by contrast medium injection. Recently occurred perforations (less than 3 hours) allowed an easy and complete suction of the mucosal edges with a subsequent optimal tissue grasp. Moreover, appendices epiploicae or omentum were always enclosed in the clip achieving a safe epiploplasty. In 14 out of 15 patients, treatment was carried out during the same endoscopic session as soon as perforation was recognized (Figure 2). In one patient with a colonic perforation, treatment was delayed by few hours after that the surgical team decided to perform an endoscopic procedure instead of a surgical procedure due to poor patient general status. All patients were kept nil by mouth for a minimum of 24 hours to a maximum of 7 days (average 3 days). Broad

spectrum antibiotics (ceftriaxone and metronidazole) were administered. All patients showed a transient rise in C-reactive protein (CRP) and hyperleukocytosis. Normalization of CRP and leukocytosis occurred within an average of 3 days (range, 2–8 days) without any signs of peritonitis. Abdominal computerized tomography (CT) scan was performed in 5/15 patients due to a prolonged rise of CRP and hyperleukocytosis. All CT scans showed a moderate amount of intra-abdominal free air without any fluid collection or extravasation of contrast medium.

After OTSC insertion, deployment of endoscopic ultrasonography (EUS)/endoscopic procedures were continued in four patients (three pancreatic EUSs with fine needle aspiration coupled by endoscopic biliary drainage and one biliary stone extraction) [Meduri *et al.* 2014]. In one patient with a partial duodenal stricture the ERCP and biliary drainage was postponed by 48 hours to reduce the risk of clip dislodgment. In three patients OTSC was successfully deployed after the end of endoscopic resection namely two gastric ESDs and one rectal EMR.

All four colonic perforations were located in the sigmoid colon (2/4 had diverticular disease). In all cases the diagnostic procedure was interrupted after clip deployment and the colon was subsequently evaluated by means of CT colonoscopy or capsule endoscopy.

In one patient deployment of two OTSCs (11/6t and 14/6t) was needed for a large duodenal wall defect. The features and results of the acute setting group are listed in Table 2.

Table 2. Features of acute setting group.

Patients (<i>n</i>)	15		
Location of defect	Upper GI: 10	Lower GI: 5	
Procedure responsible for perforation	1 ERCP 7 EUS 2 gastric ESD	4 diagnostic colonoscopy 1 rectal EMR	

EMR, endoscopic mucosal resection; ERCP, endoscopic retrograde cholangio pancreatography; ESD, endoscopic submucosal dissection; EUS, endoscopic ultrasonography; GI, gastrointestinal.



Figure 3. a: Leak following sleeve gastrectomy. A surgically placed drainage tube is visible through the defect. b: Water-tight closure of defect after OTSC (t-type 12/6) deployment.

c: Fluoroscopy confirmed water-tight closure of the defect.

d: endoscopic follow up showing OTSC migration and leak persistence.

OTSC, Over-The-Scope Clip.

The chronic setting group comprised 30 patients treated for fistula following GI surgery with the deployment of 35 OTSCs (Figure 3). OTSCs were delivered after an average period of 146.6 days (range, 5–880 days) after primary surgery. Due to a long standing fistula a thick-ened scar tissue was present and therefore a suboptimal clip grasp was achieved. The technical and clinical success rate was 50% (15/30).

In the 15 patients in whom successful OTSC deployment was achieved, clip grasp on the tissue was judged to be mediocre. Whereas in the subset of patients (15/30) in whom the OTSC failed to achieve a watertight closure clip grasp on the tissue was intraprocedurally judged to be poor. All these subjects needed further endoscopic or surgical treatment for definite fistula closure.

Among the 15 patients in whom technical success was achieved, 11 (73.3%) achieved longterm clinical success with a mean follow up of 23 months (range, 1-34 months). A total of 6 out of 11 successfully-treated patients had a prior endoscopic internal drainage (EID) with double pigtail plastic stents for an average of 60 days that allowed reduction of leak orifice size [Donatelli et al. 2015]. A total of 4 out of 15 patients with technical success presented with OTSC migration and fistula reappearance after an average of 110 days (range, 30-270 days) (Figure 4). Thus overall OTSC clinical success in the chronic setting group was achieved in 11/30 (36.6%) patients. Meanwhile 19 out of 30 patients needed further treatment. A total of seven patients underwent a surgical procedure, nine were cured by EID and three died from underlying pathologies (ovarian cancer, gastric cancer and massive bleeding from splenic artery pseudo-aneurysm due to pre-existing chronic inflammation) (Table 3).



Figure 4. Inflammatory cascade threw off OTSC before adequate tissue healing was achieved. OTSC, Over-The-Scope Clip.

A total of two complications were reported in the chronic setting group. It was found that one patient who had a leak following sleeve gastrectomy, closed by means of an OTSC, developed a stricture at the level of the gastroesophageal junction after 30 days. The stricture was successfully treated by placement of a fully-covered metallic stent. The stent was kept in place for 4 weeks. The other patient presented with OTSC migration across the fistula orifice after 19 days. A follow up CT scan at 395 days showed OTSC persistence in the same intra-abdominal location with no further complaints.

Overall (acute setting group and chronic setting group) the OTSC clinical success rate was 58% (26 out of 45 patients) with a median follow up of 17 months (range, 1–36 months).

A maximum indwelling time of 395 days was reported in our series

Discussion

An OTSC is a clip installed on the tip of the endoscope (similar to band ligation devices) that is released by pulling a wire passing through the working channel. It allows a higher mechanical tissue compression [Kirschniak *et al.* 2007]. OTSCs have been successfully used for multiple purposes such as acute GI bleeding control, iatrogenic GI perforation or leak and fistula closure and self-expandable metal stent anchoring to reduce migration rate [Mudumbi *et al.* 2014]. Furthermore OTSCs have been proposed to achieve complete exclusion of pylorus, to reduce the volume of gastric pouch or to tighten gastrojejunal anastomoses following weight regain in obesity surgery [Pinho *et al.* 2015; Heylen *et al.* 2011].

Just like other types of clips [Shin *et al.* 2007] OTSCs tend to fall off after a certain period of

Patients (<i>n</i>)	30				
	Upper GI: 29	Lower GI: 1			
Location	2 partial gastrectomy (duodenal stump) 25 bariatric surgery (22 SG and 3 RYGB) 1 remnant fistula after PEG removal 1 bilio-pancreatic surgery (duodenum)	1 low RAR leak			
GI, gastrointestinal; PE bypass; SG, sleeve gast	G, percutaneous endoscopic gastrostomy; RAR, rectal anterior rese rectomy.	ction; RYGB, roux en y gastric			

 Table 3. Features of chronic setting group.

time; such a timespan is usually sufficient to cure pathologies like bleeding and acute GI perforation; however it might not be adequate for chronic pathologies like fistula or GI leaks. In chronic settings, and when scar tissue is already present, if an OTSC falls off, symptomatology might reappear. Different studies have reported an overall success rate ranging from 57-100%. Maximum follow-up periods in literature are 23 months for an acute perforation [Weiland et al. 2013], 12 months for a leak or fistula [Keren et al. 2015] and 1 month in case of bleeding [Manno et al. 2015]. However, a correlation between quality of clip grasp and clinical outcome has not vet been reported. Our experience showed that in cases of acute perforation, immediate repair within 3 hours achieves an optimal tissue grasp leading to efficient and long-lasting closure of the defect. This is mainly related to soft mucosal defect edges and absence of loco-regional sepsis. Consequently, by the time an OTSC falls off, the GI defect is already sealed and completely healed. Moreover, in most cases the primary endoscopic procedure can be completed after the application of the clip. In our study we achieved 100% clinical success rate in the acute setting group. In our experience, differently from other studies, simple and careful suction of mucosal edges is appropriate to successfully deploy the OTSC. In literature, erroneous suction and entrapment of small intestine after OTSC deployment has been described [Loske et al. 2016].

To avoid such complications, the cap of the OTSC has to be adherent to the edges of the defect. In this way, when applying a soft suction only a small amount of perivisceral fat will be enclosed inside the clip. Furthermore, it is advisable to rehearse suction maneuver before definite OTSC deployment in order to evaluate the amount and content of tissue entrapment.

In the chronic setting group, a significantly lower success rate was achieved. The following factors might lead to poor OTSC results for fistula after GI surgery: presence of thickened and fibrotic mucosal edges, surrounding scar tissue, and inflammation. These factors, which are typical of chronic defects, reduce the clip's ability to enclose the right amount of tissue. Most often, this leads to either a 'medium' or a 'low' quality clip grasp.

Unlike other studies, we always chose an endoscopic cap bigger than the defect. Such an approach allows placement of the cap adherent to the mucosal edges circumferentially thus avoiding enclosing too much tissue. We never used any endoscopic grasping forceps. In our experience, such grasping devices are of limited utility for approximating thickened and edematous edges of GI defects. In our opinion, the suction technique allows a better approximation of the edges and to enclose epiploic fat or omentum inside the clip. Moreover, this method gives the endoscopist a good view of the suppleness of the tissue. One additional shortcoming related to traction devices is the consequent hampered flexibility of the endoscope and reduced suction force applied at the cap [Zhang *et al.* 2012].

We observed that the long indwelling time of OTSCs reflects their correct deployment over suitable tissue and ultimately translates into an higher clinical success rate; whereas an early sloughing off of the OTSC reflects the presence of tissue not suitable for OTSC deployment resulting in the leak or fistula reappearance.

Systematic analysis of the impact of timing of OTSC deployment (before or after 3 hrs) in GI defects and its clinical success rate has never been reported before. We believe the timing of intervention for closure of the GI defect is one of the best predictors for clinical success.

The success rate in the chronic setting group (36.6%) was significantly lower compared with the success rate in the acute setting group (100%). These data clearly suggest OTSCs are less effective for long-standing GI defects. Prompt availability of OTSCs in the endoscopic armamentarium should be an asset as it may prevent the patient to undergo a major surgical procedure.

OTSCs should be incorporated as an essential component of today's endoscopic arsenal for management of GI defects in acute settings. In acute settings OTSC deployment is an effective minimally-invasive endoscopic procedure that may obviate emergency surgery.

OTSCs have relatively low rates of complications and in most cases allow successful completion of the primary endoscopic procedure. Moreover, they do not interfere with the future surgical procedure, if needed. In chronic settings OTSC deployment is less effective and prolonged treatment with additional endoscopic or surgical procedures is often required. In chronic settings OTSCs may induce, in some cases, a durable closure; however, we recommend their use only in selected cases after a careful evaluation.

Acknowledgements

Gianfranco Donatelli performed endoscopic procedures, analyzed data and wrote the paper; Parag Dhumane and Fabrizio Cereatti analyzed data and performed critical revision of the manuscript for important intellectual contents and made the final manuscript; Jean-Loup Dumont, Thierry Tuszynski, Christian Marie, Bertrand Marie Vergeau and Bruno Meduri performed endoscopic procedures.

Funding

This research received no specific grant from any funding agency in the public, commercial, or notfor-profit sectors.

Conflict of interest statement

Dr Donatelli is a consultant for Boston Scientific. The other authors declare no conflict of interest.

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