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# **Over-the-scope clip (OTSC) represents an effective endoscopic treatment for acute GI bleeding after failure of conventional techniques**

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# Abstract

## Background

Through-the-scope clips are commonly used for endoscopic hemostasis of gastrointestinal (GI) bleeding, but their efficacy can be suboptimal in patients with complex bleeding lesions. The over-the-scope clip (OTSC) could overcome the limitations of through-the-scope clips by allowing compression of larger amounts of tissue, allowing a more efficient hemostasis. We analyzed the use of OTSC in a consecutive case series of patients with acute GI bleeding unresponsive to conventional endoscopic treatment modalities.

## Methods

In a retrospective analysis of prospectively collected data in tertiary referral centers, patients undergoing emergency endoscopy for severe acute nonvariceal GI bleeding were treated with the OTSC after failure of conventional techniques. All patients underwent repeat endoscopy 2–4 days after the procedure. Data analysis included primary hemostasis, complications, and 1-month follow-up clinical outcome.

## Results

During a 10-month period, 30 patients entered the study consecutively. Bleeding lesions unresponsive to conventional endoscopic treatment (saline/adrenaline injection and through-the-scope clipping) were located in the upper and lower GI tract in 23 and 7 cases, respectively. Primary hemostasis was achieved in 29 of 30 cases (97 %). One patient with bleeding from duodenal bulb ulcer required emergent selective radiological embolization. Rebleeding occurred in two patients 12 and 24 h after the procedure; they were successfully treated with conventional saline/adrenaline endoscopic injection.

## Conclusions

OTSC is an effective and safe therapeutic option for severe acute GI bleeding when conventional endoscopic treatment modalities fail.

# Keywords

Gastrointestinal bleeding Hemostasis Over-the-scope clip

Peptic ulcers are still the most frequent cause of acute upper gastrointestinal (GI) bleeding [1]. Endoscopic interventions such as injection therapy, thermal coagulation and clip application have been shown to decrease mortality rate and the need for surgery and blood transfusions, therefore representing the first-line therapy for acute upper nonvariceal GI bleeding. Acute nonvariceal GI bleeding frequently occurs in daily clinical practice. Although several improvements concerning clip devices have been introduced, including the routable clip, the possibility of reopening the branches and the single-shot systems [2, 3], sometimes complete hemostasis of complicated lesions (such as severe bleeding from large vessels and ulcers of the posterior wall of the duodenal bulb) can be difficult to achieve. In fact, the massive bleeding may impair endoscopic visibility and traditional clipping devices often appear insufficient to provide adequate tissue compression to obliterate large bleeding vessels [4, 5].

The over-the-scope clip (OTSC) (Ovesco Endoscopy AG, Tubingen, Germany) system is a recently developed endoscopic device. In a preliminary experience, it has been successfully used in patients with severe bleeding or deep wall lesions, or perforations of the GI tract [6]. Such encouraging results have been confirmed in case series concerning patients with GI bleeding or leaks [7-11].

However, the main question is whether the OTSC is useful in patients with acute nonvariceal GI bleeding after failure of conventional endoscopic treatment modalities. Given the high efficacy of the latter, we felt that only a review of data from high-volume endoscopy units can tentatively address this question. Here we report a retrospective analysis of prospectively collected data in 6 high-volume endoscopy units concerning patients with acute nonvariceal GI bleeding unresponsive to conventional endoscopic techniques.

# **Patients and methods**

Data were prospectively collected from six high-volume endoscopy units. Data from all patients undergoing emergency endoscopy for acute severe nonvariceal GI bleeding in the period between December 2011 and September 2012 and in whom OTSC treatment was employed after failure of conventional endoscopic treatment modalities were reviewed. Conventional endoscopic treatment modalities consisted of through-the-scope clipping and/or saline/adrenaline injection.

All endoscopic procedures were carried out in deep sedation with anesthesiologist support by skilled endoscopists. Use of the traumatic clip with sharp teeth or of the nontraumatic version with blunt teeth of the OTSC device was at the discretion of the treating endoscopist.

All patients underwent repeat endoscopy after 2–4 days and were followed up for 1 month after the procedure.

# Results

Data from 30 consecutive patients (14 men, 16 women; mean age, 64 years; range, 16–94 years) treated with the OTSC device between December 2011 and September 2012 for severe acute upper (23 cases) or lower (7 cases) GI bleeding unresponsive to conventional endoscopic treatment modalities were retrospectively analyzed. During the study period, 1,418 and 722 endoscopic procedures for acute upper and lower GI bleeding, respectively, were performed in the six

endoscopy units participating in the study, procedures with OTSC usage representing 1.4 % of the total. The nontraumatic and traumatic OTSC devices were used in 14 and 16 cases, respectively, with traumatic clips being favored for lesions with edematous tissue. Indications for OTSC placement and main results are reported in Table <u>1</u>. Table 1

Indications for OTSC placement and main results

GI tract	t Bleeding lesion	n	No. OTSC, N/	Г Primary hemostasis, <i>i</i>	n Rebleeding, n
Upper	Duodenal ulcer	$12^{a}$	<sup>a</sup> 3/9	11	1
	Gastric ulcer	6 <sup>b</sup>	2/4	6	1
	Mallory-Weiss	2	2/0	2	0
	Dieulafoy	2	2/0	2	0
	Surgical anastomosis	1	1/0	1	0
Lower	EMR	5	3/2	5	0
	ESD	1	0/1	1	0
	Colonic diverticulum	1	1/0	1	0

OTSC over-the-scope clip, GI gastrointestinal, N nontraumatic, T traumatic, EMR endoscopic mucosal resection, ESD endoscopic submucosal dissection

<sup>a</sup>Forrest 1a = 5; Forrest 1b = 4

<sup>b</sup>Forrest 1a = 2; Forrest 1b = 2

Primary hemostasis with OTSC was achieved in 27 of 28 (96 %) cases. In one patient with a posterior duodenal wall ulcer emergency selective radiological embolization was required to stop bleeding after failure of the OTSC procedure. Rebleeding was observed in two cases (one duodenal bulb and one gastric ulcer), respectively, at 12 and 24 h after the OTSC procedure; both cases were successfully treated with endoscopic injection of saline and adrenaline within the tissue surrounding the lesion.

No complications caused by the clip or the applicator system were registered. Repeat endoscopy was carried out in all patients 2–4 days after the procedure: the clips were still in place in all cases. The patients experienced no symptoms from excreting the clip during follow-up. No late procedure-related complications were registered during the 1-month follow-up.

# Discussion

The OTSC represents a new endoscopic device reportedly useful for endoscopic closure of leaks and treatment of bleeding lesions in the GI tract [6-11]. The mechanism of action of clipping devices is through the compression of the vessels by grasping the surrounding tissue [2]. The main problem of through-the-scope clipping is related to the relatively small size of the clips, in turn limited by the diameter of the working channel, allowing compression of limited amounts of tissue. Accordingly, the hemostatic effect may not be sufficient for large-size vessels. Moreover, there is often the need to apply more than one clip to achieve an effective hemostasis. The main advantage of the traditional clipping method is the facility to reload the system without removing the endoscope; conversely, reloading of the OTSC system needs removal of the instrument. However, the larger diameter of the OTSC device, differently from through-the-scope clips, allows circumferential compression of tissue surrounding the vessel without direct trauma.

Thus far, in the largest reported series use of the OTSC device proved effective as initial treatment in 27 patients with GI bleeding with a primary success rate of 100 % and recurrence in 1 case only [9]. Our results are quite close to those reported by Kirschniak et al. [9], with the remarkable difference that our series consisted of patients with severe acute GI bleeding unresponsive to conventional endoscopic treatment modalities. All interventions were successfully carried out without complications caused by the clips or the application system, and a primary hemostatic effect was successfully achieved in 97 % of cases. In two peptic ulcers cases, rebleeding occurred soon after the OTSC procedure: both patients were successfully treated by conventional endoscopic means (local injection of saline/adrenaline) and we speculate that OTSC failure could have been due to the presence of callous tissue in the borders of the ulcers hampering effective compression.

In the present report, data have been retrospectively collected by experienced endoscopists at highvolume endoscopy units. It could be argued that use of the OTSC device requires particular skills by the endoscopist. However, application of the OTSC is quite similar to variceal band ligation, suggesting a short learning curve for endoscopists already familiar with this technique.

In conclusion, OTSC is an effective and safe endoscopic tool for treatment of patients with severe acute upper and lower GI bleeding unresponsive to conventional treatment modalities and represents a useful adjunct to the therapeutic armamentarium during endoscopic emergencies.

### Disclosures

Raffaele Manta, Giuseppe Galloro, Benedetto Mangiavillano, Luigi Pasquale, Alberto Arezzo, Rita Conigliaro, Enzo Masci, Gabrio Bassotti, and Marzio Frazzoni have no conflicts of interest or financial ties to disclose.

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