

First-line endoscopic treatment with OTSC in patients with high-risk non-variceal upper gastrointestinal bleeding: preliminary experience in 40 cases

Mauro Manno¹ · Santi Mangiafico¹ · Angelo Caruso² · Carmelo Barbera¹ · Helga Bertani² · Vincenzo G. Mirante² · Flavia Pigo¹ · Khanna Amardeep³ · Rita Conigliaro²

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Abstract

Background and study aims The over-the-scope clip (OTSC; Ovesco, Tübingen, Germany) is a novel endoscopic clipping device designed for tissue approximation. The device has been used in the closure of fistulas and perforations. We hereby report a series of patients with high-risk non-variceal upper gastrointestinal bleeding (NVUGIB) lesions in whom OTSCs were used as first-line endoscopic treatment.

Patients and methods We prospectively collected and retrospectively analysed data over a period of 12 months from October 2013 to November 2014 from all consecutive patients who underwent emergency endoscopy for acute severe high-risk NVUGIB and were treated with OTSC as primary first-line therapy.

Results We included forty consecutive patients with mean age 69 years (range 25–94 years). All patients were treated with the non-traumatic version of the OTSC system (23 with the 11 mm version and 17 with the 12 mm version). Indications for OTSC treatment included gastric ulcer with large vessel (Forrest IIa) ($n = 8$, 20 %), duodenal ulcer (Forrest Ib) ($n = 7$, 18 %), duodenal ulcer with large vessel (Forrest IIa) ($n = 6$, 15 %), Dieulafoy's lesion

($n = 6$, 15 %) and other secondary indications ($n = 13$, 32 %). Technical success and primary haemostasis were achieved in all patients (100 %). No re-bleeding, need for surgical or radiological embolization treatment or other complications were observed during the follow-up period of 30 days.

Conclusions We conclude OTSC placement as a first-line endoscopic treatment seems to be effective, safe and easy to perform and should be considered in patients with high-risk NVUGIB lesions.

Keywords Non-variceal gastrointestinal bleeding · Ulcers peptic and other · Over-the-scope clip · Endoscopy upper GI tract

Despite major advances in the management of non-variceal upper gastrointestinal bleeding (NVUGIB) over the past decade including prevention of peptic ulcer bleeding, optimal use of endoscopic therapy and high-dose proton pump inhibition, this still carries considerable morbidity, mortality and health economic burden [1]. Of particular note are the re-bleeding rates, one of the most crucial predictive factors of morbidity and mortality that has not significantly improved as evident from longitudinal data in the past 15 years [2, 3]. Although huge advances have been made in terms of therapeutic endoscopic devices available today, complete haemostasis of complicated lesions (i.e. severe bleeding from large vessels or fibrotic ulcer) still remains a challenge and can be difficult to achieve. In particular, traditional clipping devices often appear technically difficult to place and 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

✉ Mauro Manno
mauromanno@gmail.com; m.manno@ausl.mo.it

¹ Digestive Endoscopy Unit-Northern Area, Ospedale di Carpi, Azienda USL di Modena, Via G. Molinari, 2, 41012 Carpi, Italy

² Gastroenterology and Digestive Endoscopy Unit, Nuovo Ospedale Civile S. Agostino-Estense, Baggiovara di Modena, MO, Italy

³ Gastroenterology and Digestive Endoscopy Unit, Queens Medical Centre, Derby Road, Nottingham, UK

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]. A recent study has demonstrated the efficacy and safety of OTSC in patients undergoing emergency endoscopy for severe acute NVUGIB after failure of conventional techniques [7]. To the best of our knowledge, no studies have been performed investigating the use of OTSC as first-line endoscopic treatment in patients with high-risk NVUGIB. We, hereby, report a retrospective analysis of prospectively collected data in patients with high-risk NVUGIB treated with OTSC as first-line endoscopic treatment based at a high-volume endoscopy unit.

Patients and methods

We prospectively collected data over a period of 12 months between October 2013 and November 2014 from all consecutive patients who underwent emergency endoscopy for acute severe NVUGIB treated with OTSC as primary therapy. Data were entered into a dedicated structured database and retrospectively analysed (Fig. 1).

All endoscopic procedures were carried out in an inpatient setting, under deep sedation with anesthesiologist support, and performed by highly skilled endoscopists. Lesions deemed as high risk for re-bleeding were treated with the non-traumatic OTSC as first-line endoscopic treatment. Lesions were defined at high risk for re-bleeding if at least one of the following characteristics were present: Dieulafoy's lesions; gastric or duodenal ulcers classed as Forrest Ia, Ib and IIa with large vessel; and ulcers larger than 2 cm and/or with fibrous component and/or located in

critical areas (i.e. angular incisura and posterior wall of the duodenal bulb).

Data on re-bleeding; need for surgical or radiological embolization intervention; and complications and death within 30 days from the endoscopic procedure were also recorded on the database (Fig. 2).

Results

During the study period, 40 consecutive patients (33 males and 7 females with a mean age of 69 year (range 25–94 years) with severe acute NVUGIB were treated with OTSC as first-line endoscopic treatment. Data were prospectively collected into a structured database and retrospectively analysed. The demographic and clinical characteristics of the patients are presented in Table 1. All patients were treated with the non-traumatic version of the OTSC system (23 with the 11 mm version and 17 with the 12 mm version).

Indications for OTSC treatment included gastric ulcer with large vessel (Forrest IIa) ($n = 8$, 20 %), duodenal ulcer (Forrest Ib) ($n = 7$, 18 %), duodenal ulcer with large vessel (Forrest IIa) ($n = 6$, 15 %), Dieulafoy's lesion ($n = 6$, 15 %) and other secondary indications ($n = 13$, 32 %). Sixteen (40 %) patients had gastric or duodenal ulcer >20 mm (20–29 mm: $n = 10$, 25 %; >30 mm: $n = 6$, 15 %) (Table 1).

Technical success and primary haemostasis were achieved in all patients (100 %). None of patients were reported to have re-bleeding or required surgical or radiological embolization treatment. No other complications were observed during the 30-day follow-up period.

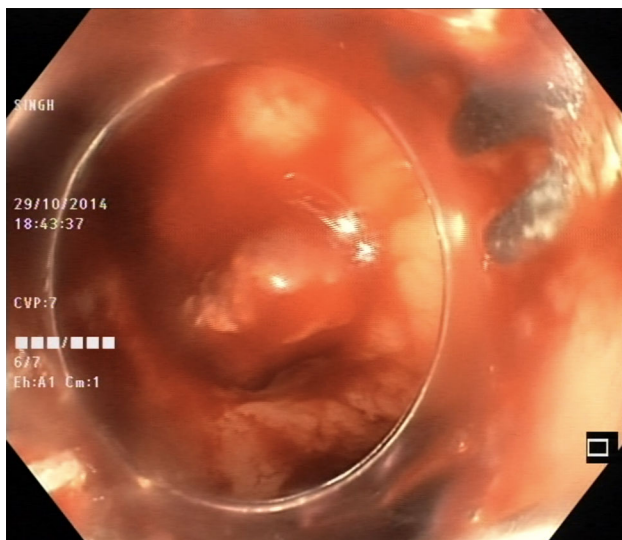


Fig. 1 Duodenal ulcer with large vessel

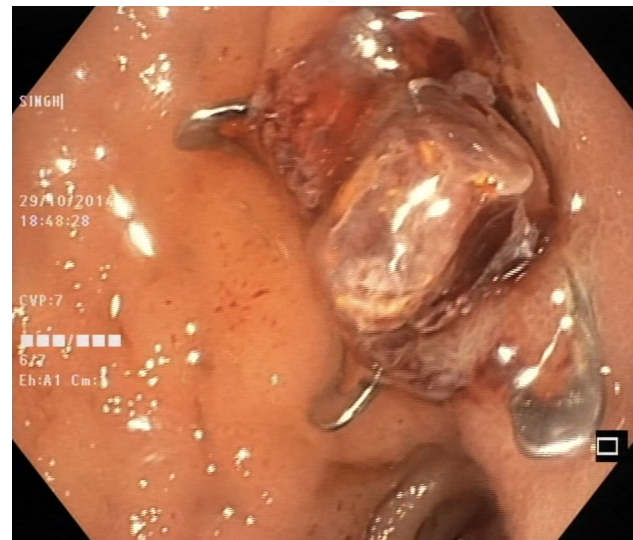


Fig. 2 Duodenal ulcer with large vessel after the OTSC treatment

Table 1 Demographic and clinical characteristics of the study population

<i>n</i>	40
Median age (years)	69 (25–64)
M/F	33/7
ASA score	
I	13 (32.5 %)
II	13 (32.5 %)
III	10 (25 %)
IV	4 (10 %)
Type of lesions	
Gastric ulcer Forrest IIa	8 (20 %)
Duodenal ulcer Forrest Ib	7 (17.5 %)
Duodenal ulcer Forrest IIa	6 (15 %)
Dieulafoy's lesion	6 (15 %)
Gastric ulcer Forrest Ib	5 (12.5 %)
Gastro-jejunal anastomotic lesion	3 (7.5 %)
Gastric ulcer Forrest Ia	2 (5 %)
Mallory Weiss	2 (5 %)
Duodenal ulcer Forrest Ia	1 (2.5 %)
Localization of the lesions	
Gastric antrum	14 (35 %)
Duodenal bulb-posterior wall	10 (25 %)
Duodenal bulb-anterior wall	5 (12.5 %)
Duodenal bulb-superior wall	4 (10 %)
Gastric fundus	3 (7.5 %)
Distal oesophagus	3 (7.5 %)
Gastric body	1 (2.5 %)
Size of the lesions	
<10 mm	9 (22.5 %)
10–19 mm	14 (35 %)
20–29 mm	10 (25 %)
>30 mm	7 (17.5 %)
Version of the OTSC	
Non-traumatic 11 mm	23 (57.5 %)
Non-traumatic 12 mm	17 (42.5 %)

Three patients (7 %) died during the hospitalization for causes not related to bleeding. All these patients were ASA IV, and they died of complications related to pre-existing severe comorbidities (one died of advanced colonic cancer, one died of severe sepsis and one died of stroke). No complications related to the OTSC treatment were registered during the follow-up period.

Discussion

Our study shows the effectiveness of the OTSC as first-line endoscopic treatment in patients with high-risk non-variceal upper gastrointestinal bleeding. Currently, the gold

standard for the management of NVUGIB is mechanical therapy with hemoclips and thermal therapy, alone or in combination with injection therapy. Several studies and a recent meta-analysis have demonstrated the inferiority of adrenaline injection therapy compared to other endoscopic haemostatic treatment in terms of re-bleeding. However, mechanical or thermal therapy fail to stop bleeding in 5–12 % of patients [8, 9]. The limits of current endoscopic therapies are linked to different variables such as type and size of the lesion to be treated, anatomical site, and presence of large vessels exposed. High-risk lesions may be technically difficult to manage, resulting in a failure of endoscopic treatment.

From a technical point of view, the limits of hemoclips application are well known. The limited diameter of the working channel of the endoscope results in a relatively small size of a through-the-scope clip and, therefore, allowing compression of limited amounts of tissue. Accordingly, the haemostatic effect may not be sufficient for large-size vessels, and there is often the need to apply more than one clip to achieve an effective haemostasis. The OTSC system was designed to overcome the limitations of traditional through-the-scope clips allowing a significantly larger mechanical circumferential compression of large tissue areas, surrounding the vessel without direct trauma. It has been shown to be effective in the endoscopic treatment of fistulas, perforations and GI bleeding. Preliminary data suggested its possible role in GI bleeding. Kirschniak et al. [10] treated 12 patients with upper GI bleedings; most of them were caused by peptic ulcer disease. Primary haemostasis was achieved in all cases. In two cases, a secondary bleeding occurred. In one case, it was observed 12 h after OTSC treatment of a Mallory–Weiss lesion, and in the other case, it occurred 7 days after treatment of bleeding duodenal ulcer. This study demonstrated the efficacy of OTSC in upper GI bleeding; however, authors did not specify the characteristics of the lesions treated in terms of Forrest classification, location and size, debarring the assessment of its possible advantage versus standard endoscopic therapy.

A recent study demonstrated efficacy and safety of the OTSC for the treatment of patients with severe acute upper and lower GI bleeding unresponsive to conventional treatment, resulting in a salvage endoscopic treatment during NVUGIB emergencies [7]. In this study, 23 cases with GI bleeding unresponsive to conventional endoscopic treatment modalities were treated with OTSC and retrospectively analysed. Primary haemostasis with OTSC was achieved in 22/23 patients. In one patient with a posterior wall duodenal ulcer, emergency selective radiological embolization was required to stop bleeding after failure of the OTSC procedure. Re-bleeding was observed in two cases; both cases were successfully re-treated

endoscopically. Authors concluded that OTSC is an effective and safe endoscopic tool for treatment of patients with severe acute upper GI bleeding unresponsive to conventional treatment modalities, although the proportion of high-risk patients were not stated. A more recent study reported a series of patients in whom OTSCs were used for endoscopic control of refractory or major upper gastrointestinal bleeding [11]. A total of nine patients were recruited to the study. Six of them had undergone previous endoscopic haemostasis therapy. The median size of the ulcers was 2.5 cm. All the ulcers and tumours demonstrated the presence of a visible vessel on endoscopy. The technical success rate of OTSC was 100 %, and endoscopic haemostasis was achieved in all patients. Two patients experienced re-bleeding, which required further intervention, and hence, the clinical effectiveness was 77.8 %. Authors concluded that OTSC should be considered in patients with refractory bleeding after failure of conventional methods of endoscopic haemostasis, before surgery or angiographic embolization. Analyzing the results of these two studies, we could suppose that previous endoscopic treatment, i.e. clip, could hamper OTSC application resulting in re-bleeding. Up to date, no data on the efficacy of the OTSC as first-line endoscopic treatment in patients with NVUGIB have been published. In our study, we used OTSC in challenging lesions with intention to treat and were able to achieve technical and clinical success in all the patients. During the 30-day follow-up, none of the 40 patients had a recurrence of bleeding requiring second-look endoscopy, radiological embolization or surgery intervention.

However, our study presents some limitations, i.e. the lack of randomization and the limited sample size. Moreover, a bias related to the execution of the procedures in a tertiary referral centre, experienced in the technical positioning of OTSC for other indications (fistulas, anastomotic dehiscence's and perforations), may be considered.

In conclusion, to the best of our knowledge, no study has been performed investigating the use of OTSC as first-line endoscopic treatment in patients with high-risk NVUGIB. In our series, OTSC placement as a first-line endoscopic treatment seems to be effective, safe and technically easy to perform.

Our data are certainly encouraging although randomized controlled trials are needed in order to confirm the value, efficacy and safety of the OTSC in this field.

Compliance with ethical standards

Disclosures Mauro Manno, Santi Mangiafico, Angelo Caruso, Carmelo Barbera, Helga Bertani, Vincenzo G Mirante, Flavia Pigò, Khanna Amardeep, and Rita Conigliaro have no conflicts of interest or financial ties to disclose.

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