CME

Over the Scope Clips for Treatment of Acute Nonvariceal Gastrointestinal Bleeding in Children Are Safe and Effective

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ABSTRACT

Objective: There is little published experience with the use of over-the-scope clips (OTSCs) in pediatric patients. The aim of this study is to present our single-center experience utilizing OTSCs for nonvariceal gastrointestinal (GI) bleeding.
Methods: This is a retrospective case series of pediatric patients who underwent endoscopic management of GI bleeding during which OTSCs were used.
Results: Eleven cases of OTSC utilization for hemostasis were identified in 10 unique patients between November 2014 and May 2016. The median age at intervention was 14.7 years (range 3.9–16.8 years) and median weight was 39 kg (range 17.4–85.8 kg). Technical success and hemostasis were achieved in all cases and there were no complications. Median follow-up was 32.9 months (range 21.2–39.4 months). All nonanastomotic ulcers (4), polypectomy bleeding (2), and sphincterotomy bleeding (1) had no evidence of recurrent GI bleeding at last follow-up. Two patients with anastomotic ulcerations required additional medical interventions.
Conclusions: Our series demonstrates the safety and effectiveness of the OTSCs in the pediatric population for acute GI bleeding throughout the GI tract. In our experience, it is effective for nonanastomotic ulcers, postpolypectomy bleeding, and postsphincterotomy bleeding even when other hemostatic techniques have failed. OTSCs may be less effective in the setting of anastomotic ulcerations, reaffirming the refractory nature of these lesions.

Key Words: endoscopy, hemostasis, pediatric

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What Is Known

- The over-the-scope clip device is useful in the management of gastrointestinal bleeding in adult patients.

What Is New

- The over-the-scope clip is useful in the management of nonvariceal, nonanastomotic ulcer bleeding in pediatric patients.

Endoscopically applied hemostatic clips have been used successfully in both adult and pediatric populations to provide mechanical tamponade in cases of gastrointestinal (GI) bleeding (1,2) Positioning and placement of hemostatic clips can be challenging, particularly in the pediatric population, due to smaller luminal size. Furthermore, dislodgement of clips can lead to recurrent bleeding. The over-the-scope clip (OTSC) is a system that provides significantly more grasping strength and better tissue capture than smaller through-the-scope clips (3). Case series and retrospective studies in the adult population have shown that an OTSC can be safely and effectively used in cases of nonvariceal upper GI and lower GI bleeding. As of this article, only 2 reports detail the use of the OTSC in the pediatric population: Wright et al (4) in 6 cases of gastrocutaneous fistula and Kondo et al (5) in one 4-year-old boy with bleeding from duodenal ulcer. This report details the clinical safety and effectiveness of OTSCs in multiple pediatric patients with GI bleeding.

METHODS

Patients

With institutional review board approval, the endoscopy database at Children's Health-Children's Medical Center Dallas was queried and cross referenced with a patient charge database to identify all pediatric patients who underwent endoscopic hemostasis utilizing the Ovesco OTSC system for acute nonvariceal bleeding from November 2014 through October 2016. We performed a retrospective chart review for each patient to identify preprocedural, procedural, and postprocedural characteristics. The location of the bleeding, previous interventions, and successful intervention with the OTSC were reviewed.

Over-the-Scope Clip System and Deployment Technique

The OTSC system uses a super elastic Nitinol alloy that can be applied via an endoscope or colonoscope. Nitinol is a

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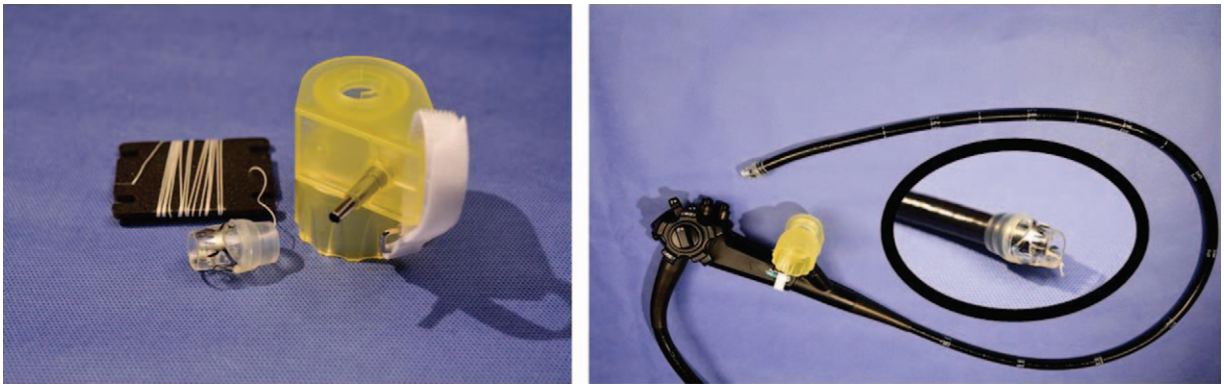

FIGURE 1. Ovesco over-the-scope clip (OTSC) system (A) before and (B) after securing it to the endoscope.

biocompatible alloy that is compatible with most magnetic resonance imaging settings. The Ovesco OTSC (Ovesco Endoscopy USA Inc, Cary, NC) is supplied preloaded onto caps of various diameters allowing the system to accommodate endoscopes with tip outer diameter (OD) ranging from 8.5 to 14 mm. The cap is secured onto the tip of the endoscope after the deployment string is back loaded through the working channel and secured to the deployment handle in a manner similar to variceal banding devices already familiar to most endoscopists (Fig. 1). Once the OTSC is attached to the scope tip, the OD will range from 16.5 to 21.0 mm depending on clip selected (3). The Ovesco OTSC system is available with several different ''tooth'' designs and 2 cap depths (3 and 6 mm). At our institution, the type of clip selected was dictated solely by the diameter of the cap, and thus the endoscope being used. Tooth design and cap depth were not considered important variables in device selection. Application aids such as tissue graspers and anchors are available and can be passed through the working channel to aid with tissue capture, but in our experience this is not necessary in the treatment of GI bleeding, and application aids were not used in any patients reported in this series. For each patient the OTSC was secured to the endoscope according to manufacturer instructions (Fig. 1) (3). The lesion was suctioned into the cap and the clip was deployed (Fig. 2). The elastic metal encloses and compresses tissue when springing closed, similar to a bear trap (4). The placement of all OTSCs was overseen by 2 experienced endoscopists at the study institution (B.A.B., D.M.T.).

Definitions

Each bleeding lesion was described using the Forrest classification system regardless of location or lesion type (6). The Forrest classification system was originally developed in an attempt to standardize the description of the appearance of gastric ulcers. Technical success was defined as ability to successfully deploy the OTSC for hemostasis to the lesion of interest. Immediate hemostasis was defined as successful hemostasis in patients with active bleeding (Forrest 1 lesions), without need for further interventions during the endoscopic session. Need for reintervention was defined as need for any intervention (endoscopy, interventional radiology, surgery) to achieve hemostasis or need for further medical interventions to treat persistent anemia such as blood transfusions or iron infusions.

RESULTS

In this case series, a total of 10 patients underwent eleven interventional procedures. The median age was 14.7 years with range from 3.9 to 16.8 years. The median weight was 39.0 kg with range from 17.4 to 85.8 kg. Table 1 demonstrates patient

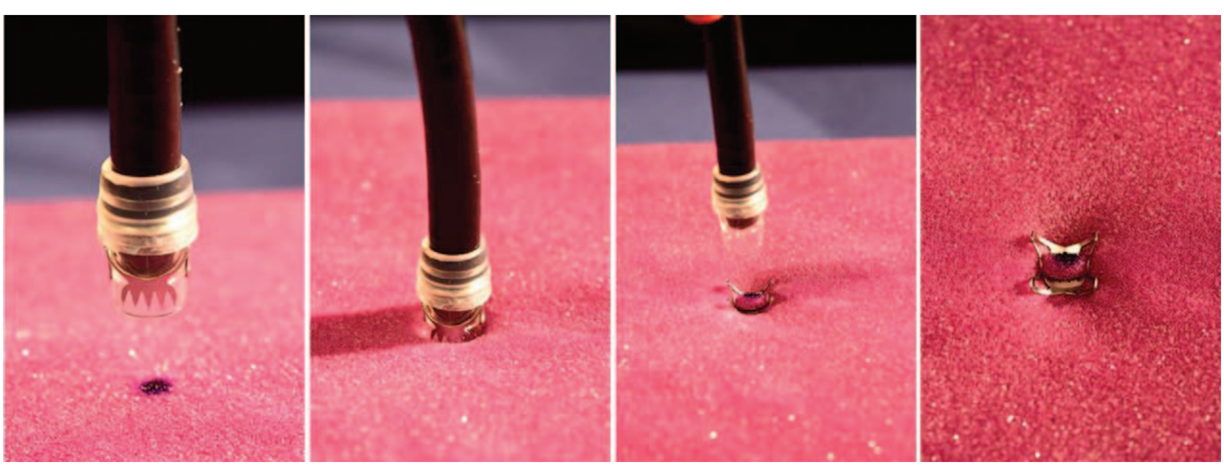

FIGURE 2. Ex vivo demonstration of technique used to deploy over-the-scope clip (OTSC) to bleeding vessel (purple dot). A, The vessel is visualized and centered within the cap. B, Suction is then applied bringing the lesion into the cap. C, The deployment wheel is turned to release the clip and the scope is pulled away. D, The vessel can typically be visualized in the center of the clip confirming successful positioning.

TABLE 1. Patient and procedural characteristics

Patient	Age, y	Sex	Weight, kg	Height, cm	Site	Diagnosis	Forrest classification	Previous interventions	Type of OTSC used	Technical success	Immediate hemostasis	Follow–up, mo	Need for reintervention
1	16.8	F	59.4	160	Stomach (angular incisura)	Ulcer	Forrest 2a	TTS during same session	1 (11/6 A)	Yes	N/A	25.2	No
2	10.0	M	30.6	124	Stomach (angular incisura)	Ulcer	Forrest 1b	None	1 (12 6 T)	Yes	Yes	32.2	No
3	11.1	F	61.1	152	Stomach (body)	Postpolypectomy	Forrest 2a	None	1 (12/6 T)	Yes	N/A	27.0	No
4	15.9	M	81.0	168	Duodenum (D1)	Ulcer	Forrest 2a	None	1 (12/6 GC)	Yes	N/A	35.8	No
5	15.8	M	85.8	174	Duodenum (D1)	Ulcer	Forrest 2c	None	1 (12/6 T)	Yes	N/A	21.7	No
6	12.4	M	38.2	156	Duodenum (major papilla)	Postsphincterotomy	Forrest 1a	Epinephrine injection, TTS clip during same session	1 (12/6 T)	Yes	Yes	34.3	No
7	16.8	M	48.6	164	Colon (sigmoid)	Ulcer	Forrest 2a	TTS placement during prior session	2 (12/6 T on separate lesions)	Yes	N/A	33.5	No
8	3.9	F	17.4	100	Colon (sigmoid)	Postpolypectomy	Forrest 1b	TTS during same session	1 (12/6 T)	Yes	Yes	21.2	No
9	9.2	M	25.0	121	Ileocolonic anastomosis	Anastomotic ulcer	Forrest 2a	Medical therapy for IDA	1 (12 6 T)	Yes	N/A	33.5	Continued need for iron infusions
10a	14.7	F	38.0	134	Ileoileal anastomosis	Anastomotic ulcer	Forrest 2c	Multiple endoscopic interventions during prior sessions	1 (11/6 A)	Yes	N/A	39.4	Continued need for chronic transfusions, repeat OTSC placement at different site
10b	15.2	F	39.0	134	Ileoileal anastomosis	Anastomotic ulcer	Forrest 2c	Multiple endoscopic interventions during prior sessions	1 (11/6 A)	Yes	N/A	32.9	Continued need for chronic transfusions

D1 = first portion of duodenum, IDA = iron deficiency anemia, OTSC = over-the-scope clip, TTS = through-the-scope clip.

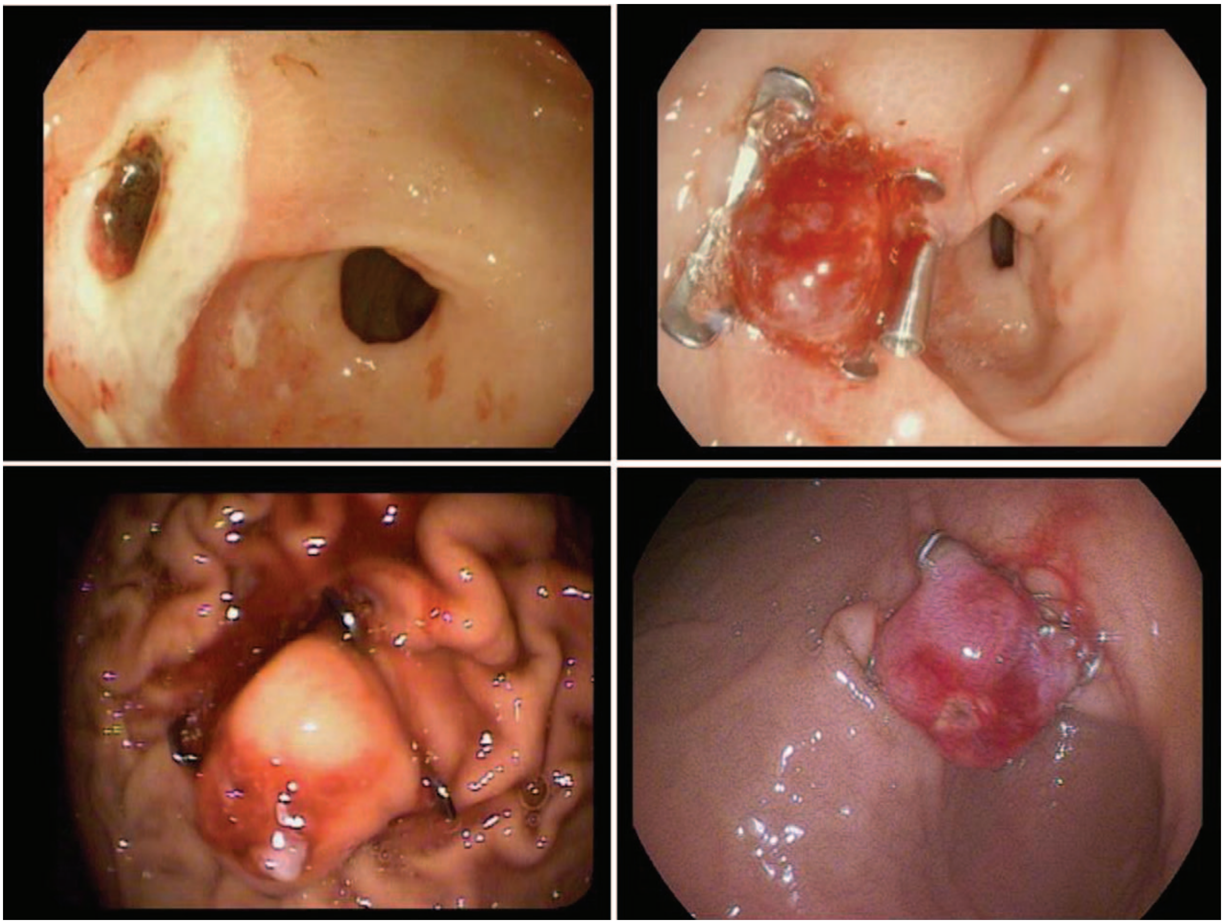

FIGURE 3. Several examples of clip deployment in this series. A gastric ulcer (A) before and (B) after application of the over-the-scope clip (OTSC) device. Also seen in (B) is a through the scope clip that was applied first but failed to adequately target the lesion and caused new bleeding. C, Example of over-the-scope clip deployed to actively bleeding gastric polypectomy site with vessel clearly seen captured within the clip. D, Over-the-scope clip applied to bleeding gastric ulcer with lesion clearly visible in the clip.

characteristic, lesion characteristics, and procedural characteristics. Ulcer size was not documented in patient charts and thus could not be reliably reported. Overall, 3 patients had Forrest 1 lesions, with active bleeding visible on initial endoscopy before any intervention. One patient had a nonbleeding (Forrest 2) lesion that began bleeding with application of a through-the-scope clip. Upper GI bleeding due to stomach or duodenal ulcer was seen in 4 patients. Two of these patients had ulcer disease of the stomach and duodenum, respectively, secondary to nonsteroidal anti-inflammatory drug use. One patient had peptic ulcer disease of unknown etiology and 1 had duodenal ulcers secondary to active *Helicobacter pylori* infection. Upper intestinal bleeding was also seen in 2 other patients, 1 with postpolypectomy bleeding in the stomach and 1 with bleeding after biliary sphincterotomy. The patient with postpolypectomy bleeding had a pedunculated polyp with stalk <1 cm in size. In the patient with postsphincterotomy bleeding, a biliary stent had previously been placed, which allowed for adequate visualization of the patent papillary orifice while placing the OTSC.

Lower intestinal bleeding was seen in the remaining 4 patients. One patient had an ulcer located in the sigmoid colon presumed to be secondary to intestinal ischemia, 1 had postpolypectomy bleeding in the sigmoid colon, and 2 patients had anastomotic ulcers, 1 at an ileoileal anastomosis and 1 at ileocolonic anastomosis. The patient with postpolypectomy bleeding had a pedunculated polyp with stalk <1 cm in size. The patient with the ileoileal anastomotic ulcer required intervention with placement of OTSCs on 2 separate occasions at separate sites. Four (40%) patients had OTSC placed as first-line intervention with no prior intervention. In 4 (40%) patients, unsuccessful attempts to achieve primary hemostasis were first made by applying through-the-scope clips. Three of those attempts occurred in the same endoscopic session when OTSC was applied, with the other unsuccessful attempt occurring in a separate endoscopic session. One of these 3 patients also underwent epinephrine injection into the site of bleeding before application of through-the-scope clips. Placement of the OTSC was technically successful in all patients resulting in immediate hemostasis at the time of the intervention for patients who were actively bleeding.

The 2 patients with anastomotic ulcers have continued to have clinical bleeding resulting in chronic anemia after placement of the OTSC. One of these patients continues to required monthly iron infusions and the other remains transfusion dependent. The remaining patients have had no evidence of recurrent bleeding at last follow-up (median 32.9 months, range 21.2–39.4 months).

DISCUSSION

GI bleeding in the pediatric population is an uncommon but potentially serious and life-threatening occurrence. Therapeutic endoscopy is universally accepted as first-line therapy for active

GI bleeding in the pediatric population (2). Compared to standard hemostatic clips, OTSCs provide increased strength and tissue capture to effectively stop active GI bleeding (3). In our study, 10 patients had OTSC placed with technical success in all patients with no immediate complications, no bleeding in high-risk lesions, and immediate hemostasis in those patients with active bleeding. We conclude that the OTSC system is a reliable and effective tool for active GI bleeding or high-risk lesions and should be considered for high risk or urgent/emergent cases of bleeding in children.

High-risk lesions (through Forrest 2A) can have up to 50% rebleeding risk (2). Rebleeding was seen in 2 of our study patients (20%) with anastomotic ulcer, with both patients needing post-intervention transfusions and 1 requiring repeat intervention with additional OTSC placement at a different site. Both of these patients had previously undergone bowel lengthening procedures with bleeding occurring at the sites of surgical anastomosis. Such anastomotic ulcers are notoriously difficult to manage and can prove refractory to medical and endoscopic interventions (7). Our series included a small sample of such patients and further study is needed to determine OTSC effectiveness in this population. In the other 8 patients with acute nonanastomotic-related GI bleeding, OTSC placement was, however, technically successful and patients were discharged without need for further interventions to control bleeding on short and long-term follow-up (Fig. 3). Our results suggest that pediatric endoscopists may consider OTSCs for use in active GI bleeding either initially or when other endoscopic interventions fail in the treatment of pediatric GI bleeding.

There is little published literature on the use of OTSC in pediatrics. Kondo et al (5) described successful utilization of the OTSC system in a 4-year-old 7.8 kg child with hemorrhagic shock from duodenal ulcer secondary to ulcerative colitis. OTSC was trialed given failed conventional therapy, multiple episodes of rebleeding, and contraindication to surgical correction. After clip placement, he did have sixth rebleeding episode due to pseudoaneurysm discovered on angiography and ultimately required arterial embolization. Wright et al (4) discussed in their case series successful use of OTSC in 5 of 6 children with gastrocutaneous fistula after gastrostomy tube removal. In the unsuccessful case, surgery was required as clip could not cover the opening of internal fistula. The demographics of their 6 patients were similar to our patients with average age 10.7 years, average weight 33.0 kg, range 13.1 to 66.4 kg. The authors suggested that OTSCs could be optimally used in patients >10 kg. We agree that the major limiting factor of OTSC use in children is the OD of the scope/cap apparatus. Surprisingly, successful application of the OTSC system has been described in a child as small as 7.8 kg (5). We have seen the most difficulty with navigating the device past the upper esophageal sphincter (UES), especially in patients <15 kg. If there is difficulty introducing the scope, the UES may be dilated before advancing the OTSC complex. After navigating the UES, generally there is little resistance to further scope passage. The authors have successfully dilated the UES to 18 mm before OTSC use in a patient with esophagogastric fistula but did not have a need to perform this in the patients presented in this series.

Multiple case series in the adult population have shown the effectiveness and utility of OTSCs in the setting of hemostasis, especially as first-line therapy (8,9). OTSCs can be deployed with 85% to 100% success rate in reviewed pediatric and adult studies (4,5,8–13). Both retrospective and prospective studies show that use of OTSCs can effectively decrease or prevent rebleeding (non-Forrest 1a lesions), especially in cases in which prior therapy has failed (10,11). Richter-Schrag et al demonstrated that higher rates of rebleeding are seen in patients in whom OTSCs are used as second-line treatment. They suggested that this was likely because these are higher-risk patients who received prior stabilization attempts (8). Higher rates of rebleeding can also be seen with patients on antiplatelet or antithrombotic therapy (14).

Published studies have discussed the limitation of scope reintroduction with the OTSC device after identifying a lesion, similarly with band ligation (10,11). In cases of emergent upper GI bleeding, we agree that time between identification of a lesion and effective hemostasis should be minimized. We, however, feel that, with increased endoscopist experience in assembling the cap and clip complex, the time between identification and effective intervention will be minimalized. Another consideration is need of clip removal in case of malposition. To this date, we have not had any indication to remove a deployed OTSC and all of our patients have had clip remain in place without adverse effect. The metal alloy can remain in the GI tract, although follow-up of some patients has demonstrated hyperplastic tissue around the clip (9). In theoretical cases in which tissue growth could cause obstruction, if there is an indication to remove clips, or if there was malposition at the time of clip placement, a bipolar cutting device can be used to remove the device as has been safely reported in adults (15). In addition, there is a direct current cutting system designed specifically to aid in the removal of OTSCs currently approved for clinical use in the United States, and other select markets (16).

In conclusion, we report this series demonstrating the safety and efficacy of OTSC in the pediatric population for acute non-variceal GI bleeding. Our report has several limitations related to its retrospective design and small sample size. In addition, the OTSCs were placed by experienced pediatric endoscopists at a single tertiary center possibly not representing more diverse experiences. Effectiveness was not established for chronic GI bleeding due to anastomotic ulcer. Future studies are needed to determine differences in efficacy between OTSCs and other hemostatic techniques. Although our patients have had OTSC clips retained in place, long-term studies are needed to monitor adverse effects of leaving clips within the GI tract indefinitely.

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