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Review Article

Endoscopic closure devices: A review of technique and application for hemostasis

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ABSTRACT

Acute gastrointestinal bleeding is a common, yet challenging, and potentially problematic medical emergency for clinicians to manage. Given its significantly high health care associated costs and increased morbidity and mortality rate, new endoscopic techniques for managing gastrointestinal bleeding has gained considerable attention. While conventional methods (i.e., injection, cautery, and hemostatic clips) have been widely used, their efficacy and reliability for initial hemostasis has been hindered by high rebleeding and variable success rates. Thus, this review sets out to characterize recent advancements with the clinical application of endoscopic closure devices as the alternatives in achieving hemostasis. Such devices include hemostatic clips, also known as through-the-scope clips, over-the-scope-clips, endoscopic detachable snare ligation devices, and endoscopic suturing system.

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Keywords: Endoscopic hemostasis; Gastrointestinal endoscopy; Gastrointestinal hemorrhage

Introduction

Gastrointestinal (GI) hemorrhage is a common medical emergency associated with high morbidity and mortality resulting in more than 200,000 admissions per year in the US and a frequent indication for endoscopic treatment by gastroenterologists.^{1,2} Conventional endoscopic management of GI hemorrhage including injection, cautery, hemostatic clips, and endoscopic band ligation (EBL) has been fraught with varying success rates for lesions and high rebleeding rates.^{3–6} Consequently, the high demand for more versatile technology has led to a flurry of advancements in endoscopic closure devices for hemostasis for high risk lesions of varying size and shape. Mechanical endoscopic closure devices including hemostatic clips, also known as through-the-scope (TTS) clips, over-the-scope-clips (OTSC), endoscopic detachable snare ligation (EDSL) devices, and endoscopic suturing will be reviewed for their technical use and clinical application. These novel devices are frequently used for endoscopic closure of luminal defects of varying dimensions however they have recently gained momentum for use in endoscopic hemostasis with promising results in early studies.

Novel Therapies

Through-the-scope clip

Description of the device & technique

TTS clips have been well studied for endoscopic hemostasis since they became commercially available greater than thirty years ago. These devices were approved for hemostasis for several indications including small visible vessels, bleeding ulcers, mucosal and submucosal defects less than 3 cm and bleeding colonic diverticula.^{7–9} An attractive feature of the TTS clip is their ability to thread the clip in virtually any endoscope with a working channel of 2.8 mm. The small size of these clips is less likely to block the view of bleeding lesions, are less cumbersome to maneuver around and maintain the patency of the intestinal lumen.

There are many manufacturers producing TTS clips in the United States including Boston Scientific, Cook Medical, Olympus, Conmed, and Microtech. These devices are constantly evolving with features that maximize functionality including rotatable heads, single-handed deployment, wide opening angle and conditional magnetic resonance imaging compatibility within specific

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parameters.^{10–13} A study comparing TTS head to head revealed no drastic differences in efficacy.⁸ Recently, Wang et al¹⁴ published a comprehensive methodical assessment of the functional profiles of the many new TTS clips including Resolution 360™ (Boston Scientific, Marlborough, MA, USA), Instinct™ (Cook Medical, Bloomington, IN, USA), Quick Clip Pro™ (Olympus America, Center Valley, PA, USA), Dura Clip™ (ConMed, Utica, NY, USA), and Sure Clip™ (Microtech, Ann Arbor, MI, USA) which authors concluded each clip has a unique functional and physical profile.

Clinical application

Given the ease of use and widespread availability, TTS clips are likely to maintain a permanent spot in the endoscopist's toolbox for hemostasis. Several studies have demonstrated the ease of use of these clips and success rates of TTS clip as monotherapy as well as in combination with injection and or cautery. Barakat et al¹⁵ published a systematic review involving 2,988 patients that evaluated several trials comparing conventional endoscopic hemostasis. This review highlights the effectiveness of TTS clip as monotherapy in comparison to combined intervention of TTS clip and injection with no demonstrable difference in success of hemostasis, frequency of rebleeding, incidence of emergency surgery or overall mortality. In fact, TTS clips were found to be superior over injection monotherapy based on rebleeding rate with a favorable number needed to treat of 6 for TTS compared

to 20 for injection monotherapy.¹⁵ Studies that compared TTS clip monotherapy to thermal coagulation also found no difference in rebleeding rates, escalation to emergency surgery or overall mortality, although these studies had significant heterogeneity in their results. Based on these findings, TTS clip remains a safe, effective, and easy-to-use option for hemostasis.^{16,17}

Over-the-scope-clip

Description of the device and technique

The OTSC (Ovesco, Tübingen, Germany) system is an innovative clipping device originally introduced for endoscopic closures of luminal wall defects (i.e., perforations, leaks and fistulas) due to its ability to effectively clamp a large circumferential area of tissues.^{18–22} Recently, OTSC has gained considerable attention as a safe and dependable tool for hemostatic closure. Kirschniak et al²³ successfully reported the first clinical experience of treating severe gastric or colonic bleeding with this device. One animal study demonstrated its superior ability over traditional TTS clips in closing arterial bleeds.²⁴ Compared to standard endoscopic devices, the OTSC's transparent cap and super-elastic nitinol clipping device enables it to firmly grasp and deliver high compression forces to larger vessels supplying the targeted tissue.^{20–22} From a technical standpoint the clip is deployed from the cylindrical cap by turning a wheel that is attached to the shaft of the endoscope.^{25,26}

Suction technique

Target the lesion with the OTSC® System.

Bring the OTSC® cap in contact with the tissue.

Suction the target tissue into the cap.

Apply the OTSC® clip by turning the hand wheel.

Anchor technique

Position the OTSC® Anchor and fix the tissue; align the OTSC® cap to the lesion by pulling the anchor and advancing the endoscope.

Mobilize the tip of the OTSC® Anchor shaft into the cap; anchor spikes may remain external; release the OTSC® clip.

After clip application, detach the OTSC® Anchor from the tissue.

Fig. 1. This figure illustrates two different techniques for the application of the over-the-scope clips (OTSC) system. The clip can be deployed by the suction technique shown in the top panel or by the anchor technique shown in the bottom panel. By applying endoscopic suction, the application cap secures the tissue and then hemostasis is attained by twisting the hand wheel which releases the entire clip. The anchor technique uses the tissue anchor to draw up the target tissue into the application cap prior to deploying the clip (used with permission, courtesy of Ovesco, Tübingen, Germany).

As shown in Fig. 1, there are two different techniques for the application of the OTSC system. The suction technique is used when the lesion is approached, the endoscope will suction it into the transparent cap and then the endoscopist releases the clip by turning the hand wheel similar in concept to the variceal banding apparatus.^{20,25} The anchor technique is used when the target tissue is fibrotic or hard tissue or requires tangential application. With this technique, the anchor is used to fix the target tissue and align the cap to the lesion by pulling the anchor and advancing the endoscope. Then the anchor shaft is mobilized into the OTSC cap followed by the release of the OTSC clip.^{20,25} Despite its high cost and somewhat steep learning curve, the advantages of this system include its safety profile and clinical effectiveness in stopping severe GI bleeding.²¹

Clinical application

From a clinical point of view, the OTSC has produced promising results in the literature. Recently, Kirschniak's group²⁷ reported successful hemostasis with OTSC in patients with bleeding due to peptic ulcers, Mallory–Weiss tear, Dieulafoy lesions and post-polypectomy bleeding. One retrospective study of 30 patients, who were treated with OTSC after failing conventional endoscopic techniques, demonstrated a 97% (29/30) success rate in achieving primary hemostasis.²⁸ Similarly, a study of 12 patients with upper GI bleeding (i.e., duodenal ulcers, gastric ulcers, Dieulafoy lesion, anastomotic ulceration, and Mallory–Weiss tear), whom failed traditional endoscopic methods, showed similar results with hemostasis achieved in all subjects.²⁹ Another case series also reported a technical success rate of 100% in 10 refractory cases with a median size ulcer of 2.5 cm.³⁰ A prospective study of 40 consecutive patients also achieved technical success and primary hemostasis in 100% of patients using OTSC as first line therapy, with no complications or rebleeding during the 30-day follow up period.³¹ Therefore, OTSC have been effective for hemostasis in several types of bleeding lesions including peptic ulcers of varying sizes, Mallory–Weiss tears, Dieulafoy lesions and post-polypectomy bleeding.

There is a growing body of evidence that this closure device should be considered as a first line therapy. In a large multicenter study, Wedi et al²⁶ illustrated the OTSC's superiority in preventing re-bleeding and reducing mortality in high risk patients which included cases of severe upper (48.8%) and lower GI bleeding (3.6%). In an effort to further explore outcomes with high risk bleeding cases—prone to failure—one group in Singapore found a clinically significant decrease and reduction in rebleeding rates in patients with high and intermediate risk Rockall scores.¹⁸ Another single center retrospective study of 100 high-risk cases reported primary hemostasis and clinical success in 88% and 78%, respectively.³² As first line therapy, there was only a 4.9% primary failure rate compared to a 23% failure rate when used as a second line treatment.³² A recent multicenter study, conducted in eleven tertiary centers, stated that OTSC can be a valid first-line tool in high risk upper and lower GI bleeding for which a 96% primary hemostasis success rate was encountered.³³ To date, this is one of the largest studies of patients treated with OTSC, who were recruited with either upper ($n = 214$) or lower ($n = 72$) GI bleeding. The procedure failure rate was only 2% and rebleeding occurred in 4.4% of subjects all of whom were on antithrombotic therapy.³³ Currently, the cost of the OTSC device kit ranges from \$438 to \$610 compared to TTS clips which range from \$150 to \$200 in the United States. There is additional cost of \$441 to \$619 if the anchor system is used with the OTSC kit. As such, in cases where more than two to three TTS clips are deployed, the OTSC may be more cost ef-

fective. If the anchor system is used with the OTSC kit, the cost effectiveness of the system would be equivalent to five to six TTS deployment.

Endoscopic detachable snare ligation

Description of the device & technique

EDSL (Olympus, Tokyo, Japan) is a mechanical tamponade

3-step ligating procedure

Fig. 2. This step-by-step depiction of the Poly-Loop, demonstrates the nylon loop's ability to effectively ligate an area of interest through a simple retraction of the handle at the channel port (used with permission, courtesy of Olympus America, Center Valley, PA, USA).

device that became commercially available in 1991.^{34,35} There are three types of detachable snares i.e., Endo-Loops, Poly-Loops and Mini-Loops.³⁵ Poly-loops are currently available, preassembled, in the USA with no need for preparation.

The nylon loop ligating device can be used directly through the 2.8 mm working channel of the endoscope and deployed by retracting the handle at the instrument channel port as described in Fig. 2. Additionally, the device can be used in combination with a clear Distal Attachment (Olympus) device to provide suction assistance as described by Akutsu et al³⁶ in cases of diverticular hemorrhage.^{36,37} To deploy the EDSL with a distal attachment, one must first target a lesion, preferably in the 5- to 7-o'clock direction to improve successful loop placement. The loop is placed around the target. Then, using full endoscopic suction, the lesion is drawn into the distal attachment. To position the EDSL, pull back the tube sheath to extend and tighten the loop around the desired area. Next, the stopper is advanced by pulling the slider and plastic sheath. The plastic sheath is then pulled to the maximum extent. Finally, to detach the loop, the slider is maximally pulled out. Afterwards, one may remove excess wire with cutting forceps.³⁶

Clinical application

Initially, EDSL was designed to aid in the removal of large

polyps and other elevated lesions due to its ability to occlude arterial flow in the polyp stalk.^{34,38} This detachable loop-ligating device has additionally been described in case reports as a salvage therapy to achieve hemostasis due to bleeding from GI cancers in patients who were otherwise poor surgical candidates.³⁹ It was also shown to be useful as an adjunct to clip hemostasis and management of colonic arterial bleeding.^{35,40} In terms of esophageal varices, one group compared endo-loop ligation ($n = 25$) to EBL ($n = 25$) and found no statistical difference in variceal eradication or recurrence.⁴¹ Compared to band ligation, the investigators did note a few technical advantages which included a greater field of vision, tighter application, and lack of device strain on the endoscope.⁴¹ In a prospective randomized trial, a group in Korea compared mini-detachable snare ligation to EBL and found comparable results in terms of immediate hemostasis and rates of recurrent bleeding.⁴²

Diverticular bleeds are the most common cause of lower GI bleeding, and reports have shown that up to 75% of cases spontaneously resolve.^{43,44} Yet, the remaining cases have a high rate of rebleeding after initial endoscopic hemostasis (11%–47%).^{43,45} On top of this, the incidence of diverticular bleeds is rising as more patients are on antithrombotic therapy.³⁷ Hence, effective endoscopic modalities are critical to avoid recurrent bleeding, surgery, reduce costs and prolonged hospital stays. In regards to treatment

1. After creating suture slack. Close needle body by squeezing the handle.

2. Push anchor exchange forward to engage anchor.

3. Push and hold blue button. Pull back 1 cm.

4. Squeeze handle open.

5. Advance tissue helix to targeted tissue. Apply forward pressure. Turn blue knob clockwise to engage tissue.

6. Pull tissue helix into needle guard. Close handle to pass anchor and suture.

7. Advance anchor exchange catheter to engage with anchor. Pull anchor exchange without pushing blue button.

8. Turn tissue helix knob counterclockwise to disengage tissue. Open handle. Repeat steps 1–8 as needed.

Fig. 3. Step by step guide to placing sutures using Apollo OverStitch™ endoscopic suturing system (used with permission, courtesy of Apollo Endosurgery, Austin, TX, USA).

options, TTS clips have a relatively high rebleeding rate and can be technically challenging in the setting of massive bleeding or with lesions located in the dome.^{37,46,47} A recent 2019 study sought out to compare EDSL ($n = 44$) to endoscopic clipping ($n = 87$) in diverticular bleeds, and the investigators found that EDSL was indeed superior to endoscopic clipping.⁴⁸ While there was no difference in total procedure time (43 vs 45 min) or time to hemostasis (12 vs 10 min), there was a clinical significant difference in early rebleeding rates between EDSL (6.8%) and endoscopic clipping (23%).⁴⁸ Curcio et al⁴⁹ also highlights the utility of EDSL in patients with unfavorable lesions and in special populations such as those who cannot stop anticoagulation. Akutsu et al³⁷ conducted a large prospective, multicenter trial at 12 institutions to comment on EDSL's efficacy, safety, and rates of recurrent bleeding (within 30 days). Of the 101 patients who were treated with EDSL, there were only 8 patients who experienced early rates of rebleeding.³⁷ Furthermore, only two adverse events occurred (i.e., mild diverticulitis and transient abdominal pain).³⁷ It is important to highlight that EDSL failed in 18 patients due insufficient suctioning, and in such cases endoscopic clipping was employed.³⁷

Endoscopic suturing

Description of the device & technique

Endoscopic suturing, initially primarily used by surgical colleagues, has recently been added to the armamentarium of gastroenterologists with growing utilization. Now, a simple literature search of endoscopic suture returns dozens of case reports of successful endoscopic closure of large mucosal defects, anchoring transluminal stents, bariatric surgery and natural orifice transluminal endoscopic surgery to name a few.⁵⁰ The initial device, Apollo OverStitch™ endoscopic suturing system (Apollo Endosurgery, Austin, TX, USA), is applied to the end of a dual channel therapeutic endoscope, currently compatible with Olympus GIF-2TH180 and GIF-2T160 scopes. The device is manipulated by a needle anchor handle, a blue needle anchor button and a knob to advance the tissue gathering device. As shown in Fig. 3, prior to placing the first suture, the needle anchor handle is squeezed closed to close the needle body (step 1) and the blue needle anchor button is depressed to engage the needle anchor (step 2). To thread the needle, push and hold the blue needle anchor button and pull back 1 cm (step 3) and finally, squeeze the needle anchor handle to prime the device to place the first suture (step 4). To acquire tissue, apply forward clockwise pressure to the blue tissue helix knob toward the targeted tissue until it draws the tissue into the tissue anchor to ensure a full thickness bite (steps 5 and 6). To place suture, close the needle anchor handle which passes the needle and suture through the tissues (step 6). To complete the suture and retract the needle, advance the needle anchor exchange catheter to engage with anchor and then retract the needle anchor catheter to release the needle (step 7). Finally, release the tissue after suture is completed by counterclockwise rotation of the tissue helix knob (step 8). Repeat steps 1 to 8 for subsequent sutures. Apollo Endosurgery recently released a new suturing device for use with single channel endoscopes, the OverStitch Sx™. This device houses the needle anchor and needle driver in an externally secured cap on the end of the endoscope as shown in Fig. 4. The tissue helix device is threaded through the single working channel and is used as previously described by the original OverStitch™ device. Each device is capable of placing sutures in customizable configurations including interrupted, running, or figure-of-eight fashion to close mucosal defects without withdrawing the scope.⁵¹

Fig. 4. Comparison of the Apollo OverStitch™ device appearance at the distal end of the dual channel endoscope (left) and the Apollo OverStitch Sx™ device appearance at the distal end of the single channel endoscope (right) (used with permission, courtesy of Apollo Endosurgery, Austin, TX, USA).

Clinical application

OverStitch™ endoscopic suturing system was initially developed and U.S. Food and Drug Administration approved in 2008 for endoscopic closure of defects of the GI lumen of a variety of sizes. In an early investigational case report, Chiu et al⁵² describes the use of endoscopic suture to achieve hemostasis by figure of eight pattern across large bleeding ulcers in 3 patients. Recently, in a small multi-center international study of preliminary experience with endoscopic suturing, 100% of patients achieved hemostasis by using endoscopic suturing for salvage therapy after failed initial attempt ($n = 9$) and primary therapy ($n = 1$).⁵¹ Chung et al⁵³ presented a case of successful endoscopic oversewing of a large ulcer with visible vessel that had failed prior endoscopic and interventional radiology treatments. Due to the novelty of this device and limited availability of the endoscopic suturing system, research regarding hemostasis success rates are limited and trials comparing endoscopic suture to other traditional modalities are future areas for research.

Discussion

Endoscopic closure devices have evolved immensely over the past thirty years since the first mainstream utilization. Despite ongoing improvements to traditional methods, rates of successful hemostasis are variable and reduction of re-bleeding rates, emergency surgery and overall mortality from GI hemorrhage have yet to significantly improve.^{51,54,55} Thus, the application of newer technology to achieve hemostasis, such as OTSC, EDSL, and endoscopic suturing devices could be the long-awaited resolution to this common medical emergency. A summary of the advantages, disadvantages and cost of each endoscopic closure device is shown in Table 1.

TTS clips are cheap, easy to use, widely available and can be loaded into the scope while maintaining position. These advantages are likely the reason why these devices are the first choice by many endoscopists. Although there are clear benefits to through the scope clips, the size and shallow depth of these clips are a major limitation for their application in densely fibrotic ulcer beds, large or awkwardly positioned bleeding lesions.⁵⁶ For these reasons, OTSC have an advantage and are capable of achieving hemostasis with reduced rates of rebleeding, in comparison to TTS clips and other traditional methods.²⁸ While these OTSC clips offer larger tissue depth and higher compression strength, only a few small studies advocate their use as primary intervention.^{27,28,57} For recurrent bleeding, OTSC have recently been shown to be more

Table 1 Comparison of the Applicable Lesions, Advantages, Disadvantages and Cost of Each Endoscopic Closure Device

Device	Applicable lesion	Advantage	Disadvantage	Cost
TTS clips	Peptic ulcer Dieulafoy Post-polypectomy Diverticular bleeding	Well studied Inexpensive Easy to use Variable sizes and features	Small size Not suitable for fibrotic ulcer base High rebleeding rate	\$150 to \$200 per clip*
OTSC	Peptic ulcer Mallory–Weiss tear Dieulafoy Post-polypectomy	Variable diameter and teeth shape Larger size clip Low rebleeding rate Similar to banding device	Expensive (if anchor system is used with the OTSC) Scope must be withdrawn to apply clip apparatus	OTSC kit \$438 to \$610 per unit, anchor \$438 to \$610 per unit*
EDSL	Post polypectomy bleeding Varices Colonic arterial bleeding Diverticular bleeding (with distal attachment)	Useful as an adjunct to TTS Comparable to band ligation for the treatment of variceal bleeding Superior to TTS in diverticular bleeding cases	Requires technical skill Limited data on use	Polyloop \$152 per unit, distal attachment \$40.70 per unit*
Endoscopic Suture	Large bleeding ulcers Salvage therapy after failed initial endoscopic treatment	No limitations on the defect or target lesion size	Expensive Requires technical skill Limited data on use Limited availability	\$1,000 with one suture system, one suture and one Cinch (additional suture and Cinch \$125/unit)*

TTS, through-the-scope; OTSC, over-the-scope-clips; EDSL, osopic detachable snare ligation.

*The listed price varies per institution with its own respective contract.

effective than TTS clip or combined injection and thermal therapy and should be considered for second-look endoscopy.⁵⁸ The high cost of the OTSC system, lack of endoscopist skill, and need for scope removal for clip application are most frequently cited as barriers to its use.^{27,28}

Surgical intervention for bleeding GI lesions includes over-sewing bleeding vessels. This surgery has high mortality which often excludes patients with several comorbidities and critical illness who are at the greatest risk of GI hemorrhage.^{59,60} Promising results by Agarwal et al⁵¹ support the consideration of endoscopic suture for these situations where traditional methods have failed and surgery is not an option. In the hands of a skilled endoscopist, endoscopic suture is not limited by the size of the bleeding lesion unlike nearly all of the alternative mechanical devices. Similarly, EDSL are capable of cinching larger lesions which has been effective in cases of bleeding cancers, failed TTS clips, diverticular and post polypectomy bleeding.^{39,48,61,62}

Conclusion

In the past three decades, the options for endoscopic hemostasis has increased significantly. However, despite advances in therapy, the in-hospital mortality rate remains high (4%–13%) and rebleeding is common (10%–39%).^{3–6} Emerging data on the novel use of endoscopic closure devices for hemostasis have suggested that these tools are effective and should be considered in patients with high risk lesions and those who have failed traditional therapies.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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