



Endoscopic clip application devices

To promote the appropriate use of new or emerging endoscopic technologies and those technologies that have an impact on endoscopic practice, the ASGE Technology Committee presents relevant information to practicing physicians in the form of technology reviews. Evidence-based methodology is employed wherein a MEDLINE literature search is performed to identify pertinent clinical studies on the topic, a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search is performed to identify the reported complications of a given technology, and both are supplemented by accessing the “related articles” feature of PubMed and by scrutiny of pertinent references cited in the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking; in such cases, large case series, preliminary clinical studies, and expert opinion are utilized. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Reviews are drafted by 1 or 2 committee members, reviewed in significant detail by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is appropriate, the most recent coding data and list prices at the time of publication are provided. For this review the MEDLINE database was searched through October 2005 for articles related to endoscopic clipping by using the keywords “endoscopic clips” and “gastrointestinal endoscopy” plus “clip application” and “hemoclip.” Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and socioeconomic aspects of these technologies.

BACKGROUND

Endoscopic clipping devices are instruments designed to accomplish approximation of tissues during gastrointestinal endoscopy. Metallic clipping devices were first introduced for the primary purpose of achieving hemostasis of focal gastrointestinal bleeding.¹⁻⁴ Indications for their use have expanded to include closure of perforations and fis-

tulas, securing of catheters and stents, and as a marking device to direct endoscopic, surgical, and radiological therapy among others.

TECHNOLOGY UNDER REVIEW

Several endoscopic clipping devices are commercially available and others are under development. All have 2 components: metallic double or triple pronged clips and a delivery/deployment catheter-handle assembly. Some clipping devices employ reusable deployment catheters, which are loaded and fired with 1 clip at a time, while others are disposable and come preloaded for delivery and application of a single clip. Currently available devices deliver 1 clip per loading and passage. Another device, which is currently pending approval, allows for serial clipping during 1 pass through the endoscope. The prongs of the clip are applied with pressure onto the target tissue and pinched closed by manually squeezing the catheter handle assembly.

The first endoscopic clipping device was introduced by Olympus Corporation (Tokyo, Japan). The terms “endoclip” and “hemoclip” have been used for this device interchangeably in the literature. Both reusable (HX-5LR-1 and MD 850) and preloaded single-use (HX-200L/U-135 or QuickClip) devices are available. The delivery/deployment catheter consists of a metal cable within a metal coil sheath, enclosed within a 2.2 mm Teflon catheter. The tip of the metal cable has a hook onto which the clip is attached. A handle consisting of 2 sliding components controls loading and deployment. A rotation mechanism on the handle allows directed orientation of the clip. The clips are 1.2 mm wide multiangled stainless steel ribbons available in several lengths (short/standard/long) with an opening angle of 90 degrees or 135 degrees. Clips open from 6 mm to 12 mm, depending on the specific clip. The clips are configured to be withdrawn into the outer Teflon sheath for delivery through the endoscope accessory channel (minimum 2.8 mm). The deployment mechanism controls re-exposure of the clip from the outer sheath, opening the clip to its greatest width, closure onto the target tissue, and disconnection from the cable hook. When the clip is exposed and open, the rotational wheel on the applicator handle may adjust the axial orientation of the clip. The device may then be removed and additional clips loaded and the process

repeated. Precision in clip loading and deployment are required for effective use.

A single use clip-fixing device (QuickClip, Olympus Corporation) with a preloaded clip offsets the need for clip loading. Its configuration and function are otherwise similar to the reusable device, though it lacks the clip rotator in its original iteration. The QuickClip opens to 6 mm between the prongs. A further modification on the single-use clipping device (QuickClip 2) incorporates the rotating axial control mechanism, with a prong opening of 9.5 mm.

Another single-use clipping device (TriClip, Cook Endoscopy, Inc, Winston-Salem, NC) delivers a 3-pronged stainless steel clip preloaded on either a 7 or 8 F catheter with a disposable handle. The 8 F devices have an integrated port for flushing the field of view. The clip opens to a maximum diameter of 12 mm between the 3 prongs. The clip is withdrawn into the sheath to allow passage through the endoscope accessory channel. The deployment mechanism re-exposes the clip from the outer sheath, opens it to its greatest dimension, closes it onto the target tissue, and disconnects the clip from the delivery device.

A third single-use, preloaded clipping device (Resolution Clip, Boston Scientific Corporation, Natick, Mass) harbors a 2-pronged stainless steel clip that tapers from 1.9 mm to 1.2 mm in width from base to tip and opens to a maximum of 11 mm. The metal coil shaft of the device is covered with a polyethylene outer sheath and is fitted with the same handle that is used on the Boston Scientific biopsy forceps. It is offered in 155 cm and 235 cm lengths and can be used through a 2.8 mm endoscope accessory channel. A unique feature of the Resolution Clip is the ability to reopen and reposition the clip after closing, up to 5 times—as long as the device has not been fired.

A fourth endoscopic clip that is nearing distribution (Multi-Clip, InScope Inc, a Division of Ethicon Endosurgery, Cincinnati, Ohio) can apply 4 clips sequentially without the need for removal and reloading. This device departs from prior clip designs with mechanisms akin to laparoscopic devices that grasp the tissue with apposing arms of a forceps before clip application. The clips can also be rotated, closed, reopened, and repositioned for optimal application.

INDICATIONS

Food and Drug Administration clearance has been gained for the following indications for endoscopic clipping devices.

- Endoscopic marking
- Hemostasis for:
 - a. Mucosal/submucosal defects
 - b. Bleeding ulcers

- c. Bleeding arteries <2 mm in size
- d. Polypectomy sites
- e. Diverticula in the colon
- Anchoring jejunal feeding tubes to the wall of small bowel
- As a supplementary method, closure of GI tract luminal perforations that can be treated conservatively.

The most common application of endoscopic clipping is hemostasis and the largest experience has been with peptic ulcer bleeding.⁵⁻¹⁴ Other bleeding lesions treated by clips include: Dieulafoy's lesion,¹⁵⁻¹⁷ Mallory-Weiss tear,¹⁸⁻²⁰ polypectomy sites,^{6,21,22} varices,²³⁻²⁵ and diverticulae.²⁶⁻²⁸ Clips have been used to close mucosal defects resulting from endoscopic mucosal resection, GI tract fistulas, and perforations of the esophagus, stomach, duodenum, and colon.²⁹⁻⁴² Clips have been used to secure feeding tubes, esophageal stents, and manometry catheters to the gastrointestinal wall.⁴³⁻⁴⁵ Radiopaque metallic clips have been used for fluoroscopic localization to guide endoscopic stent placement, esophageal function testing, external beam radiation therapy, embolization therapy, and surgical resection.⁴⁶⁻⁴⁸ Intraoperative palpation of clips also guides surgical resection. Case reports describe clip assisted biliary cannulation in periampullary diverticulum and clip and cut diverticulectomy.^{49,50}

EFFICACY

Most of the publications pertaining to endoscopic clipping are based on experiences employing reusable Olympus clipping devices. At the time of this writing there is only a single case report pertaining to the TriClip⁵¹ and no peer-reviewed literature specifically addressing the QuickClip or Resolution devices.

Several case series indicated efficacy of clipping for hemostasis of nonvariceal GI bleeding. Haschisu reported his experience in 51 patients presenting with GI bleeding from gastroduodenal ulcers, Mallory-Weiss tear, gastric cancer, Dieulafoy's lesion, and postpolypectomy ulceration.² Primary hemostasis was achieved in 84% of patients. Binmoeller et al reported an initial hemostasis rate of 91% and a rebleeding rate of 5.6% among 88 patients treated with clipping for actively bleeding nonvariceal lesions.⁶ Lai et al, using the rotatable clip device in the treatment of 40 patients with ulcer bleeding, achieved hemostasis in 95% of the patients, with 7.5% rebleeding.⁵

Retrospective series using historic controls have compared hemostasis of peptic ulcer bleeding by injection and/or thermal therapies to either clip placement alone or in combination. Clip placement was comparable to absolute alcohol for initial hemostasis but demonstrated lower rebleeding and hospital length of stay.⁹ Clipping plus epinephrine injection achieved a similar hemostasis rate but a lower rebleeding rate compared with epinephrine alone.¹¹ Clip placement alone demonstrated a similar

hemostasis rate and a significantly lower rebleeding rate compared to epinephrine injection/heater probe combination therapy.¹²

Two randomized, controlled trials comparing clipping alone to injection therapy and a third comparing clipping to combination injection plus clipping therapy demonstrated equivalency in initial hemostasis.^{14,52,53} Rebleeding rates showed a trend in favor of endoscopic clipping. A randomized, controlled trial comparing clipping to Heat Probe (Olympus, Corporation) thermal coagulation therapy in 113 patients with major stigmata of ulcer hemorrhage reported equivalent rates of initial hemostasis and a significantly lower rebleeding rate in the clipping group ($P < .05$).¹³ However, another randomized, controlled trial of clipping versus Heat Probe in 80 patients with ulcer hemorrhage demonstrated superior initial hemostasis in the thermal probe group ($P = .01$) and no difference in rebleeding rates between the 2 therapies.⁵⁴

A case series of clip application in 58 patients with actively bleeding Mallory-Weiss tears demonstrated a 100% hemostasis rate, with no rebleeding.¹⁸ A randomized, controlled trial ($n = 35$) of clipping versus epinephrine injection for bleeding from Mallory-Weiss tears reported similar hemostasis and recurrent bleeding rates.¹⁸ Two randomized, controlled trials demonstrated parity of clipping compared to epinephrine injection for initial hemostasis of actively bleeding Dieulafoy lesions.^{15,16} Clipping was associated with lower rates of rebleeding.

There are limited published data on clipping for the management of variceal bleeding. A case series of 51 patients reported endoscopic clipping combined with intravariceal or paravariceal sclerotherapy with polidocanol in the management of esophageal varices for initial hemostasis,⁵ primary prophylaxis,²⁶ and secondary prophylaxis.^{21,23} Varices were eventually obliterated in 88% of patients, with a 4% esophageal ulceration rate. The authors concluded that combination treatment with clipping and sclerotherapy may require lower volumes of sclerosant. A single randomized, controlled trial of endoscopic clipping versus endoscopic band ligation in 40 patients with acute esophageal variceal bleeding demonstrated equivalence for control of acute bleeding and for successful variceal obliteration.²⁴ Clipping has also been described as efficacious for treatment of bleeding from sclerotherapy-induced ulceration.²⁵

Two large series demonstrated effective hemostasis of postpolypectomy bleeding with clipping.^{6,21} Several reports describe clipping of the stalk of large polyps before snare resection or double clipping followed by needle-knife resection of the stalk to prevent bleeding.⁵⁵ A randomized, controlled trial of prophylactic clipping after EMR did not demonstrate a decrease in the incidence of delayed bleeding among 413 patients (0.98% vs 0.96%).²²

Three case reports describe successful endoscopic clipping for hemostasis of duodenal and colonic diverticular bleeding.²⁶⁻²⁸

Literature defining the efficacy of clipping for nonhemostasis applications is limited to case reports and small series. There are several reports of clip application for closure of perforations of the esophagus, stomach, duodenum, and colon as a component of nonoperative management in selected cases.³⁰⁻⁴¹ In small perforations a single clip may be applied across the entire defect whereas larger perforations may require sequential clipping from the edges toward the center of the defect. In all case reports the patients were also treated with bowel rest and antibiotics.

Case reports have described the use of endoscopic clipping for fixation of manometry catheters, feeding tubes, and esophageal stents to the gastrointestinal mucosa.⁴³⁻⁴⁵ Application of clips through a duodenoscope is difficult. However, case reports have demonstrated their use through a duodenoscope to assist in biliary cannulation of a major papilla located within a duodenal diverticulum,⁵⁰ for hemostasis after postsphincterotomy bleeding, and for closure of defects after ampullectomy.⁵⁶

SAFETY

Endoscopic clipping using the currently available devices appears safe. There is only 1 report of a complication attributed to clipping, wherein a clip inadvertently perforated a gastric ulcer and was applied to the splenic artery.⁵⁷ Initial failure of clip placement may be due to inability to achieve proper orientation or inability to grasp flat fibrotic tissue neighboring chronic lesions. Orientation challenges are diminished by using the rotatable devices. Malfunction of the reusable clip-fixing device is frequently due to improper clip loading. Familiarity with device loading, delivery, and deployment enhances safe and successful application. This familiarity may be obtained through ex vivo training. Intentional removal of an applied clip results in no more tissue effect than mucosal forceps biopsy.⁴³ Spontaneous sloughing of the Olympus clips typically occurs at approximately 18 to 26 days and clips pass uneventfully.^{3,43} However, clips have been known to remain at the site of application for up to 1 year. The rate of sloughing of the TriClip is unreported. Clip retention rates in ulcer bases and at mucosectomy sites may be different than that in normal tissue.

FINANCIAL CONSIDERATIONS

The list price for the Olympus reusable clip-fixing device is \$567.00. Each clip costs ~\$10.00 and they are available in boxes of 50 (\$550.00). The single use QuickClip costs ~\$50.00 per device and is available in boxes of 5 or 20. The Wilson-Cook TriClip costs ~\$99.00 per device and is available in a box of 3. The Resolution Clip is sold in boxes of 1, 10, or 20 at a cost of \$150 per clip. Final pricing is not yet available for the InScope device. One to 5 or

TABLE 1. CPT codes for endoscopic control of bleeding

43227	Esophagoscopy with control of bleeding
43255	EGD with control of bleeding
44366	Enteroscopy with control of bleeding
45334	Flexible Sigmoidoscopy with control of bleeding
45382	Colonoscopy with control of bleeding

more clips may be required per case, depending on the application, and this will considerably influence the associated costs and the differential between reusable and single use varieties.

Several Current Procedural Terminology (CPT®) codes exist to report endoscopic clipping for control of bleeding (Table 1). There are no established CPT codes for other applications of endoscopic clipping.

CONCLUSIONS

Endoscopic clipping is safe and effective for hemostatic therapy of bleeding peptic ulcers, Mallory-Weiss tears, and other bleeding lesions. Clipping may be effective for closure of mucosal defects after endoscopic mucosal resection, iatrogenic perforations, and fistulae. Innovative applications to fix catheters and stents to the luminal mucosa have been demonstrated. Pending and anticipated developments include multiclippling devices⁵⁷ and potentially larger and more durable clips.

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