TECHNOLOGY STATUS EVALUATION REPORT

Endoscopic hemostatic devices

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INTRODUCTION

To promote the appropriate use of new or emerging endoscopic technologies, the ASGE Technology Committee has developed a series of status evaluation papers. This process may present relevant information about these technologies to practicing physicians for the education and care of their patients. In many cases, data from randomized controlled trials are lacking and only preliminary clinical studies are available. Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and social economic aspects of the technologies.

BACKGROUND

Endoscopic hemostatic therapy has been shown to improve outcomes in upper gastrointestinal bleeding.[1-6] Hemostatic devices used for upper gastrointestinal bleeding have been applied to the lower GI tract.[7] These include contact thermal devices (heater probe and multipolar electrocautery probes), noncontact thermal devices (argon plasma coagulator and lasers), injection needles, and mechanical devices (band ligators, clips, and loops).

TECHNOLOGY UNDER REVIEW

Thermal hemostatic devices

All thermal devices generate heat either directly (heater probe) or indirectly by tissue absorption of light energy (laser) or passage of electrical current through tissue (multipolar probes, argon plasma coagulator). Heating leads to edema, coagulation of tissue protein, and contraction of vessels, resulting in a hemostatic bond.[8] Contact devices allow coaptation of vessels that may contribute to hemostasis. Tissue coagulation requires a temperature of approximately 70°C. Repeated application of these devices can result in the build-up of coagulum at the tip, which can impede conductivity and necessitates removal of the probe and cleaning the tip.

Multipolar electrocautery/bipolar electrocautery. Multipolar electrocautery (MPEC) probes deliver thermal energy by completion of an electrical circuit between two electrodes on a probe tip through nondesiccated tissue. In contrast to monopolar electrocautery, the circuit is completed locally; therefore, no grounding pad is required. As the targeted tissue desiccates, loss of conductivity occurs, limiting maximum temperature (100°C) and depth and breadth of tissue injury.[9] A port at the tip delivers water for irrigation, which improves overall visualization. A foot pedal controls coagulation and irrigation. Both the thermal and coaptive components can be applied tangentially or en-face to the targeted lesion. Commercially available MPEC probes include HEMArrest (Bard Interventional Products, Billerica, Mass.), BICAP (Circon, Calif.), Gold probe (Microvasive, Natick, Mass.), and Quicksilver (Wilson-Cook Medical, Inc., Winston-Salem, N.C.).

Heater probe. The heater probe (HP) (Olympus America, Melville, N.Y.) consists of a Teflon-coated hollow aluminum cylinder with an inner-heating coil. A thermocoupling device at the tip of the probe maintains a constant temperature. In contrast to MPEC, the mechanism of tissue coagulation is direct heat transfer. Coaptive pressure is also used with HP therapy and there is an irrigation port. A foot pedal controls coagulation and irrigation. HP activation delivers a preselected quantity of energy in Joules to the diode in the probe tip, thus once the pulse has been initiated the duration of activation is predetermined.[10]

Argon plasma coagulator. Argon plasma coagulator (APC) is a noncontact electrocoagulation device that utilizes high-frequency monopolar alternating current conducted to target tissues through ionized argon gas (argon plasma). Electrons flow through a channel of electrically activated, ionized argon gas from the probe electrode to the targeted tissue causing a thermal effect at the interface. As the tissue surface loses its electrical conductivity because of desiccation, the plasma stream shifts to adjacent nondesiccated (conductive) tissue. The APC probe consists of a flexible Teflon tube with a tungsten electrode contained in a ceramic nozzle at its distal end. Coagulation depth is dependent on generator power setting, duration of application, and distance from the probe tip to the target tissue.[11] The operative distance between probe and tissue ranges from 2 to 8 mm.[12] The argon arc contacts tissue closest to the electrode allowing for direct or tangential coagulation. The APC unit (ERBE USA, Marietta, Ga.; ConMed Electrosurgery, Englewood, Colo.) includes a high-frequency electrosurgical generator, source of argon gas, gas flow meter, flexible delivery catheter, grounding pad, and foot switch to activate both gas and energy. Probes are available that direct the plasma parallel or perpendicular to the axis of the catheter.

Laser photocoagulation. Laser is an acronym for light amplification by stimulated emission of radiation. The lasing medium (or active medium) is excited to a higher energy state by a pump source, which provides electromagnetic energy. Light energy of a characteristic wavelength is emitted, amplified, and focused into a coherent monochromatic beam, which when applied to tissue may result in coagulation or vaporization. A flexible optical fiber transmits the laser beam, which can be used in a contact or noncontact fashion. Sapphire or ceramic tips are necessary for contact applications, which increase the energy density of the laser beam. An aiming beam facilitates targeting. Some fiber tips require cooling with a coaxial flow of carbon dioxide.[13]

Injection needles

Injection needles are devices passed through the working channel of an endoscope that allow the injection of liquid agents into target tissue. They consist of an outer sheath (plastic, Teflon, or stainless steel) and an inner hollow-core needle (21G-25G), and are available in lengths of 200 to 240 cm. Injection of various solutions achieves hemostasis by mechanical tamponade and cytochemical mechanisms.[14]

Mechanical devices

Band ligation. The ligating device consists of a friction fit adapter affixed to the tip of the endoscope, preloaded elastic band(s), and a release mechanism. The target tissue is suctioned into the hollow chamber of the friction-fit adapter. The trigger mechanism deploys an elastic band, ligating the target tissue. Tissue ligation results in hemostasis with subsequent necrosis and sloughing.[15,16] Single and multiple band ligators are available.

Hemoclips. Metallic clips (Hemoclip; Olympus America, Melville, N.Y.) have been developed for use through flexible endoscopes.[17-19] The clip fixing devices vary in lengths (165-230 cm) and diameters requiring a 2.8 mm or 3.2 mm diameter accessory channel. A rotational mechanism on the delivery catheter allows directed orientation of the clip. A preloaded single-use version is also marketed. The clips are multiangled stainless steel ribbons that are available in several lengths (short/standard/long) and angulations (90°/130°). Clips are loaded onto the fixing device and drawn into a sheath. At the target lesion, the clip is advanced out of the sheath, oriented with the rotational handle, and then deployed. The mechanism of hemostasis is mechanical compression.

Detachable loops. A detachable nylon loop can be deployed to ensnare target tissue. The device (Endoloop; Olympus America, Melville, N.Y.) consists of nylon loops and a delivery system that includes a Teflon sheath that is 1950 mm long and 2.5 mm in diameter. A hook wire is advanced out of the sheath to load a circular or elliptically shaped loop. The loop is then retracted into the sheath, which is passed down the accessory channel of the endoscope. The loop is advanced out of the sheath and placed around the target tissue. The loop is tightened with advancement of a silicon-rubber stopper. When the loop is closed to the desired extent, as evidenced by tissue cyanosis or hemostasis, it should then be released.

INDICATIONS AND EFFICACY

In two meta-analyses comprising over 30 randomized trials involving over 2400 patients, endoscopic therapy significantly reduced rebleeding, need for emergency surgery, and mortality.[5,6]

Thermal hemostatic devices

Bleeding gastroduodenal ulcers. MPEC has been compared with sham treatment in patients with active bleeding or a nonbleeding visible vessel and shown to reduce rebleeding, emergency surgery, mean hospital stay, and cost of hospitalization.[1,2] A 10F probe may be more effective than a 7F probe.[20] The recommended power setting is 15 to 25 watts with repeated applications of 6 to 10 seconds duration.

Two prospective analyses comparing HP with no endoscopic intervention in patients with peptic ulcer disease and active bleeding or nonbleeding visible vessels showed significant benefit for HP in immediate hemostasis and rebleeding.[21,22]

Two randomized controlled studies comparing Nd:YAG laser photocoagulation to medical therapy demonstrated a benefit in reducing rebleed and emergency surgery.[23,24] However, a third study failed to show an improved outcome.[25]

The use of APC has been reported to be beneficial in achieving hemostasis in bleeding peptic ulcers.[26,27]

Gastric antral vascular ectasias. HP, MPEC, Nd:YAG, and APC have all been used successfully to control bleeding from gastric antral vascular ectasias (GAVE) (also referred to as watermelon stomach).[28-32]

Dieulafoy lesion. Primary hemostasis was achieved in over 90% of patients with Dieulafoy lesions using HP.[33]

Radiation-induced angiectasias. MPEC, HP, APC, and laser have been used successfully to treat bleeding from radiation-induced angiectasias. Multiple sessions were typically required.[34-42]

Diverticular bleeding. MPEC, HP, and laser have been used to treat colonic diverticular hemorrhage in the rare instance in which active bleeding or high-risk stigmata have been identified during colonoscopy.[7,43,44]

Angiodysplasia. MPEC, HP, and laser have been used to treat bleeding angiodysplasias encountered during upper endoscopy, push enteroscopy and colonoscopy. In contrast to treating bleeding peptic ulcers, lower power settings, and lighter appositional forces are used with MPEC and HP treatment of angiodysplasias.[45,46]

Injection needles

Peptic ulcer disease. Injection needles have been shown to be effective vehicles for the delivery of a variety of solutions to achieve hemostasis.[14] In sham controlled trials, injection therapy reduced rebleeding, transfusion requirement, emergency surgery, and hospital stay.[47,48]

Variceal hemorrhage. Injection needles have been proven as effective delivery devices for a variety of sclerosing agents including sodium tetradecyl sulfate, polidocanol, ethanolamine oleate, sodium morrhuate, and absolute alcohol in the treatment of esophageal variceal hemorrhage.[14,49] None of these agents has been shown to be clearly superior. In this procedure, a catheter-sheathed needle is advanced through the endoscope and a sclerosing agent is injected by using the free-hand technique, either into the varix (intravariceal) or into the mucosa adjacent to the varix (paravariceal), resulting in a thrombosis of the varices and fibrosis of the surrounding tissue.

Esophageal variceal sclerotherapy has been shown to achieve acute hemostasis in 71% to 95% of cases and provides a benefit in the prevention of rebleeding and mortality.[4]

The efficacy of primary prophylaxis of esophageal varices with sclerotherapy remains controversial.[50] Sclerotherapy has been used for nonesophageal varices including gastric, intestinal, and colonic varices, but the effectiveness is generally lower and data are limited.

Diverticular bleeding. Injection therapy with epinephrine may be used during colonoscopy to treat bleeding diverticula.[7,44]

Mechanical devices/band ligation

Esophageal variceal hemorrhage. Variceal band ligation is effective in the control of active hemorrhage in 86% to 91% of cases.[3,51] Subsequent sessions result in eradication of esophageal varices and decreased rebleeding.[3] Band ligating devices have been used for nonesophageal varices including gastric, intestinal and colonic varices but data are limited.

Nonvariceal hemorrhage. Case reports and small series have described the use of endoscopic band ligation for treatment of bleeding angiectasias, Mallory-Weiss tears, polypectomy sites, Dieulafoy lesions, and duodenal ulcers.[52-58] One commercially available multi-band ligator has an extra long trigger cord and a larger friction fit adapter that can be used with a colonoscope (MBL-4-XL-C; Wilson-Cook Medical, Inc., Winston-Salem, N.C.). A standard polypectomy snare has been used to extend the working length of the "single shot" trip wire for use through a colonoscope.[52]

Endoscopic hemoclips

Endoscopic hemoclips have achieved hemostasis in 84% to 100% of patients with a variety of upper GI bleeding sources including peptic ulcers, Mallory-Weiss tears, Dieulafoy lesions, gastric angiectasias, gastric tumors, and following polypectomy, sphincterotomy, and biopsy.[17,18,59-61]

Hemoclips have also been used to treat bleeding lesions in the lower GI tract including diverticula, hemorrhoids, solitary rectal ulcers, and after polypectomy and biopsy.[18,62-64]

Detachable loops

Detachable loops were developed for the prevention and treatment of post-polypectomy bleeding. The largest published study to date of 25 cases highlights technical challenges including accidental stalk transection, insufficient loop tightening, entanglement of the loop with the snare, and inability to place the loop after polypectomy because of stalk retraction.[65] Detachable loops have also been used for gastric varices.[66]

COMPARATIVE TRIALS

Gastroduodenal ulcers (active bleeding or non-bleeding visible vessels)

A prospective randomized study comparing MPEC, HP, and Nd:YAG laser for the treatment of active bleeding showed no significant differences in rates of rebleeding (10%, 19.4%, 10%), length of stay (5 days, 4 days, 4 days), and emergency surgery (7%, 13%, 7%), respectively. The cost per patient was higher with Nd:YAG laser than with MPEC and HP.[67] A study comparing MPEC to HP demonstrated no significant difference in hemostasis (92% vs.

100%), length of stay (5.0 vs. 5.4 days), emergency surgery (7.5% vs. 7.5%), or mortality (7.5% vs. 5%), respectively.[68] A study comparing MPEC alone, epinephrine injection alone, and combination MPEC-epinephrine injection demonstrated that combination therapy significantly reduced rebleeding (6.7% combination therapy vs. 30% MPEC vs. 35.5% epinephrine) and the need for blood transfusion.[69]

A randomized trial demonstrated the superiority of HP over ethanol injection in achieving "permanent hemostasis" (95% vs. 71%).[70] A randomized study comparing HP to epinephrine injection in patients with active bleeding found higher initial hemostasis with injection therapy (96% vs. 83%), but no differences were seen in other outcomes.[71] Two subsequent randomized trials comparing HP with epinephrine or epinephrine-polidocanol injection showed both therapies to be equally effective.[72,73] A randomized study comparing HP with APC showed no significant differences in measured outcomes but lacked statistical power.[12]

Two randomized trials comparing Nd:YAG with injection therapy (epinephrine or polidocanol) showed no significant difference in outcomes.[74,75]

Hemoclips were compared with hypertonic saline solution-epinephrine injection therapy and combination clip/injection therapy in a prospective randomized trial involving 124 patients. No significant differences in initial hemostasis, rebleeding, or need for urgent surgery were noted, but there were trends favoring hemoclips and combination therapy.[19] A retrospective study of 99 patients comparing the above modalities also showed similar outcomes although rebleeding was significantly less in the subset of patients with active oozing treated with clips.[76] A randomized trial of 113 patients comparing hemoclips with HP found similar rates of initial hemostasis, emergent surgery, and 30-day mortality, although hemoclip therapy was associated with significant decreased rebleeding, units of blood transfused, and length of stay.[77]

Dieulafoy lesion

In the only prospective randomized trial comparing mechanical (hemoclips and band ligation) and injection methods for Dieulafoy's lesions, the rate of rebleeding was significantly lower in the former (8% vs. 33%).[78]

Esophageal varices

A meta-analysis of 7 randomized trials comparing esophageal variceal ligation (EVL) to esophageal variceal sclerotherapy (EVS) in 547 patients demonstrated reduced rebleeding, local complications, number of sessions to eradication, death caused by rebleeding, and overall mortality reduction with EVL.[3] Three subsequent randomized studies comparing endoscopic band ligation to sclerotherapy showed similar efficacy in control of active hemorrhage. EVL was associated with fewer sessions to eradication, fewer local complications, but a greater recurrence of varices.[79-81] In an effort to reduce the rate of recurrence, combination EVL with low dose EVS has been compared with EVL alone. Four comparative trials have failed to demonstrate significant differences to favor combination therapy over EVL alone.[82-85]

EASE OF USE

Power generators for contact thermal probes and the APC are portable and use a standard 110 V outlet. Ten-French probes require a large diameter endoscope-working channel. Injection needles require no additional components. Laser systems are cumbersome and may require a 220 V power source limiting portability; additional components may include continuous flow gas source and coolant water source. Other considerations include specific safety training, protective eyewear, and special provisions for limiting access to the laser area. Both hemoclips and detachable loops have more complex delivery devices and require a higher degree of coordination between the endoscopist and endoscopy assistant. The use of band ligators requires initial removal of the endoscope for assembly. The band-ligating device may increase the difficulty of reintubation and endoscopic visualization.

SAFETY

MPEC

Rare perforations of peptic ulcers treated with MPEC and precipitation of bleeding in up to 18% have been reported.[1] Colonic perforation after treatment of angiodysplasia, particularly in the right colon can be seen in up to 2.5% of cases.[45] Forceful coaptation in this region should be avoided.

Heater probe

The rate of perforation following treatment of GI bleeding with HP ranges from 1.8% to 3% and precipitation of bleeding has been reported up to 5%.[5,86,87]

APC

Rare complications from APC use for hemostasis have been reported in the limited published experience including distention of the gastrointestinal tract with argon gas, submucosal emphysema, pneumomediastinum, pneumoperitoneum, and perforation.[12,27,32] Complications may be related to power setting, duration of application, and distance of the probe tip to the target tissue.[11]

Table 1. CPT codes for endoscopic hemostasis

	Esophagoscopy	EGD	Enteroscopy	Stoma	Flex sig	Colonoscopy
Injection sclerosis	43204	43243				
Band ligation	43205	43244				
Control of bleeding, any method	43227	43255	44366	44391	45334	45382
Removal by ablation technique	43228	43258	44369	44393	45339	45383

Table 2. Thermal hemostatic devices

Device	Manufacturer	Retail price*
Heat probe 2.8, 3.7 mm†	Olympus	$865
MPEC Probes		
BICAP 5F, 7F, 10F	Circon	$275, $245
Gold Probe 7F, 10F	Boston Scientific	$262
Injection Gold Probe		$310
Quicksilver 7F, 10F	Wilson Cook	$175
HEMArrest 7F, 10F	Bard	$205
Argon plasma coagulation probes		
2.3 mm probe (220 cm and 440 cm)	ERBE	$189
3.2 mm probe (220 cm)		
2.3 mm probe (240 cm)	ConMed	$270
Nd:YAG 80 W/100 W	Coherent	$155,000[40]

*Costs determined as of 1/01.
†Reusable.

Laser

The incidence of perforation following Nd:YAG treatment of GI bleeding is reported up to 2.4%.[30] Precipitation of bleeding can be seen in up to 29%.[25,87] Luminal gaseous distention is common.

Injection

Complications of injection therapy for nonvariceal bleeding are rare.[14] Cardiac arrhythmias have been reported after epinephrine injection.[88] Complications of esophageal variceal sclerotherapy are common and occur in up to 50% of patients.[4,89-92] They can be separated into local complications including retrosternal pain, dysphagia, odynophagia, ulcerations, strictures, bleeding, perforation, and systemic complications including fever, bacteremia, sepsis, pleural effusions, pneumonia, and adult respiratory distress syndrome.

Band ligation

The complications reported after EVL have included local complications of chest pain, treatment induced ulceration, hemorrhage from ulcerations and esophageal strictures but are uncommon. Systemic complications of bacteremia, bacterial peritonitis, and pulmonary infections have been reported at a significantly lower incidence compared with sclerotherapy.[15,16,50,51,79-85]

Clips

No procedure-related complications have been reported in the limited published series with hemoclips for GI bleeding.

Loops

Inadvertent transection of polyp stalk with the loop and subsequent bleeding has been reported but data are limited.[65]

COST CONSIDERATIONS

The CPT codes applicable to the use of hemostatic devices during upper and lower endoscopy are displayed in Table 1. Table 2 lists the thermal hemostatic devices available in the United States by cost and vendor. The costs of the various ligating devices are in Table 3. The cost of the reusable rotating clip fixation device is $500.00. The metallic clips cost $10.00 each and come in boxes of 50. A mean use of 3 clips per patient for peptic ulcer bleeding has been reported.[18] A disposable clipping device is available at a cost of $50 per single-use device. All costs are as of January 1, 2001.

SUMMARY

Endoscopic therapy improves outcome for most causes of gastrointestinal bleeding. There are many effective devices for endoscopic hemostatic therapy. Table 4 cross-references the hemostatic devices with the various target lesions. There are no compelling data favoring a particular device for treatment of peptic ulcer bleeding. For variceal bleeding, EVL has shown equal efficacy, less recurrent bleeding, fewer complications, and improved survival when compared with EVS. Selection of the optimal hemostatic device may also depend on characteristics of the lesion, local expertise, equipment availability, and cost.

Table 3. Band ligators

Device/manufacturer	Order No.	Specification	Retail price*
Bard (MA)			
Rapid fire multiple band ligator	000608	5 Bands; 2 kits/box	$490
Steigmann-Goff Endoscopic single band ligators	100225	1 Band-colonoscope; 5 kits/box	$250
Bandito (hemorrhoids)	100226	1 Band-sigmoidoscope; 5 kits/box	$250
	200220	5 Cylinders; 5 kits/box	$350
Varices ligator	200221	10 Cylinders; 5 kits/box	$465
	000221	5 Cylinders; 5 kits/box	$390
Clearvue ligators	000227	10 Cylinders; 5 kits/box	$520
Overtube	000230	25 Reuses; 1/box	$100
Boston Scientific			
Speedband superview multiple band ligator	4225-02	5 Bands; 2 kits/box	$580
	4228-02	8 Bands; 2 kits/box	$645
	4235	5 Bands; 1 kits/box	$315
Injection superview	4238	8 Bands; 1 kit/box	$350
Wilson Cook (N.C.)			
Multi-band ligator			
4 Shooter	MBL-4	4 Bands; 1 kit	$175
6 Shooter	MBL-6	6 Bands; 1 kit	$185
10 Shooter	MBL-10	10 Bands, 1 kit	$205
XL versions for larger scope diameters available			
XL-C version with longer trigger cord available			

*Costs determined as of 1/01.

Table 4. References by hemostatic device and target lesion

	MPEC	HP	Laser	Inject	APC	Band	Clip	Loop
Varices				3,4,16,79, 80,81,82,83, 84,85,91,92		3,4,15,16 51,79,80,81, 82,83,84,85, 89		66
PUD	1,2,5,6,9, 20,67,68, 69	5,6,10,12, 21,22,67,68, 70,71,72,73, 77,86	5,6,23,24, 25,67,74, 75,87	5,6,19,48, 49,69,70,71, 72,73,74,75, 76,86	12,27	49,55	17,18,19,59, 61,76,77	
MW tear						55,56,58	18,60	
Gave	28	29	30,31		32			
Dieulefoy	33	33	33	33,78		33,54,55,56, 57,78	18,33,61,78	
Angiodys	45	46		26,27	53,55,56	17,18		
RAD proc	34,36	36	34,39,40,41		37,38,42			
Divertic	7,43,44		44	7,44			18,63,64	
Tumor					26,27		18	
P-polyp					27	52,56	17,18,61,62	65

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