Emerging technologies for endoscopic hemostasis

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of emerging endoscopic technologies that have the potential to affect the practice of GI endoscopy. Evidence-based methodology is used, with MEDLINE and PubMed literature searches to identify pertinent clinical studies on the topic. Because many topics have a limited number of peer-reviewed articles, abstracts from scientific meetings are used to supplement the review. The reports focus on the current status of the technologies, areas in need of further research, and barriers to incorporation into the mainstream practice of GI endoscopy.

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BACKGROUND

Endoscopic hemostatic therapy has been shown to improve clinical outcomes for several GI bleeding conditions. Established interventions include injection therapy, thermal ablation (eg, bipolar electrocoagulation and argon plasma coagulation), and application of mechanical devices (eg, clips and band ligators).[1] Although these modalities are usually effective in controlling GI hemorrhage, there are cases in which successful hemostasis can be difficult to achieve because of the lesion features, extent, or location. As a result, new endoscopic hemostatic devices and innovative adaptation of existing techniques and technologies have emerged as alternative modalities for primary control of bleeding or when bleeding is refractory or not amenable to standard therapy.

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TECHNOLOGIES

Hemostatic sprays

Rationale for use. Advantages of noncontact catheter spray delivery of hemostatic agents include ease of use, lack of need for precise targeting, access to lesions in difficult locations, and the ability to treat a wider surface area.

Devices and techniques. Various chitosan- and mineral-based hemostatic granules or powders are used for the control of compressible external hemorrhage in combat casualties and are incorporated in first-aid kits used by the military.[2] One of these compounds (TC-325) is currently undergoing evaluation as a hemostatic agent for endoscopic use. TC-325 is a proprietary, inorganic, absorbent powder that rapidly concentrates clotting factors at the target site, thereby forming an adherent coagulum. The Hemospray (Cook Medical Inc, Winston-Salem, NC) is a hand-held device consisting of a pressurized CO_2 canister, a through-the-scope delivery catheter, and a reservoir for the 21-g powder cartridge. The powder is delivered via push button in 1- to 2-second bursts until hemostasis is achieved. The maximum amount of TC-325 that can be safely administered during 1 treatment session has not been established, but a maximum of 150 g of the powder per patient was used in the only published clinical trial to date.[3] The coagulum typically sloughs within 3 days and is naturally eliminated from the gut. The Hemospray has received regulatory clearance in some countries, but is not yet approved by the U.S. Food and Drug Administration for use in the United States.

Hemostatic sprays derived from plants have also been explored. Clinical experience with these agents for endoscopic hemostasis is currently limited to the off-label use of the Ankaferd Blood Stopper (ABS) (Ankaferd Health Products Ltd, Istanbul, Turkey), a mixture of extracts from several plants that is approved in Turkey for topical treatment of dental and postsurgical external bleeding. ABS promotes formation of an encapsulated protein mesh that acts as an anchor for rapid erythrocyte aggregation without significantly altering individual coagulation factors or platelets.[4] The ABS solution, available in 2-mL vials, is delivered onto the bleeding site via a spray catheter until an adherent yellowish-gray coagulum is formed. The amount required (2-25 mL) and time to hemostasis (seconds to minutes) vary according to the severity of the bleed and the surface area to be treated.

The endoscopic application of cryogenic sprays (liquid nitrogen or CO_2) is used primarily for mucosal ablation (eg, Barrett's esophagus) and, to a lesser extent, for treatment of chronic hemorrhage caused by gastric antral vascular ectasia or radiation proctopathy. The available devices for delivery and the role of cryotherapy in hemostasis were reviewed recently in an ASGE Status Evaluation Report.[5]

Clinical applications. Preclinical, randomized, controlled testing of Hemospray was performed in a heparinized porcine model of severe arterial bleeding. Initial hemostasis was achieved in all pigs treated with Hemospray (n = 5) compared with none in the sham group (n = 5). However, the mean time to hemostasis was 13.8 minutes, and the rebleeding rate was 20%. Foreign-body embolization and tissue injury at the treated site were not observed at necropsy.[6] In a prospective pilot study of 20 patients with actively bleeding peptic ulcers, Hemospray achieved hemostasis in 19 patients with oozing-type bleeding, but failed in the single patient with a pulsatile pseudoaneurysmal bleed. Recurrent bleeding occurred in 2 patients for an overall hemostasis rate of 85%. Second-look endoscopy at 72 hours showed elimination of the coagulum and residual clean-base ulcers. No complications were reported at 30-day follow-up.[3]

Several single case reports and small case series have described control of acute bleeding with the application of ABS in various GI conditions, such as Mallory-Weiss tears,[7] Dieulafoy lesions,[7] gastric antral vascular ectasia,[7] gastric varices,[8-10] anastomotic ulcers,[11] sphincterotomy sites,[12] postpolypectomy sites,[7] radiation proctopathy,[7,13] solitary rectal ulcers,[14] and tumor bleeding.[15-18] As yet, there are no published prospective trials regarding the use of ABS for endoscopic hemostasis.

The available data demonstrate the potential for hemostatic sprays as definitive or bridge therapy, particularly in the management of oozing-type lesions. The efficacy of these agents is unknown in brisk arterial bleeding and may be limited because of the rapid "wash-away" effect of the hemostatic agent by blood flow.[19] Given their mechanism of action, hemostatic agents are also unlikely to be of value for the treatment of nonbleeding visible vessels.

Devices that use pressurized gas for delivery of hemostatic agents, such as Hemospray, interfere with endoscopic visualization because of the transient misting effect, although they may not impair the outcome because precise targeting is not required. Theoretically, hemostatic agents delivered under high pressure could exceed the venous pressure, resulting in embolization. Therefore, the safety of use in the setting of variceal bleeding is unknown.

Research agenda. Additional studies are needed to determine the type of lesions most likely to benefit from hemostatic sprays and the durability of response[20] associated with their use. Potential complications, such as bowel obstruction from foreign-body impaction, embolization, and allergic reactions, have not been reported, but data from larger clinical trials are needed to assess safety. The effects of Hemospray on tissue damage and healing should also be assessed because of the description of tissue injury from exothermic reactions caused by similar compounds.[21] Prospective, randomized trials comparing hemostatic sprays with standard endoscopic hemostatic techniques for primary intervention are anticipated.

Stents for variceal tamponade

Rationale for use. Placement of a covered self-expandable metal stent (SEMS) has been used as salvage therapy for patients with esophageal variceal bleeding that is refractory to standard endoscopic techniques and vasoactive drugs. Compared with balloon tamponade (BT), SEMS placement allows continuation of oral nutrition, does not mandate ongoing endotracheal intubation or impair patient mobility, and can be left in situ for as long as 2 weeks to allow time for recovery and institution of definitive therapy.[22] SEMS placement has also been used in patients who are unable to undergo transjugular intrahepatic portosystemic shunt because of patient instability or contraindications.

Placement of a conventional esophageal SEMS may not be suitable for variceal tamponade for several reasons (eg, incompatible diameter, traumatic retrieval with variceal tearing). However, an SEMS was recently designed for esophageal variceal tamponade and atraumatic removability (SX-Ella Danis stent; Ella-CS, Hradec Kralove, Czech Republic).

Devices and techniques. The SX-Ella Danis stent is a fully covered, nitinol SEMS with variable pitches in stent braiding that conform to esophageal peristalsis in an effort to minimize migration. The stent (13.5 cm long; 30-/25-mm flare/body diameter) is constrained on a 9.4-mm delivery catheter, which also houses an inflatable balloon at the distal end of the stent. The catheter is typically inserted over an endoscopically placed guidewire in the stomach, but can be passed transorally without endoscopic or fluoroscopic guidance in emergent situations. Once in the stomach, the distal portion of the constraining sheath is partially withdrawn to expose and enable inflation of the balloon with 100 mL of air. The delivery system is pulled back as a whole until resistance is felt from impaction of the balloon at the cardia (similar to BT), which corresponds to the level of the distal end of the stent. The stent is then deployed, followed by deflation of the gastric balloon and withdrawal of the stent delivery system.

Removal of the SX-Ella Danis stent is achieved by using a dedicated extraction device (PEX-Ella; Ella-CS). At endoscopy, the loop at the proximal end of the stent is snared and locked with the hook of a wire. The endoscope is removed, leaving in situ the wire attached to the loop. A blunt-tip plastic sheath is then inserted over the wire. Wire traction while advancing the sheath gradually

constrains the stent within the sheath extractor. Once fully constrained, the device is removed from the esophagus.

The SX-Ella Danis stent is CE (Conformité Européenne) marked and available in Europe, but is not currently approved for use in the United States.

Clinical applications. In the largest series reported to date (N = 34), placement of the SX-Ella Danis stent resulted in hemostasis in all patients with active variceal bleeding in whom conventional therapy failed (banding, n = 21; injection sclerotherapy, n = 7; BT, n = 6). The mean stent dwell time was 5 days (range 1-14 days) and allowed the majority of the patients to undergo more definitive therapy during this time interval. Stent migration occurred in 21% of patients, confirmed radiographically, but this did not result in bleeding. All migrated stents could be reconstrained and repositioned by using the extractor.[23]

In another small pilot study (N = 10), stent placement was technically successful in 90% of patients with variceal bleeding who had contraindications to transjugular intrahepatic portosystemic shunt placement or BT. Six of 9 successfully stented patients survived the acute bleeding episode, and the stents were removed uneventfully a median of 9 days after insertion. Failure to control bleeding was observed in 3 patients, in whom bleeding gastric varices were the cause in 2. Minor ulceration of the esophagus caused by stent insertion was observed in 1 patient.[24]

Although the SX-Ella Danis stent appears to be effective at tamponading varices in the mid-distal esophagus in these initial studies, it is unlikely to be useful for the control of bleeding from gastric fundal varices (GFV) or proximal esophageal varices because of its position in the distal esophagus.

Research agenda. Stent placement is an attractive alternative to BT for variceal tamponade, but additional data on efficacy and safety are needed before they can be recommended for routine use. Complications, such as tissue necrosis and fistulization, may become apparent as more data accumulate. A prospective, randomized trial comparing SEMS and BT is desirable, but such a study is unlikely to be performed given the uncommon occurrence of refractory esophageal variceal hemorrhage.

Acute bleeding from some nonvariceal bleeding conditions, such as post-sphincterotomy[25,26] and wide esophageal mucosectomy, may respond favorably to tamponade by SEMS placement when conventional endoscopic therapies have failed. The role of SEMS in these settings should be explored further, including the utility of self-expandable biodegradable stents.

Devices for mechanical closure

Rationale for use. Among the various suturing and clipping devices recently developed for endoscopic antireflux, bariatric and/or natural orifice transluminal endoscopic surgery procedures, the over-the-scope clip (OTSC) (Ovesco Endoscopy AG, Tübingen, Germany) appears most suitable as a hemostatic tool for selected bleeding lesions.

The OTSC is significantly different in design compared with standard endoscopic clips, with higher compression force and capacity to capture a larger volume of tissue. A study on an ex vivo porcine model for arterial bleeding showed the OTSC to be significantly more efficacious than traditional clips for vascular closure,[27] which may translate into more durable and effective hemostasis.

Although endoscopic placement of sutures to control hemorrhage is appealing, the use of current endoscopic suturing techniques may be technically challenging in the setting of acute hemostasis given device complexity, impaired visibility, longer procedure time, and limited maneuverability/access to certain locations.

Devices and techniques. The setup and deployment of the OTSC are analogous to a band ligator. The shape-memory nitinol clip resembles a bear trap and comes preloaded in an opened state on a transparent cap that is mounted on the tip of an endoscope. Suction is applied to capture tissue in the cap, and the clip is released around the entrapped tissue by rotating a hand wheel at the entrance port of the working channel. In addition to suction, dedicated through-the-scope grasping or anchoring devices can be used to approximate tissue margins and capture more tissue in the cap before clip release, although these devices necessitate a 3.2-mm or larger working channel for use. The OTSCs are available in different sizes (11, 12, 14 mm) and shapes of teeth (blunt or pointed). The OTSC caps also differ in diameter and depth to accommodate a range of endoscopes and applications.

The OTSC device is approved by the U.S. Food and Drug Administration for the purpose of endoscopic marking, hemostasis, and closure of luminal perforations less than 20 mm in size.

Clinical applications. Data on the efficacy and safety of the OTSC device are limited to small, descriptive studies.[28-30] In 1 study (N = 27), initial hemostasis was achieved in all patients for a variety of lesions, including peptic ulcer, Mallory-Weiss tear, gastric Dieulafoy lesion, diverticular bleeding, and postbiopsy or postpolypectomy bleeding. Recurrent bleeding occurred in 2 patients (7%).[29] In another study, the OTSC was applied to various bleeding lesions (duodenal ulcer, n = 4; gastric ulcer, n = 1; endoscopic mucosectomy site, n = 1; colonic diverticulum, n = 1) for which conventional clip placement or injection therapy failed. Hemostasis was achieved initially in all patients, but rebleeding (n = 2) and perforation (n = 1) were observed during the follow-up period.[30]

The OTSC device should be suitable for any lesion that is amenable to endoscopic clip placement, but technical limitations apply regarding access (eg, posterior duodenal wall and gastric lesser curve) and grasping of certain lesions (eg, deep, indurated ulcers). Additionally, the endoscope must be withdrawn to mount the device, unlike through-the-scope therapies for bleeding.

Research agenda. Prospective studies with long-term follow-up are needed to identify patients and lesions that are most suitable for the OTSC device, in addition to randomized trials comparing its efficacy and safety relative to those of established techniques (eg, traditional endoscopic clips and coaptive coagulation). Although the cost of a single OTSC is three- to fivefold higher than that of a traditional clip, the cost differential may be offset because multiple standard clips are often required to achieve an effective outcome. Cost-analysis studies are warranted.

EUS-guided angiotherapy

Rationale for use. EUS-guided angiotherapy may play a role in the management of bleeding lesions that are refractory to standard endoscopic and/or angiographic techniques. EUS can identify feeding vessels that are not visible with a standard endoscope and are inaccessible with conventional hemostatic techniques. EUS may enable precise fine-needle injection (FNI) delivery of selected therapy to targeted vessels and assess treatment response with Doppler monitoring.

Devices and techniques. Various agents such as sclerosants, thrombins, and cyanoacrylates (glues) can be administered to targeted vessels by using standard EUS-guided FNI techniques.[31-33]

The coils that are used currently for angiographic embolization[34] can also be delivered to the target vessel through an FNA needle by using the stylet as a pusher. For gastric varices, FNI of coils followed by cyanoacrylate may minimize the risk of glue embolization, with the coils serving as a scaffold to trap the glue within the varix, thereby decreasing the amount of glue needed to achieve variceal obliteration.[35] The coil diameter is selected to approximate that of the targeted varix, and coils of 8 to 20 mm in diameter have been delivered to gastric varices.[35,36]

Clinical applications. The feasibility of EUS-guided angiotherapy was reported initially in a small series of 5 patients, 4 of whom had severe bleeding refractory to standard endoscopic and/or interventional radiologic techniques. EUS-guided alcohol or cyanoacrylate injection in a pancreatic pseudoaneurysm, a duodenal Dieulafoy lesion, a duodenal ulcer, and GI stromal tumors was found to be safe and effective in achieving long-term hemostasis.[37]

EUS-guided coil embolization was successful in a patient with refractory bleeding secondary to anastomotic varices[38] and in 3 of 4 patients with GFV.[36]

The efficacy and safety of EUS-guided transesophageal FNI of GFV with combined coil-glue therapy were described recently in a retrospective study (N = 30).[35] Hemostasis was secured in patients with active bleeding (n = 2), and variceal obliteration was achieved after a single treatment session in 23 of 24 of patients (96%) who underwent follow-up endoscopy. Over a mean follow-up of 193 days (range 24-589 days), recurrent bleeding from GFV was noted in 1 patient. No procedure-related complications or glue-related damage to the endoscope were observed.

Potential limitations to EUS-guided angiotherapy include the presence of intraluminal blood clots that may interfere with conventional endoscopic visualization and identification of the bleeding source, image artifacts from retained luminal contents that may compromise US transmission, induction of extraluminal bleeding that may require salvage angiographic or surgical intervention, instrument availability and transportation issues, and glue-related instrument damage.[39] Additionally, this method is technically challenging and requires special expertise.

Research agenda. The development of criteria for patient selection and studies assessing the efficacy, safety, and role of EUS-guided angiotherapy relative to established endoscopic, angiographic, and surgical interventions is anticipated. The development of new instrument designs and dedicated accessories (eg, EUS-specific microcoils) to facilitate EUS-guided angiotherapy are encouraged. For the treatment of bleeding gastric varices, further studies are needed to determine whether EUS-guided coil-glue injection improves safety and efficacy over standard endoscopic glue injection alone.

SUMMARY

Novel endoscopic hemostatic devices and techniques have emerged for use as definitive, adjunctive, or bridge therapy. Their ease of use, efficacy, safety, cost, and role relative to established hemostatic techniques are among factors that will ultimately determine inclusion of these devices in the armamentarium of tools for endoscopic hemostasis.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publicaton.

Abbreviations: ABS, Ankaferd Blood Stopper; BT, balloon tamponade; FNI, fine-needle injection; GFV, gastric fundal varices; OTSC, over-the-scope clip; SEMS, self-expandable metal stent.

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