Endoscopic treatment of acute variceal hemorrhage by using hemostatic powder TC-325: a prospective pilot study

Mostafa Ibrahim, MD,[1,2] Ahmed El-Mikkawy, MD,[2] Ibrahim Mostafa, MD, PhD,[2] Jacques Devière, MD, PhD[1]

Brussels, Belgium; Cairo, Egypt

Background: Current standard of care of acute variceal bleeding (AVB) combines hemodynamic stabilization, antibiotic prophylaxis, pharmacological agents, and endoscopic treatment. The latter may be challenging in an emergency setting with active bleeding that interferes with visualization.

Objective: To assess the effectiveness of a pre-established delivery protocol of a hemostatic powder to control AVB originating from the esophagus or the gastroesophageal junction.

Design: Prospective, 2-center study.

Setting: Two tertiary-care referral university hospitals.

Patients: Nine patients who received endoscopic hemostatic powder for actively bleeding varices.

Interventions: Endoscopic hemostasis.

Main Outcome Measurement: Primary hemostasis and rebleeding rates.

Results: Nine consecutive patients with confirmed AVB underwent treatment within 12 hours of hospital admission. Bleeding stopped during the endoscopy performed with application of 21 g of hemostatic powder from the cardia up to 15 cm above the gastroesophageal junction. No rebleeding was observed in any of the patients within 24 hours. No mortality was observed at 15-day follow-up.

Limitations: Small sample size.

Conclusion: Hemostatic powder has the potential to temporarily stop AVB. (Clinical trial registration number: NCT01783899.)

Acute variceal bleeding (AVB) is a severe adverse event of portal hypertension in patients with liver cirrhosis. The primary therapy includes the administration of vasoactive drugs, antibiotics, and endoscopic therapy; esophageal banding ligation and/or cyanoacrylate injection when bleeding occurs from gastric varices is preferable.[1]

Although timely endoscopy (within 24 hours of admission) plays a central role in the management of AVB, it

Abbreviations: AVB, acute variceal bleeding; GE, gastroesophageal.

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This video can be viewed directly from the GIE website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

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Current affiliations: Department of Gastroenterology, Hepatopancreatology, and Digestive Oncology, Erasme Hospital, Université Libre de Bruxelles, Brussels, Belgium (1), Department of Gastroenterology and Hepatology, Theodor Bilharz Research Institute, Cairo, Egypt (2).

Reprint requests: Mostafa Ibrahim, MD, Department of Gastroenterology, Hepatopancreatology, and Digestive Oncology, Erasme Hospital, Université Libre de Bruxelles, Brussels 1070, Belgium.

If you would like to chat with an author of this article, you may contact Dr Ibrahim at mostafa.ibrahim@webgit.net

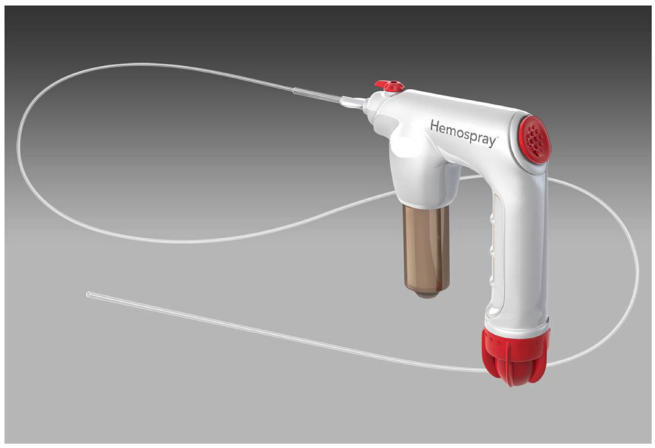

Figure 1. Hemospray Kit

cannot be offered at every center because of the lack of resources and limited access in expert endoscopy services.[2] Moreover, treatment may be technically challenging, and treatment failures are reported in 10% to 15% of the cases. This early phase of AVB management remains important, even when early transjugular intrahepatic portosystemic shunt placement is indicated.[3]

A hemostatic powder (Hemospray; Cook Medical, Winston-Salem, NC) (Fig. 1) was recently introduced for the management of nonvariceal upper GI bleeding and was shown to be effective in preliminary studies for the management of peptic ulcer bleeding[4] and cancer-related bleeding[5] and temporarily control bleeding in severe situations[6]; in addition, the use of Hemospray for salvage hemostasis in variceal bleeding was described in 2 previous case reports.[6,7]

We conducted a 2-center prospective trial to evaluate the use of this hemostatic powder, administered according to a simple and potentially less operator-dependent protocol in early control of acute esophageal variceal bleeding.

PATIENTS AND METHODS

Patients

Fourteen consecutive patients with known liver cirrhosis and suspected acute variceal bleeding originating from the esophagus up to the gastroesophageal (GE) junction consented to be included in the study. The ethics committees of Erasme University Hospital (B406201214760) and Theodor Bilharz Research Institute (TBRI-IRB01/13) approved the protocol, and the study was registered in clinicaltrials.gov under the number NCT01783899.

Take-home message

- Endoscopic treatment of acute variceal bleeding is still challenging in emergency situations.
- Hemostatic powder may have a role in controlling acute variceal bleeding, at least temporarily.

Hemostatic powder

TC-325 is a granular, mineral, nonabsorbable powder used for the management of arterial wounds. It produces hemostasis by increasing the concentration of clotting factors, activating platelets, and forming a mechanical plug on the injured blood vessel.[8] It appears to principally affect hemostasis through its ability to quickly absorb water, creating a physical barrier and a local lattice. It also alters clotting time in ex vivo study.[9]

When the powder comes into contact with moisture in the GI tract, it becomes cohesive and adhesive, forming a stable mechanical barrier that adheres to and covers the bleeding site to achieve hemostasis. As the powder is not absorbed or metabolized by mucosal tissue, there is no risk of systemic toxicity. The covering formed by the powder separates from the intestinal wall and is naturally eliminated from the GI tract.[4] Its delivery system consists of a syringe containing the Hemospray powder (21 g per syringe), a delivery catheter that is inserted into the working channel of the endoscope, and an introducer handle with a built-in CO_2 canister to propel the Hemospray powder out of the catheter.

Endoscopic procedure

All endoscopies were performed within 12 hours after admission in patients having a first episode of suspected variceal bleeding. All patients had confirmed AVB characterized by actively bleeding varices or fibrin plugs and/or red streaks of the mucosa overlying the varices with the presence of fresh blood within the lumen of the esophagus and the stomach.

After identification of a bleeding site located in the esophagus or at the GE junction, the hemostatic powder was administered after a standard protocol, the catheter being located at the level of the cardia and the powder being delivered (21 g per syringe) by a noncontact delivery approach, over the distal 15 cm of the esophagus (ie, always avoiding application within the proximal 5 cm of the esophagus), while slowly pulling back the endoscope (Fig. 2; Video, available online at www.giejournal.org).

Hemospray was then delivered in short spray bursts (for 1–2 seconds) until hemostasis was confirmed. Once bleeding was controlled (first application), the bleeding site was observed for 3 minutes under endoscopy. If bleeding recurred during this 3-minute