

Topical Hemostasis in Endoscopy

Hemospray® Endoscopic Hemostat

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Background

- Non-Variceal Bleeding in the GI Tract is a significant medical event
 - Over 500,000 admissions annually in the US
- Current therapy includes sclerosants, vasoconstrictive agents, cautery and ligation with clips
 - Between 10-20% have continued or recurrent bleeding¹
 - Mortality rate is between 2-4%¹
- Malignant bleeding outcomes are poor
 - Successful hemostasis rate as low as 40%^{2,3}
 - Recurrent bleeding over 50% within 1 month after standard treatments^{2,3}
 - Mortality 95% within first 3 months after treatment^{2,3}

¹Lau J, Barkun A, Fan D, Kuipers E, Yang Y, Chan F. Challenges in the management of acute peptic ulcer bleeding. Lancet 2013; 381: 2033–43

²Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489-95.

³Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

Hemospray

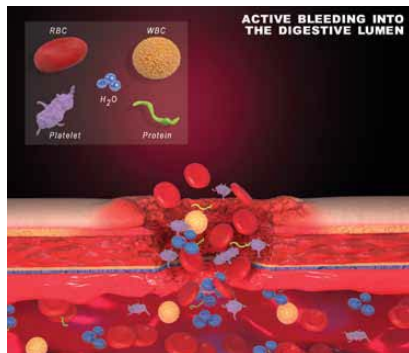
- Hemospray® Endoscopic Hemostat is a device consisting of a hemostatic agent and a delivery system. The hemostatic agent is an inert, bentonite powder developed for endoscopic hemostasis of nonvariceal gastrointestinal bleeding
- Bentonite rapidly absorbs water and becomes cohesive to itself and adhesive to tissue forming a physical barrier to aqueous fluid (e.g., blood)
- Nontraumatic, nonthermal, noncontact, nonspecific targeting option for patients



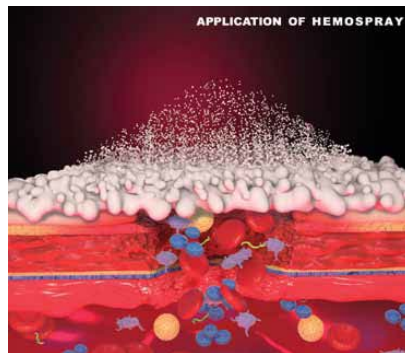
Procedure Description

- An endoscope is first passed into the gastrointestinal tract to identify the source of bleeding. Once the source is located, the Hemospray® delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site, without making contact with the gastrointestinal (GI) tract wall. The material is propelled through the application catheter by release of carbon dioxide from the cartridge located in the device handle and sprayed onto the bleeding site.
- Hemospray® is not absorbed by the body and does not require removal as it passes through the lower GI tract within 72 hours.

Hemospray Method of Action

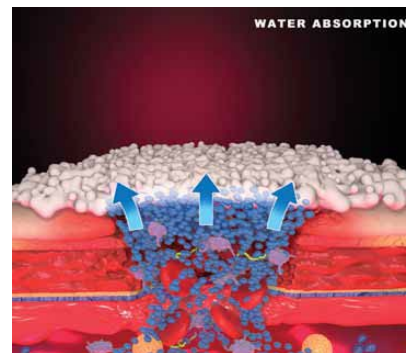


1 Active bleeding



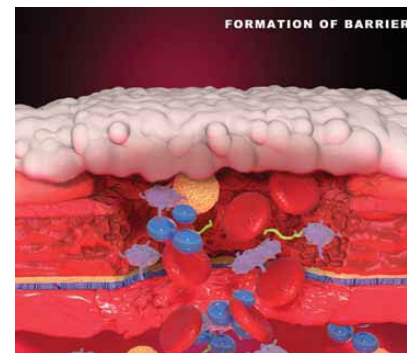
2 Application

When Hemospray powder comes in contact with an active bleed, it begins to absorb water from the blood.



3 Water absorption

As Hemospray powder absorbs water from the blood, it acts both cohesively and adhesively to form a mechanical barrier.



4 Barrier

The mechanical barrier formed by Hemospray powder will remain until the active bleeding has stopped and a clot has formed.

How does Hemospray work?



Before



During



After

Alternative Treatments

- Treatment for continued bleeding
 - Repeated endoscopic intervention
 - Trans Arterial Embolization
 - Surgery
- Urgent surgery has poor outcomes¹
 - 55% morbidity
 - 30% mortality
- Embolization carries significant risk²
 - Rebleeding higher than surgery
 - No difference in mortality vs surgery

Hemospray for Non-variceal bleeding

- High immediate hemostasis rates with Hemospray
 - 88-96% when used as part of first line treatment^{1,4}
 - 85-92% when used as rescue after failure of other methods^{1,3}
- Utility as a rescue treatment with Hemospray
 - Moole V, et al: Hemospray as rescue therapy has significantly higher rates of hemostasis than other available interventions²
 - Rodriguez de Santiago et. al.: 92.6% intraprocedural hemostasis as rescue treatment³
 - Intraprocedural hemostasis with Hemospray was the only predictor of improved survival³

1) Changela K, Papafragkakis H, Ofori E, et. al. Hemostatic powder spray: a new method for managing gastrointestinal bleeding. Ther Adv Gastroenterol 2015; 8(3): 125-135

2) Moole, V., Chatterjee, T., Saca, D., Uppu, A., Poosala, A., & Duvvuri, A. A Systematic review and meta-analysis: analyzing the efficacy of hemostatic nanopowder (TC-325) as rescue therapy in patients with nonvariceal upper gastrointestinal bleeding. Gastroenterology 2019; 156(6), S-741

3) Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et. al. Hemostatic spray TC-325 for GI bleeding in a nationwide study: survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581-590.

4) Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019 doi:10.1111/den.13502

Hemospray for Malignant Bleeding

- Malignant bleeds pose a significant clinical challenge
 - Typically diffuse with friable mucosa
 - Successful hemostasis as low as 40%^{1,2}
 - Recurrent bleeding in over 50%^{1,2}
 - 95% mortality within 3 months^{1,2}
- Hemospray offers significant improvement
 - Over 90% immediate hemostasis³
 - Better outcomes when used as first line treatment
 - Chen et al: 90% Hemospray first line vs. 40% standard of care⁴
 - Recurrent bleeding 20% vs 60% standard of care⁴
 - Rebleeding 17.1% as first line vs 46.7% when used as rescue⁴

¹Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489-95.

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⁴Chen Y-I, Wyse J, Lu Y, Martel M, Barkun AN, TC-325 hemostatic powder versus current standard of care in managing malignant GI bleeding: a pilot randomized clinical trial. Gastrointestinal Endoscopy (2019), doi: <https://doi.org/10.1016/j.gie.2019.08.005>.

Summary

- Currently, there is no code that describes the application of a topical gastrointestinal hemostat
- Hemospray achieves immediate hemostasis in a high percentage of patients who fail with standard of care dual therapy
- Hemospray appears to be a particularly effective treatment option for bleeding from malignant lesions