

A different approach to hemostasis

Cook Medical is excited to now offer US clinicians and their patients the Hemospray[®] Endoscopic Hemostat—an important, effective option for patients with nonvariceal bleeds in the gastrointestinal tract.

“We are extremely happy to receive this approval to market from FDA,” said Barry Slowey, president of Cook Medical’s Endoscopy speciality. “Hemospray gives physicians in the United States another tool to treat patients suffering GI bleeds. We have worked diligently to bring a different approach to hemostasis for gastroenterology teams across the United States.”

The revolutionary treatment modality has been making a clinical impact internationally since 2012. In this special issue of The Channel, you will find 13 cases that demonstrate Hemospray’s efficacy as a unique endoscopic treatment option for certain GI bleeds.

There is a list of clinical studies at the back of this publication and at our dedicated Hemospray website*: hemospray.cookmedical.com. The website includes Hemospray case videos, product specifications, FAQs and other supporting information for physicians and their patients. You will also learn about upcoming Hemospray Vista Education and Training events in your area.

*The Hemospray website is accessible only to those countries where Hemospray is available.



NOW

**Available
in the USA**

Hemospray® Endoscopic Hemostat changing GI bleed management options

Nursing perspective from Tara Shepherd

Nottingham University Hospitals (NHS Trust) supports the healthcare service needs of more than 2.5 million residents of Nottingham, England and nearby communities. In addition, specialist expertise impacts the care of 3 to 4 million people in the region.

The Channel: Hemostasis procedures can be very stressful especially for clinicians new to the GI endoscopy suite. What factors can contribute to decreasing this stress for those assisting and supporting the patient?

Deputy Sister Tara Shepherd: We decrease this stress level by having simple and effective treatment options to ensure a positive outcome for our patients. Hemospray is quick to set up and very easy to use. Staff members have found upper GI bleed cases less stressful since we have been using Hemospray. They feel more confident in being able to provide a positive safe treatment option for these patients. Sometimes we are faced with cases where you know the site of bleeding. However due to the obscure nature you may not be able to apply certain hemostasis devices, so it is comforting to know that you have Hemospray and in those emergency situations you can have it ready for immediate response.

The Channel: What are the most challenging issues that your team encounters most often in hemostasis-related procedures?

Shepherd: When you are faced with an upper GI bleed, you try to assess source and decide what will be the best way to treat it. Some other hemostasis devices using a contact approach can cause further trauma such as thermal devices which can be successful in these procedures. However with a large oozing area such as a post EMR/ESD site, personally I have found Hemospray to be very effective.

Hemostasis-related procedures are difficult cases where we need to think of other alternative treatments. Technique and scope positioning do have an impact on some hemostasis devices. An important consideration is that the Hemospray catheter can be used in retroflexion. This again has increased the confidence level for physicians and staff members.

The Channel: Do you have a specific training approach for your staff when it comes to learning about the different hemostasis modalities in GI bleed management?

Shepherd: All staff members are given a Hemostasis booklet to complete both by the Trust and Cook. These booklets go through the types of hemostasis procedures and let the staff identify ulcers, grading of varices and the different modalities of treatment (ideally two). The clinicians have hands-on training from the Cook representatives in actual cases and simulated cases.

The Channel: What has been the learning curve with regard to your team's support of Hemospray utilization? Can you briefly discuss how long Hemospray has been available in your unit and approximately how many cases so far have involved its use?

Shepherd: Hemospray has been used in the unit since its release in late 2013. We have used it on around 200 cases. These cases include both emergency and elective (EMR's) procedures. Hemospray was first used in our Trust following a complication from an EUS procedure with lifesaving effect. Hemospray provides us with time and helps us identify areas of bleeding. I have witnessed in one case where the physician could not identify the exact point of bleeding and used Hemospray in the area of suspicion. The next day when we had another look endoscopically, we could see where the Hemospray had been used and successfully stopped a bleeding vessel. This allowed us to then treat the vessel successfully with a contact therapy to prevent a re-bleed.

The Channel: In general, how do you foresee Hemospray's impact as an addition to the bleed management options available to your physicians?

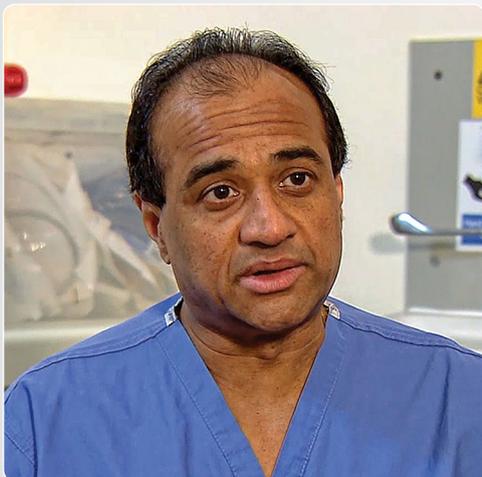
Shepherd: Hemospray already has a positive impact on bleed management, and I believe this is going to continue to grow. As an addition to bleed management, this is a positive advance in patient treatment.

“ Staff members have found upper GI bleed cases less stressful since we have been using Hemospray. ”
- Deputy Sister Tara Shepherd

See Nottingham University Hospitals' clinicians discuss benefits of Hemospray®

Go to the www.cookmedical.eu/endoscopy/giving-clinicians-another-option-in-their-toolkit to view a video, featuring Dr. Martin James, Prof. Krish Raganath and Deputy Sister Tara Shepherd of Queens Medical Centre in Nottingham, a facility that has been using Hemospray since its release. In the video, Dr. James notes: "There are difficult cases where we need to think of other options. Without the investment in innovations such as Hemospray, it's hard to see that we can advance the field of medicine."

The video is co-produced by ITN Productions, Cook Medical and the RSM.



*Professor Krish Raganath
Professor of GI Endoscopy
Head of Endoscopy Service Consultant
Gastroenterologist
Nottingham University Hospitals NHS Trust*



*Deputy Sister Tara Shepherd
Nottingham University Hospitals NHS Trust*



*Dr. Martin James
Consultant Hepatologist and Gastroenterologist
Nottingham University Hospitals NHS Trust*

“There are difficult cases where we need to think of other options. Without the investment in innovations such as Hemospray, it's hard to see that we can advance the field of medicine.”

- Dr. Martin James

*Dr. Martin James is a paid consultant for Cook Medical.
Prof. Krish Raganath and Deputy Sister Tara Shepherd are not paid consultants for Cook Medical.*

Upper GI bleeding treated with Hemospray® in Brazil



Felipe I. Baracat, MD



Diogo T. Hourneaux De Moura, MD

Gastrointestinal Endoscopy Unit
University of São Paulo Medical School
São Paulo, Brazil



An 89-year-old patient was hospitalized for complex incisional hernia surgery after surgical treatment of colon cancer. The patient has a history of multiple comorbidities, such as hypertension and diabetes, as well as a previous heart surgery for acute ischemic infarction. The patient uses ASA chronically and was on anticoagulant medications because of his post-operative condition.

The patient presented with two episodes of upper gastrointestinal bleeding during the same hospitalization. The first episode was caused by a Cameron ulcer. At the moment of the EGD, it was actively bleeding (oozing) as seen in (Figure 1). The bleeding lesion was properly treated with Hemospray and epinephrine injection (Figure 2). As Hemospray is a new treatment technique, we performed second-look endoscopy on the next day to ensure the success of the therapy. Since the bleeding episode, the patient remained in a poor hemodynamic condition and high pulse rate.

Curiously, at second-look endoscopy, the patient presented an actively bleeding Dieulafoy lesion, about 2 cm distal to the Cameron ulcer lesion (that showed a good response to the Hemospray therapy performed the day before) as seen in (Figure 3). Once again, the patient was treated with Hemospray and epinephrine injection. A new EGD was performed on the following day and both bleeding lesions appeared to be very well controlled (Figure 4).

The patient needed two packed red blood cells after each bleeding episode (a total of four packs). Despite the adverse clinical conditions, the patient had a favorable outcome with the use of this new hemostatic tool.

Drs. Felipe I. Baracat and Diogo T. Hourneaux De Moura are not paid consultants for Cook Medical.



Figure 1: Oozing bleeding from a Cameron ulcer.

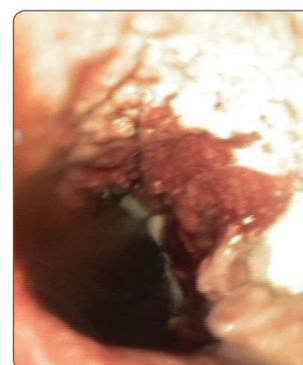


Figure 2: Treatment of the Cameron ulcer with Hemospray.

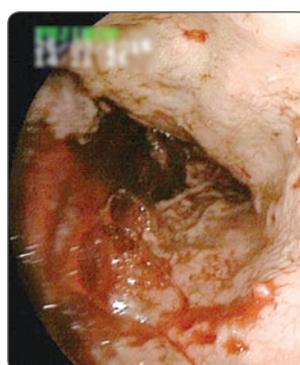
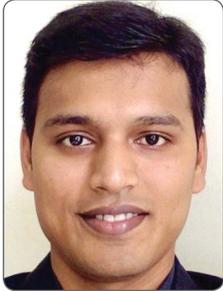


Figure 3: Active bleeding from a Dieulafoy lesion, 2 cm distal from the Cameron ulcer properly treated on the day before.



Figure 4: Both lesions with controlled bleeding at the third EGD.

Hemospray® in the treatment of bleeding malignant duodenal ulcer



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Duke-NUS GMC
Singapore*

A 64-year-old patient, who was treated with rivaroxaban for atrial fibrillation, presented with melena. The patient's history included diabetes mellitus and ischemic heart disease. After stabilization, an endoscopy was performed and showed a large (3 cm), deep fibrotic ulcer in the duodenal bulb. The surface of the ulcer appeared friable and was bleeding actively from multiple punctate spots, as seen in (**Figure 1**). We used Hemospray (Cook Medical, Winston-Salem, North Carolina, USA) to provide hemostasis of the diffuse bleeding. We sprayed the powder through a 10 Fr catheter in short bursts (**Figure 2**). Complete cessation of bleeding was immediately achieved (**Figure 3**).

We repeated the endoscopy 24 hours later, which showed no bleeding. The ulcer was whitish as it was covered with coagulated Hemospray powder (**Figure 4**). Because the lesion appeared neoplastic, we performed multiple biopsies and re-applied the Hemospray to prevent re-bleeding. The biopsy showed duodenal adenocarcinoma. A CT scan was subsequently performed. There was no evidence of metastasis but multiple bilateral pulmonary emboli were found. As a result of these CT findings, a third endoscopy was



Figure 1

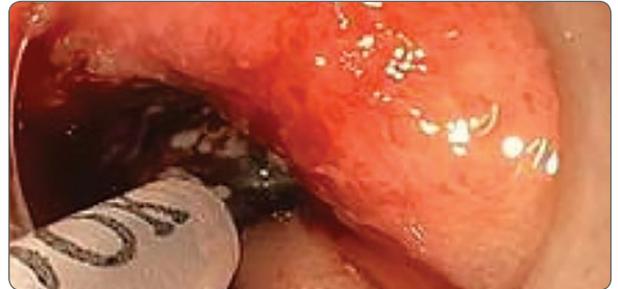


Figure 2



Figure 3



Figure 4

performed to show absence of high-risk features for bleeding prior to starting low molecular weight heparin. Unfortunately, the patient developed a concurrent cerebrovascular event and severe GI bleeding one week later. The rapidity of the patient's deterioration precluded further endoscopic therapy.

In this case, we found that the use of Hemospray was safe and effective to treat diffuse bleeding from an ulcerated duodenal cancer. We did not use hemostatic clips or thermal coagulation because of the diffuse nature of the bleeding spots. Further, the fibrotic base and depth of the ulcer would make treatment using other modalities difficult to apply. The non-contact and non-specific target application of Hemospray makes it easier in these situations.

In conclusion, diffuse bleeding from malignant ulcers may be effectively managed with Hemospray. Definitive treatment targeting the underlying etiology, along with Hemospray, can provide sustained hemostasis.

Drs. Ravishankar Asokkumar, Brian Schwender and Roy Soetikno are not paid consultants for Cook Medical.

Hemospray® management of critical bleeding in the duodenal bulb



Luca Rodella, MD
Chief



Filippo Catalano, MD

Emergency Surgical Endoscopy Unit
University of Verona, Italy

Background

Since 1987, the Endoscopic Surgery Unit at University of Verona, Italy, has treated more than 7,000 patients with digestive bleeding. Retrospectively, a complete hemostasis has been obtained in more than 94% of cases with the majority of them successfully treated with injection of dilute adrenaline and 1% polidocanol. In case of failure, especially for severe bleeding from the posterior wall of the stomach and duodenum, cyanoacrylate, argon plasma coagulation or hemoclips were used. In a limited number of cases, with large and deep ulcers, bleeding from large vessels, hemodynamic instability and frequent rebleeding, a successful endoscopic treatment was impossible and a surgical intervention required.

Case Report

An 80-year-old was admitted to the First Aid Department for hematemesis and melena. The patient suffered from the outcomes of a previous stroke, atrial fibrillation and gallbladder cancer. At admittance, a severe hemorrhagic shock was present with hypotension, tachycardia, sweating and, finally, gasping. Blood test showed a hemoglobin level of 4.2 g/dl. The patient received concentrated red cells (3 units) and crystalloids during the intervention. After resuscitation and intubation, an urgent gastroscopy was performed.

Procedure

The examination was conducted with an Olympus therapeutic endoscope and Olympus Endowasher. Gastroscopy showed an external compression on the gastric antrum (**Figure 1**) and an active bleeding (**Forrest IA**) from a large, deep ulceration in the duodenal bulb (**Figures 2 and 3**). Any traditional endoscopic treatment was impossible to apply due to the ulcer's characteristics. The last chance was to apply Hemospray Endoscopic Hemostat.

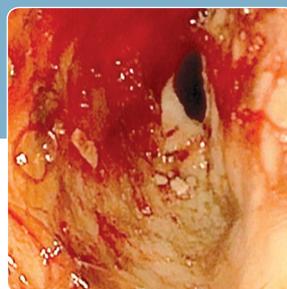


Figure 1

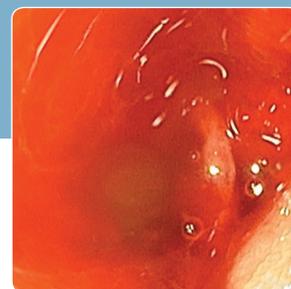


Figure 2

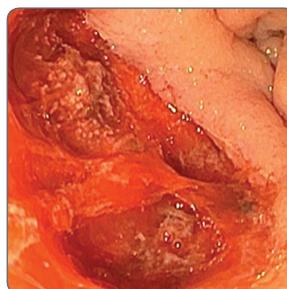


Figure 3



Figure 4

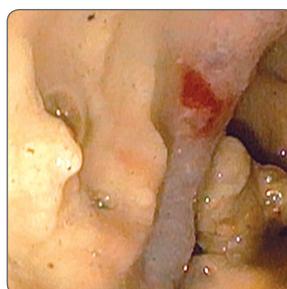


Figure 5

Immediate hemostasis was obtained (**Figures 4 and 5**). At the end of the procedure, no bleeding could be found.

The patient was admitted to ICU without rebleeding in the successive three days. An abdominal CT scan showed a gallbladder cancer with adhesion to the antro-duodenal region as well as fistulisation and an abscess that produced a large and deep ulceration in the duodenal bulb.

Four days after admission, the patient was awake and conscious, although aphasic as a stroke sequela and hemodynamically stable. The patient was transferred to the geriatric ward where, after discussion with oncologists and psychiatrists, the patient decided to avoid any other form of treatment. No rebleeding was observed after one month.

Conclusion

The reported case is unique, due to fistulisation in the duodenal bulb of an abscess in a gallbladder cancer. Bleeding was massive, causing a hemorrhagic shock. Hemospray was successful, avoiding a surgical intervention that, considering the multiple comorbidities, would have been dramatic for the patient.

Hemospray may be an interesting alternative to other traditional endoscopic treatments to reduce the number of patients that need urgent surgical intervention for massive digestive bleeding and any emergency endoscopy unit should be so equipped.

Drs. Luca Rodella and Filippo Catalano are not paid consultants for Cook Medical.

Hemospray is contraindicated in patients who have gastrointestinal fistulas, are suspected of having a gastrointestinal perforation, or are at high risk of gastrointestinal perforation during endoscopic treatment.

Hemospray® Endoscopic Hemostat

A welcomed, effective addition to current treatment



Alan Barkun, MD McGill University Montreal, Canada

Hemospray is a granular, mineral-based compound applied as a powder through an endoscope. The compound adheres to actively bleeding lesions and absorbs water locally to effect a protective and occlusive bandage-like slurry that results in stoppage of bleeding. It is a welcomed and effective addition to current treatment options to stop active GI bleeding through an endoscope.

Hemospray has been released in Canada, Mexico, Hong Kong and

throughout Europe. It is being progressively launched in many other areas of the world after appropriate training. Indeed, education of physicians is critical to ensure the appropriate use of Hemospray.

Although Hemospray has been shown to be successful in treating a wide range of GI bleeds, perhaps one of the most promising and gratifying contexts is its potential role in treating patient bleeds that result from cancers in the gastrointestinal tract.

Hemospray has also been useful to stop bleeding from benign causes when other modalities—including injection with thermal hemostasis, clipping, percutaneous embolization and even surgery—have failed.

Dr. Alan Barkun is a paid consultant for Cook Medical.



Actively bleeding lesion



Application of Hemospray

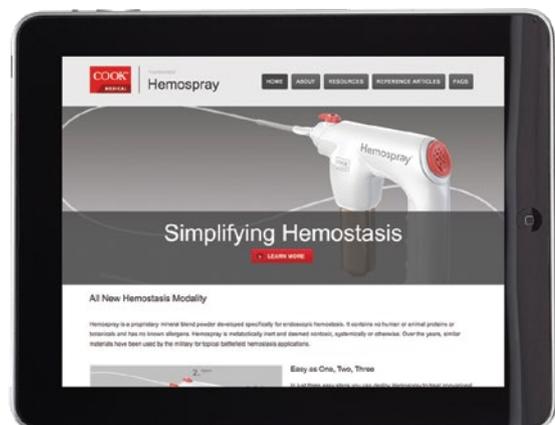


Post application of Hemospray

Easy access to the latest news and clinical data on Hemospray®

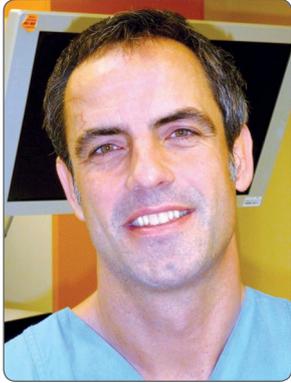
Cook Medical's Hemospray website is your ultimate destination for the most comprehensive and relevant information on this exciting hemostatic treatment modality. In one place, you can easily access literature, clinical references, FAQs, a video library, links to reference articles and much more. The site also allows you to request a schedule of Vista educational events and other valuable information.

Our goal is to give you everything you need to support you and the patients you serve. Be sure to let us know what you're thinking with your feedback and comments.



Visit hemospray.cookmedical.com

Hemospray® in hemodynamic relevant bleeding in the area of a Billroth II anastomosis



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Background

The Asklepios Hospital St. Georg in Hamburg has one of the largest emergency departments in the city, where gastrointestinal bleeding represents a quite common reason for hospitalization. Therefore, we have to offer an effective endoscopic 24-hour emergency service. As an additional option for hemostatic therapy, we now have Hemospray Endoscopic Hemostat and have trained the medical and the nursing team in the use of this new method. In emergency cases, we do work with a therapeutic endoscope containing a large working channel, so we can use Hemospray with the 10 French catheter.

Presentation and Diagnosis

An 86-year-old patient came to our central emergency unit in an ambulance. The otherwise fully mobile and participatory patient had collapsed several times in the last few hours and had severe weakness and dizziness. For the last three days, the patient observed a black colored stool without observation of fresh bleeding. Many years ago, a Billroth II operation for a gastric ulcer had been accomplished. In the 1990s, there had been upper gastrointestinal bleeding for more than 10 years and no gastroscopy had been carried out. There has been long-term medication with Clopidogrel.

Initial blood testing showed a Hemoglobin-value of 8.1 g/dl with a normal amount of thrombocytes and normal plasmatic blood coagulation. A digital rectal investigation with a test on occult blood in the stool proved the suspected melena.

Because of the slowly decreasing hemoglobin value and an unstable blood pressure, we suspected upper gastrointestinal bleeding and set up an emergency gastroscopy.

Procedure

The patient was sedated with Propofol and received red cell concentrate and electrolyte solution during the intervention.

The examination was conducted with an Olympus therapeutic endoscope and an Olympus Endowasher. The examination showed a typical Billroth II anastomosis with, in that combination, considerable bleeding from multiple shallow ulcerations, classified as Forrest Ib (**Figure 1**). No other bleeding was noted in the upper GI tract. Four endoscopic clips were placed but sufficient hemostasis could not be achieved. In fact, below the clips, the bleeding became stronger (**Figure 2**). We then injected Suprarenin 1:10,000 circular in the area of the bleedings.

But even with this method, sufficient hemostasis could not be reached. Then the patient became more and more circulatory unstable. And because of the large amounts of intragastric blood, we discussed an intubation to avoid aspiration. But before taking that step, we decided to use Hemospray (**Figure 3**).

First, as much liquid as possible was suctioned off the remainder of the stomach. The working channel was dried by a multiple air perturbation with a 50 cc syringe and the Hemospray catheter was inserted. We then followed with the circular application of multiple sprays of Hemospray until the whole area of the anastomosis was covered (**Figure 4**). Intermittently, the catheter became blocked due to the still large amount of gastric blood.

At the end of the procedure, no bleeding could be found. The patient stabilized noticeably. Despite the overall administration of six red cell concentrates, the hemoglobin value was only at 9.6 g/dl at the end of the procedure, which shows the degree of the initial bleeding. Following the intervention with Hemospray, no further blood transfusions were necessary. Since an intubation was no longer necessary, the patient could be brought to an intermediate care unit for surveillance.

The next day, the shallow ulcerations showed a noticeable healing tendency (**Figure 5**). In one location, there were smaller fresh bleeding sites and Hemospray was applied again. Further endoscopic interventions were not necessary.

“ This was our staff’s first procedure using Hemospray. In this emergency situation, they found it intuitive and easy to use. The hemostasis was successful while previous, established therapies hadn’t worked. ”



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5

Conclusion

In this case, the use of Hemospray in a distinct upper gastrointestinal bleeding helped us avoid a dramatic course of events. An operation would have been a high risk considering the Billroth II situation and the advanced age of the patient.

This was our staff's first procedure using Hemospray. In this emergency situation, they found it intuitive and easy to use. The hemostasis was successful while previous, established therapies hadn't worked.

Hemospray offers important features to perform easy-to-use and effective hemostatic therapy and can, as in this case, expand the endoscopic options in the crucial moment.

Dr. Karsten Ohlhoff and Brigitte Zawallich are not paid consultants for Cook Medical.

Potential complications

Use of Hemospray in the presence of bowel obstruction and/or an anastomosis may pose a risk of injury due to over-distention.

Successful Hemospray® treatment of duodenal bulb ulcer



*Dr. Lars Karlsen
Stavanger University
Hospital Stavanger,
Norway*

A 76-year-old patient—diagnosed with pulmonary embolism and was being treated with 80 mg of enoxaparin twice a day—presented with melena and a drop in hemoglobin from 12.3 to 8.7 g/dl. Endoscopy revealed a duodenal bulb ulcer with visible vessel and oozing bleeding.

Hemospray was applied and the bleeding stopped. Anticoagulation was stopped for 12 hours and resumed after endoscopy on the following day showed an ulcer with rest of a visible vessel in the ulcer base. There were no signs of further bleeding and the patient was transferred to the department of hematology for further treatment.

Dr. Lars Karlsen is not a paid consultant of Cook Medical.



At 24 hour endoscopy follow-up

Images courtesy of Dr. Lars Karlsen, Stavanger University Hospital, Stavanger, Norway.

Hemospray® controls bleeding during ESD



*Dr. David Martins Serra
Hospital da Luz Lisbon,
Portugal*

A 67-year-old patient presented for ESD-gastric adenoma width 30 mm. During ESD, oozing started without control with adrenaline injection and clipping. We used Hemospray with total control of bleeding. Durable, hemostatic control found at 72-hour follow-up endoscopy.

Dr. David Martins is a paid consultant of Cook Medical.



Images courtesy of Dr. Serra, Hospital da Luz, Lisbon, Portugal.

At 72 hours

The use of Hemospray® to control sphincterotomy bleeding



*Dr. George Webster
University College Hospital
London, UK*

A 64-year-old patient presented with right upper quadrant pain, jaundice, and imaging showed stones in CBD. Previous medical history includes placement of metal stents, transient ischemic attack and currently taking Dalteparin (form of heparin). Upon admission, ERCP was completed along with sphincterotomy, small stone extraction, and placement of a pancreatic stent. At 4-day follow-up endoscopy post-ERCP bleed was discovered at ulcerated sphincterotomy site. Adrenaline was injected and acute hemostasis was achieved.

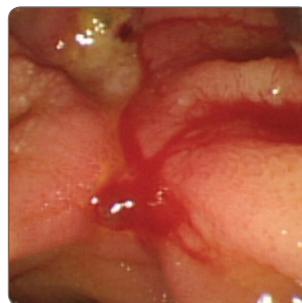
At day 6, the patient suffered from ongoing melena and was re-scoped. Placement of two hemostatic clips offered by a different manufacturer was attempted, but failed. The procedure was completed with adrenaline injection and contact thermal therapy. One week later (day 13), arterial bleeding persisted from the ulcerated sphincterotomy site. Contact thermal therapy and IV PPIs were provided. Five days later (day 18), the bleeding continued with visible vessel distal to the sphincterotomy site; clipping was attempted but failed once again. The procedure was completed with additional adrenaline injection and contact thermal therapy.

The patient's melena continued and the patient received 10 units of blood before being referred to University College Hospitals (UCH) (at day 21) for further management. Upon endoscopy at UCH, active bleeding from the point below the sphincterotomy was visualized. This bleeding was related to the trauma caused by the attempted placement of the different manufacturer's clips and use of the contact thermal therapy, due to the obscured view from duodenoscopy bridge. The procedure was completed by deploying two Cook Instinct clips onto the bleeding site, placing a prophylactic pancreatic stent, and applying Hemospray to the general bleeding area.

Post-Procedure/Follow-up:

No further bleeding/transfusion requirement.

Day 44: Repeat OGD at UCH
Pancreatic stent migrated
Clips displaced
Scar at bleeding point
Ulceration resolved
Patient well and discharged



At follow-up endoscopy

Images courtesy of Dr. Webster, University College London Hospitals, London, UK

The Case Demonstrated:

1. The difficulty with controlling sphincterotomy bleeding, particularly the deployment of older generation clips through the bridge of the duodenoscope.
2. The ease of application of Hemospray.
3. The speculative risk of pancreatic orifice obstruction with Hemospray, hence the use of a prophylactic pancreatic stent.
4. The success of hemostasis using the combined technique of Hemospray and Instinct clips.

Dr. George Webster is a paid consultant of Cook Medical.

Successful hemostasis of late stage gastric cancer using Hemospray®



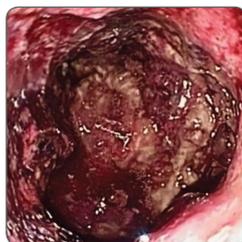
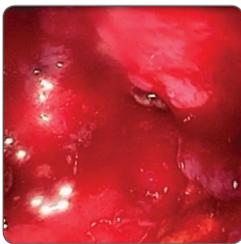
*Dr. Mary Anne Cooper
Sunnybrook Health Sciences
Centre Toronto, Canada*

An 88-year-old patient presented with late-stage gastric cancer. With limited options to treat bleeding mass in first part of the stomach (gastric remnant from previous B1 surgery), a decision was made to use Hemospray. There was extensive oozing from multiple areas, and it was difficult to assess the exact source of bleeding. Because of the previous surgery, there was not much room to maneuver and clearly ascertain the bleeding site.

After initially injecting in 3-4 sites to minimize active oozing and flushing/suctioning to clear the site for Hemospray, the device was prepped and set aside. Once site was well prepared for Hemospray, an initial air injection of the working channel with 60 cc

syringe was performed and a catheter advanced to treatment distal treatment site. A few bursts of Hemospray were applied and application continued moving proximally. We proceeded to apply powder to multiple areas until bleeding was under control. Given the condition of this patient and our limited treatment options, we were pleased with the results of Hemospray.

Dr. Mary Anne Cooper is not a paid consultant of Cook Medical.



*Images courtesy of Dr. Cooper,
Sunnybrook Hospital, Toronto, Canada.*

Hemospray® used to treat bleeding ulcer of duodenal bulb



Dr. Enzo Masci



Dr. Benedetto Mangiavillano

Gastrointestinal Endoscopy; Azienda Ospedaliera San Paolo -
Universitary Hospital - University of Milan; Milan, Italy

Background

Acute nonvariceal upper GI bleeding (UGIB) remains a common medical problem that has significant associated morbidity, 30 day mortality, and health care resource use. Several prospective databases confirm that ulcers are by far the most common cause of nonvariceal UGIB, accounting for more than 60 percent of cases. The different causes of nonvariceal bleeding are usually grouped together, but the presence of a bleeding peptic ulcer is usually considered the most clinically relevant finding at urgent endoscopy. It is therefore conceivable that most acute setting and post-endoscopy care efforts should be directed at these patients.

Case Information

A 73-year-old patient with history of nonsteroid, anti-inflammatory drug (NSAID) abuse was referred to our endoscopic unit because of melena. An esophagogastroduodenoscopy (EGD) showed, in the anterior wall of the bulb, a 3.5 cm spurting bleeding ulcer invading and deforming the pylorus, with a big clot over (**Figure 1**). After clot removal (**Figure 2**), Hemospray was sprayed on (**Figure 3**), stopping the bleeding. Moreover, because of the large dimension of the ulcer, we preferred to inject 12 cc of epinephrine (3 cc in every ulcer border).

Post-Procedure/Follow-up

The days after the procedure the patients was clinically and hemodynamically stable and had no rebleeding. A second endoscopic look was performed on the fifth day, showing the large ulcer, covered by fibrin, with the presence of a visible vessels (**Figure 4**). Biopsies and endoultrasonography (EUS) were also performed for excluding the presence of neoplasia.

Drs. Enzo Masci and Benedetto Mangiavillano are not paid consultants of Cook Medical.



Figure 1



Figure 2



Figure 3



Figure 4

Successful treatment of bleeding duodenal ulcer with Hemospray®



Dr. Adrian Stanley

Consultant
Gastroenterologist,
Glasgow Royal Infirmary,
UK

Background

An 86-year-old patient was admitted under the geriatricians with a chest infection. The patient was on aspirin for known atrial fibrillation. Initial treatment consisted of antibiotics and physiotherapy.

Case Information

After five days in hospital, the patient had an episode of melaena with tachycardia, systolic blood pressure 95mm Hg and initial Hb of 90. After successful resuscitation, emergency endoscopy was undertaken.

Endoscopy revealed an actively bleeding duodenal ulcer (**Figure 1**). Washing and suction alone did not significantly improve visualization, therefore 4 mL dilute adrenaline were injected into the presumed site of bleeding to temporarily improve the view and allow definite endostasis (**Figure 2**). Four short bursts of Hemospray were then applied to good effect with immediate cessation of bleeding (**Figures 3 and 4**).

Post Procedure/Follow up

The patient remained haemodynamically well and was treated with 72 hours of IV omeprazole (Hong Kong regime) then continued on long term oral omeprazole (and aspirin as before). Helicobacter Pylori test was negative. The patient had no evidence of rebleeding and, after rehabilitation with physiotherapy and occupational therapy input, was discharged home three weeks later.

Dr. Adrian Stanley is not a paid consultant of Cook Medical.

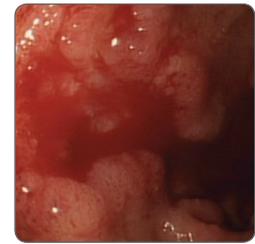


Figure 1



Figure 2



Figure 3



Figure 4

Hemospray® highly effective rescue therapy in a difficult to treat duodenal ulcer



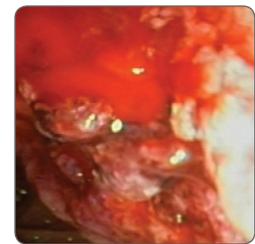
Prof. Jacques Bergman

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A 47-year-old patient was referred for gastroduodenoscopy because of hypovolemic shock, hematemesis and melena after a severe pneumosepsis. Gastroduodenoscopy showed multiple deep ulcers with a visible vessel (**Forrest IIA**), which was clipped and treated with coagulation. However, a severe rebleed occurred for which the Hemospray was used. This led to hemostasis immediately. One day later a rebleed occurred (**Forrest IA**) and because coagulation failed, the Hemospray had to be used again with immediate hemostasis. Hereafter, the patient underwent coiling of the gastroduodenal artery.

The following week two endoscopies had to be performed for rebleedings (**Forrest IIA**) and during the third episode, Hemospray was used three times to achieve hemostasis. Hereafter, patient underwent laparoscopic endarterectomy of the gastroduodenal artery and coiling of two branches, one of the superior mesenteric artery and one of the pancreatic duodenal artery. Eventually, the bleedings stopped and the patient recovered fully. In this case, the Hemospray was highly effective as rescue therapy in difficult to treat bleedings and could be used as bridging therapy for re-interventions.

Prof. Jacques Bergman is not a paid consultant of Cook Medical.



Forrest IA



Forrest IIA

Endoscopic treatment for Dieulafoy's lesion



E.T.T.L. Tjwa, MD

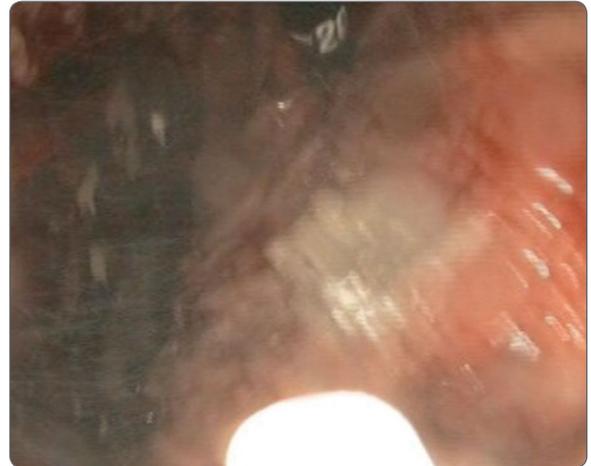


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Background

A Dieulafoy's lesion consists of a dilated tortuous artery with a diameter up to 3 mm that protrudes through the mucosa. These lesions most commonly occur in the proximal stomach along the lesser curve, but they are incidentally seen in the oesophagus, small intestine and colon. Dieulafoy's lesions may cause massive gastrointestinal haemorrhage by rupture of the artery, accounting for one to six percent of cases of acute nonvariceal upper gastrointestinal bleeding. Rupture occurs probably by a combination of factors like straining of the vascular wall during peristalsis, morphologic changes of the artery and peptic digestion. The high prevalence of comorbidity (90 percent) and correlated drug use in patients with Dieulafoy's lesions is likely to play an additional role in the process of vessel rupture. Endoscopic treatment is the first choice in bleeding Dieulafoy's lesions, and is able to achieve haemostasis in more than 90 percent of cases. Treatment is usually performed with clipping or banding of the lesion¹. The below described case is one of the first cases of a Dieulafoy's lesion treated with Hemospray.

Case Information

A 63-year-old patient presented at the Emergency Department with hematemesis and black stools since one day. The patient had a history of hemophilia B with severe arthropathy, chronic hepatitis C virus infection, T2N0Mx larynx carcinoma for which the patient had received radiotherapy, and alcohol abuse. The patient used a beta blocker, a proton pump inhibitor and a factor IX-product. At presentation the patient had a blood pressure of 60/40 mm Hg with a pulse rate of 160 with peripheral cyanosis. Examination of heart, lungs and

abdomen showed no abnormalities. Rectal digital exam revealed melena. Laboratory test results showed a low Hb (5.6 mmol/L), a high urea (10.7 mmol/L) with a normal creatinine (51 mmol/L). Coagulation tests were normal.

Because of medical history, the patient was immediately treated with 7000 IE factor IX, fluid resuscitation and packed cells suppletion. Upper endoscopy was performed within six hours of admission in suspicion of an upper gastrointestinal bleeding. Oozing arterial bleeding from Dieulafoy's lesion in the body of the stomach was seen. The patient was treated with Hemospray as first line monotherapy, thereafter hemostasis was reached.

Post-Procedure/Follow up

On the ward, the patient was treated with high dose intravenously administered proton pump inhibitor therapy (esomeprazole 80 mg bolus, followed by 8 mg/h continuous infusion for 72 h). The patient was discharged with a recipe of an oral proton pump inhibitor for four weeks. At follow up, one month after the gastrointestinal bleeding, the patient was in good clinical condition and had no recurrent bleeding.

References:

¹Holster IL, Kuipers EJ. Chapter 8: Other causes of upper gastrointestinal bleeding. In: J.J. Sung, E.J. Kuipers, A.N. Barkun. *Gastrointestinal bleeding, second edition*, Blackwell Publishing Ltd 2012, ISBN 978-1-4051-9555-3

Drs. E.T.T.L. Tjwa and I.L. Holster and Prof. E. J. Kuipers are not paid consultants of Cook Medical.

Hemospray Reference Articles

CLINICAL

Mourad FH, Leong RW. Role of hemostatic powders in the management of lower gastrointestinal bleeding: A review. *Journal of Gastroenterology and Hepatology*. E-published 22 March 2018.

Haddara S, Jacques J, Leclaire S, et al. A Novel Hemostatic Powder for Upper Gastrointestinal Bleeding: A Multicenter Study (the "GRAPHE" registry). 2016 Dec; 48(12): 1084-1095.

Chen Y, Barkun A. Hemostatic Powders in Gastrointestinal Bleeding: A Systematic Review. *Gastrointestinal Endoscopy Clinics of North America*. 2015 July; 25(3): 535-552.

Changela K, Papfragkakos H, Ofori E, et al. Hemostatic powder spray: a new method for managing gastrointestinal bleeding. *Therapeutic Advances in Gastroenterology*. 2015 May;8(3):125-35.

Szalai M, Kullmann T, Durcsán H, et al. Hemospray: a novel therapeutic option in the management of acute upper gastrointestinal bleeding. *Orvosi Hetilap*. 2015 Mar;156(13):528-31.

Chen YI, Barkun AN, Nolan S. Hemostatic powder TC-325 in the management of upper and lower gastrointestinal bleeding: a two-year experience at a single institution. *Endoscopy*. 2015 Feb;47(2):167-71.

Appleby VJ, Hutchinson JM, Beckett CJ, Moreea S. Use of the haemostatic agent TC-325 in the treatment of bleeding secondary to endoscopic retrograde cholangiopancreatography sphincterotomy. *QJM*. 2015 Jan;108(1):79-80.

Parsi MA, Jang S. Hemospray for diffuse anastomotic bleeding. *Gastrointestinal Endoscopy*. 2014 Dec; 80(6):1170.

Selvapatt N., Hoare J. A novel method of achieving haemostasis in transfusion-dependent small bowel malignancy-related bleeding. *BMJ Case Reports*. E-published 16 December 2014.

Zimmer, V., Lammert F. Retrograde transpyloric hemostatic powder intervention of a concealed prepyloric antral ulcer. *Gastrointestinal Endoscopy*. 2014 Dec; 80(6): 1207.

Masci E, Arena M, Morandi E, et al. Upper gastrointestinal active bleeding ulcers: review of literature on the results of endoscopic techniques and our experience with Hemospray. *Scandinavian Journal of Gastroenterology*. 2014 Nov;49(11):1290-5.

Morris AJ, Smith LA, Stanley A, et al. Hemospray for non-variceal upper gastrointestinal bleeding: Results of the Seal Dataset (survey to evaluate the application of Hemospray in the luminal tract). *Journal of Clinical Gastroenterology*. 2014 Nov; 48(10): E89-92.

Bustamante-Balén M, Plumé G, World J. Role of hemostatic powders in the endoscopic management of gastrointestinal bleeding. *Gastrointest Pathophysiol*. 2014 Aug 15;5(3):284-92.

Sulz MC, Frei R, Meyenberger C, Bauerfeind P, Semadeni GM, Gubler C. Routine use of Hemospray for gastrointestinal bleeding: prospective two-center experience in Switzerland. *Endoscopy*. 2014 Jul;46(7):619-24.

Iacucci M. Hemostatic spray- a welcome addition to the armamentarium against gastrointestinal bleeding. *Canadian Journal of Gastroenterology and Hepatology*. 2014 Feb; 28(2): 71.

Yau A, Ou G, Galoport C, et al. Safety and efficacy of Hemospray in upper gastrointestinal bleeding. *Canadian Journal of Gastroenterology and Hepatology*. 2014 Feb; 28(2): 72-76.

Holster IL, Kuipers EJ, Tjwa ET. Hemospray in the treatment of upper gastrointestinal hemorrhage in patients on antithrombotic therapy. *Endoscopy*. 2013 Jan;45(1):63-6.

Dietrich, C., Hochdörffer, R., et al. Successful use of Hemospray to control refractory duodenal diverticular bleeding. *Endoscopy*. 2014. 46(S01): E605-E606.

Kratt T, Lange J, Königsrainer A, et al. Successful Hemospray treatment for recurrent diclofenac-induced severe diffuse lower gastrointestinal bleeding avoiding the need for colectomy. *Endoscopy*. 2014; 46(S 01): E173-E174.

Tarantino, Barresi, Granata, et al. Hemospray for arterial hemorrhage following endoscopic ultrasound -guided pseudocyst drainage. *Endoscopy*. 2014;46(S01):E71.

Granata, Curcio, Azzopardi, Barresi, Tarantino, Traina. Hemostatic powder as rescue therapy in a patient with H1N1 influenza with uncontrolled colon bleeding. *Gastrointestinal Endoscopy*. 2013 Sept; 78(3): 451.

Babiuc RD, Purcarea M, Sadagurschi R, Negreanu L. Use of Hemospray in the treatment of patients with acute UGIB - short review. *Journal of Medicine and Life*. 2013 Jun; 6(2):117-119.

Moosavi S, Chen YI, Barkun AN. Topical hemostatic agents: a systematic review with particular emphasis on endoscopic application in GI bleeding. *Gastrointestinal Endoscopy*. 2013 May; 77(5):692-700.

Soulellis CA, Carpentier S, Chen YA, et al. Lower GI hemorrhage controlled with endoscopically applied TC-325. *Gastrointestinal Endoscopy*. 2013 Mar;77(3):504-507.

Holster IL, Kuipers EJ, Tjwa ET. Hemospray in the treatment of upper gastrointestinal hemorrhage in patients on antithrombotic therapy. *Endoscopy*. 2013 Jan;45(1):63-6.

Chen YI, Barkun AN, Soulellis C, et al. Use of the endoscopically applied hemostatic powder TC-325 in cancer-related upper GI hemorrhage: preliminary experience. *Gastrointestinal Endoscopy*. 2012 Jun;75(6):1278-81.

Sung JJ, Luo D, Wu JC, et al. Early clinical experience of the safety and effectiveness in achieving hemostasis in patients with acute peptic ulcer bleeding. *Endoscopy*. 2011 Apr; 43(4):291-5.

NON-CLINICAL

Barkun AN, Adam V, Lu Y, et al. Using Hemospray Improves the Cost-effectiveness Ratio in the Management of Upper Gastrointestinal Nonvariceal Bleeding. *J Clin Gastroenterol*. 2018 Jan; 52(1): 36-44.

Beye B, Barret M, Alatawi A, et al. Topical hemostatic powder promotes reepithelialization and reduces scar formation after extensive esophageal mucosal resection. *Diseases of the Esophagus*. 2016 Aug; 29(6): 520-527.

Giday SA, Van Alstine WG, Van Vleet JF, et al. Safety analysis of a hemostatic powder in a porcine model of acute severe gastric bleeding. *Digestive Disease Sci*. 2013 Dec; 58(12):3422-8.

Giday SA, Kim Y, Krishnamurthy DM, et al. Long-term randomized controlled trial of a novel nanopowder hemostatic agent (TC-325) for control of severe arterial upper gastrointestinal bleeding in a porcine model. *Endoscopy*. 2011 Apr;43(4):296-9.

Summary of Clinical Data: Clinical data summary information that was, in part, the basis for granting the de novo can be found on the Cook Medical website at CookMedical.com/HemosprayData

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