

Safety and efficacy of Hemospray® in upper gastrointestinal bleeding

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BACKGROUND: Hemospray (Cook Medical, USA) has recently been approved in Canada for the management of nonvariceal upper gastrointestinal bleeding (UGIB).

OBJECTIVE: To review the authors' experience with the safety and efficacy of Hemospray for treating UGIB.

METHODS: A retrospective chart review was performed on patients who required endoscopic evaluation for suspected UGIB and were treated with Hemospray.

RESULTS: From February 2012 to July 2013, 19 patients (mean age 67.6 years) with UGIB were treated with Hemospray. A bleeding lesion was identified in the esophagus in one (5.3%) patient, the stomach in five (26.3%) and duodenum in 13 (68.4%). Bleeding was secondary to peptic ulcers in 12 (63.2%) patients, Dieulafoy lesions in two (10.5%), mucosal erosion in one (5.3%), angiomyomatous lesions in one (5.3%), ampulllectomy in one (5.3%), polypectomy in one (5.3%) and an unidentified lesion in one (5.3%). The lesions showed spurting hemorrhage in four (21.1%) patients, oozing hemorrhage in 11 (57.9%) and no active bleeding in four (21.1%). Hemospray was administered as monotherapy in two (10.5%) patients, first-line modality in one (5.3%) and rescue modality in 16 (84.2%). Hemospray was applied prophylactically to nonbleeding lesions in four (21.1%) patients and therapeutically to bleeding lesions in 15 (78.9%). Acute hemostasis was achieved in 14 of 15 (93.3%) patients. Rebleeding within seven days occurred in seven of 18 (38.9%) patients. Potential adverse events occurred in two (10.5%) patients and included visceral perforation and splenic infarct. Mortality occurred in five (26.3%) patients but the cause of death was unrelated to gastrointestinal bleeding with the exception of one patient who developed hemoperitoneum.

CONCLUSIONS: The high rates of both acute hemostasis and recurrent bleeding suggest that Hemospray may be used in high-risk cases as a temporary measure or a bridge toward more definitive therapy.

Key Words: Efficacy; Hemospray; Safety; Upper gastrointestinal bleeding

Hemospray (TC-325) (Cook Medical, USA), a novel proprietary inorganic powder, has recently been approved in Canada for the management of nonvariceal upper gastrointestinal bleeding (UGIB) (1). It achieves hemostasis by adhering to the bleeding site, which leads to mechanical tamponade and, by concentrating and activating platelets and coagulation factors, promotes thrombus formation (2). Preliminary results on safety and efficacy appear to be promising for various types of gastrointestinal bleeding including those secondary to peptic ulcers (3-6), gastric varices (6-8), esophageal tear (5), gastric antral vascular ectasia (4), duodenal diverticula (6), colonic ulcer (9), radiation proctitis (10), Dieulafoy lesions (4,6,10), malignancy (4,6,11,12), sphincterotomy (5,12,13), ampulllectomy (6,12), polypectomy (4,5,10) and endoscopic mucosal resection (4,12).

Endoscopic hemostasis has been widely accepted as first-line treatment for nonvariceal UGIB (3,14). Combined endoscopic

La sécurité et l'efficacité de la poudre Hemospray^{MC} en cas de saignements cœsogastroduodénaux

HISTORIQUE : La poudre Hemospray (Cook Medical, États-Unis) a récemment été approuvée au Canada pour la prise en charge des saignements cœsogastroduodénaux (SOGD) non variqueux.

OBJECTIFS : Examiner l'expérience des auteurs à l'égard de la sécurité et de l'efficacité de la poudre Hemospray pour traiter les SOGD.

MÉTHODOLOGIE : Les chercheurs ont effectué une analyse rétrospective des dossiers des patients qui avaient besoin d'une évaluation endoscopique en raison d'une présomption de SOGD et qui ont été traités à l'aide de poudre Hemospray.

RÉSULTATS : De février 2012 à juillet 2013, 19 patients (d'un âge moyen de 67,6 ans) ayant des SOGD ont été traités à l'aide de poudre Hemospray. Une lésion hémorragique a été décelée dans l'œsophage d'un patient (5,3 %), l'estomac de cinq patients (26,3 %) et le duodénum de 13 patients (68,4 %). Les saignements étaient secondaires à un ulcère gastroduodénal chez 12 patients (63,2 %) et à des ulcères de Dieulafoy chez deux patients (10,5 %). Chez cinq patients (5,3 % chacun), les saignements étaient respectivement causés par une érosion muqueuse, une angiomyomatose, une ampulllectomie, une polypectomie et une lésion non identifiée. Les lésions ont révélé une hémorragie pulsatile chez quatre patients (21,1 %), une hémorragie sifflante chez 11 patients (57,9 %) et aucun saignement actif chez quatre patients (21,1 %). La poudre Hemospray a été administrée en monothérapie à deux patients (10,5 %), en première ligne à un patient (5,3 %) et en traitement de sauvetage à 16 patients (84,2 %). Elle a été appliquée en prophylaxie aux lésions non hémorragiques de quatre patients (21,1 %) et en traitement des lésions hémorragiques de 15 patients (78,9 %). Quatorze des 15 patients (93,3 %) sont parvenus à une hémostase aiguë. Sept des 18 patients (38,9 %) ont saigné de nouveau dans les sept jours. Deux patients (10,5 %) ont souffert d'effets indésirables potentiels, soit une perforation viscérale et un infarctus splénique. Cinq patients (26,3 %) sont décédés, mais la cause du décès n'était pas liée au saignement gastro-intestinal, à l'exception d'un patient qui a subi un hémopéritoine.

CONCLUSIONS : D'après les taux élevés d'hémostase aiguë et de saignements récurrents, dans les cas à haut risque, la poudre Hemospray peut être utilisée temporairement ou en attendant un traitement plus définitif.

therapy using injection, thermal and mechanical modalities is highly effective, with initial hemostasis achieved in 85% to 95% of cases (14,15); however, recurrent bleeding still occurs in 5% to 10% of cases (16). In addition, conventional endoscopic therapies may not be feasible in patients with active multifocal bleeding sites, particularly those with challenging anatomy and coagulopathy, in which contact coagulation efforts may be hampered by further tissue damage and induction of more bleeding (3). In contrast, Hemospray can quickly cover large areas and does not require en face view or direct contact with the bleeding lesion (10). However, the optimal indications and technical limitations of Hemospray are still being characterized (5). The present study provides additional experience with regard to the safety and efficacy of Hemospray in patients presenting with UGIB in a real-life setting outside of the clinical trial experience.

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TABLE 1
Patient characteristics

Patient	Age, years	Sex	Hematemesis	Pre-		Hgb, g/L			INR	Antiplatelet	Anticoagulant
				Melena	Syncope	Syncope	SBP	HR			
1	55	M	–	Yes	Yes	–	84	95	79	232	1.1 ASA (160 mg PO × 1)
2	74	M	–	Yes	Yes	–	55	122	42	168	1.5 ASA (325 mg PO × 1) Clopidogrel (600 mg PO × 1)
3	49	M	Yes	Yes	Yes	–	115	93	101	183	1.0 Ibuprofen (PO as needed)
4	61	M	–	Yes	–	–	98	86	90	180	1.0 ASA (81 mg PO daily) Clopidogrel (75 mg PO daily)
5	67	F	Yes	Yes	Yes	–	119	121	53	135	1.1 Diclofenac (50 mg PR twice per day)
6	88	F	–	Yes	–	–	82	135	70	86	2.0 ASA (81 mg PO daily)
7	71	M	–	Yes	–	–	132	129	72	362	1.9 –
8	90	M	–	Yes	Yes	–	75	94	54	175	1.2 ASA (325 mg PO daily)
9	29	M	Yes	Yes	–	–	115	97	68	241	1.2 –
10	54	M	Yes	–	Yes	–	139	125	76	55	2.0 Ibuprofen (PO as needed)
11	94	F	Yes	Yes	–	–	101	82	85	210	1.2 ASA (81 mg PO daily) Clopidogrel (75 mg PO daily)
12	88	M	–	Yes	Yes	Yes	69	100	64	100	1.2 ASA (325 mg PO daily)
13	56	F	Yes	Yes	–	–	76	>100	64	43	2.4 –
14	40	M	–	Yes	–	–	80	113	74	384	1.5 ASA (81 mg PO daily)
15	72	M	–	Yes	–	–	98	110	71	17	1.2 –
16	86	M	–	Yes	–	–	142	68	107	144	1.1 –
17	72	M	–	Yes	–	–	78	120	87	122	–
18	53	F	Yes	Yes	–	–	60	98	41	118	1.8 –
19	85	M	Yes	–	Yes	–	112	85	76	295	1.0 –

ASA Acetylsalicylic acid; F Female; Hgb Hemoglobin (normal range 135 g/L to 170 g/L); HR Heart rate (beats/min); INR International normalized ratio (normal range 0.9 to 1.2); M Male; PLT Platelet count (normal 150×10⁹/L to 440×10⁹/L); PO Per oral; PR Per rectum; SBP Systolic blood pressure

METHODS

From February 2012 to July 2013, 19 patients who required endoscopic evaluation for suspected UGIB were treated with Hemospray. A retrospective chart review was performed collecting demographic data (age and sex); clinical data (symptoms, vital signs, medical history and medications); diagnostic data (complete blood count, renal function, coagulation study and endoscopic findings); and therapeutic data (resuscitative measures, hemostatic interventions and hemostatic outcomes). All patients provided written informed consent for study participation. The study was approved by the institutional review board.

Patients were resuscitated as needed to achieve hemodynamic stability before undergoing endoscopy. Hemospray was used as monotherapy (Hemospray only); first-line modality (Hemospray followed by conventional endoscopic therapy) or rescue modality (conventional endoscopic therapy followed by Hemospray) at the discretion of the endoscopist. Hemospray was delivered through a 10 Fr catheter that was inserted into the working channel of a therapeutic endoscope (Olympus, Japan). The bleeding site was observed for 5 min under endoscopy and, if recurrent bleeding occurred, Hemospray was reapplied as needed to a maximum of 20 g (one canister). Endoscopy was repeated and Hemospray was reapplied as needed in patients with clinical or laboratory evidence of recurrent bleeding.

The primary end point was acute hemostasis (defined as endoscopic observation of bleeding cessation for >5 min). The secondary end points were: recurrent bleeding at seven and 30 days (defined as clinical presentation of hematemesis or melena; hemoglobin level decrease >20 g/L within 48 h or direct visualization of active bleeding at the previously treated lesion at repeat endoscopy); mortality at seven and 30 days (related to gastrointestinal bleeding); and adverse events in hospital (related to Hemospray use). Hemospray failure was defined as the inability to achieve acute hemostasis after application

of 20 g of Hemospray or recurrent bleeding despite application of Hemospray on two separate occasions.

RESULTS

Patient characteristics (Table 1)

A total of 19 patients (mean age 67.6 years; range 29 to 94 years; five [26.3%] women) with UGIB were treated with Hemospray during the study period (February 2012 to July 2013).

Clinical presentation included hematemesis in eight (42.1%) patients, melena in 17 (89.5%), presyncope in eight (42.1%) and syncope in one (5.3%). Physical examination revealed hypotension (systolic blood pressure <90 mmHg) in nine (47.4%) patients and tachycardia (heart rate >100 beats/min) in 10 (52.6%). Laboratory investigations showed a mean hemoglobin nadir of 72.3 g/L (normal 135 g/L to 170 g/L), thrombocytopenia (platelets <150×10⁹/L) in nine (47.4%) patients and coagulopathy (international normalized ratio >1.2) in seven (38.9%).

Medication review found the use of antiplatelet agents in 11 (57.9%) patients and anticoagulants in 10 (52.6%). Acetylsalicylic acid, clopidogrel and heparin (therapeutic dose) were administered to one patient who presented with unstable angina before cardiac catheterization (patient 4) and another who was admitted for transfemoral closure of severe mitral prosthetic paravalvular leak (patient 2). Warfarin and heparin (therapeutic dose) were given to one patient who had developed bilateral deep vein thrombosis in the lower extremities (patient 7).

Endoscopic findings (Table 2)

A bleeding lesion was identified in the esophagus in one (5.3%) patient, the stomach in five (26.3%) and duodenum in 13 (68.4%). Bleeding originated from peptic ulcers in 12 (63.2%) patients, Dieulafoy lesions in two (10.5%), mucosal erosion in one (5.3%), angiomyolipoma in one (5.3%), ampulllectomy site in one (5.3%), polypectomy site in one (5.3%) and an unidentified lesion in

TABLE 2
Endoscopic findings

Patient	Location	Lesion	Stigmata
1	Gastric (prepylorus)	Ulcer	Oozing, clot
2	Gastric (cardia, fundus)	No discrete lesions	Adherent clots
3	Gastric (incisura)	Ulcers × 3 (5 mm)	Oozing
4	Gastric (fundus)	Angiodysplastic lesions × few	Oozing
5	Duodenal (D1/D2)	Ulcer	Multiple red spots, clean base
6	Duodenal (D2)	Ulcers × several	Spurting, visible vessel
7	Duodenal (D1/D2)	Ulcer (2 cm)	Oozing, large clot
8	Duodenal (D1/D2)	Dieulafoy lesion	Oozing
9	Duodenal (D1/D2)	Ulcer	Oozing, visible vessel
10	Esophageal (mid, 34 cm to 36 cm)	Ulcer with distal varices (3 cm)	Oozing, surrounding clot
11	Gastric (lesser curvature)	Dieulafoy lesions × 2	Oozing, clot
12	Duodenal (bulb)	Ulcer (hemicircumferential)	Spurting, visible vessel, adherent clots
13	Duodenal (D1/D2)	Ulcers × 2 (1.5 cm)	Spurting, visible vessel
14	Duodenal (D2)	Ulcers × 3 (hemicircumferential)	Adherent clots
15	Duodenal (D1/D2)	Erosion (linear)	Oozing
16	Duodenal (D1/D2)	Polypectomy site (3 cm, sessile)	Bleeding artery
17	Duodenal (major papilla)	Ulcer at ampullectomy site	Oozing, visible vessels × 4
18	Duodenal (D1/D2)	Ulcers × multiple (7 mm to 8 mm)	Spurting, visible vessel
19	Duodenal (bulb)	Ulcer	No active bleeding

D1 First part of the duodenum; D2 Second part of the duodenum

one (5.3%). The lesions demonstrated spurting hemorrhage in four patients (21.1%), oozing hemorrhage in 11 (57.9%) and no active bleeding in four (21.1%). Importantly, all four patients with spurting hemorrhage were found to have hemodynamic instability, thrombocytopenia and coagulopathy.

Hemostatic interventions (Table 3)

Hemospray was administered as monotherapy in two (10.5%) patients, first modality in one (5.3%) and rescue modality in 16 (84.2%). Other hemostatic modalities were injection methods in 16 (84.2%) patients, thermal methods in 10 (52.6%), mechanical methods in nine (47.4%), transarterial embolization in two (10.5%) and surgical oversewing in one (5.3%). Interestingly, in the latter three patients who ultimately required aggressive hemostatic interventions, all had received antiplatelets and demonstrated hemodynamic instability, but only one was found to have spurting hemorrhage on endoscopy.

Hemostatic outcomes (Table 4)

Hemospray was applied prophylactically to nonbleeding lesions in four (21.1%) patients and therapeutically to bleeding lesions in 15 (78.9%). Among patients with bleeding lesions, acute hemostasis was achieved in 14 of 15 (93.3%). The one patient who did not achieve acute hemostasis essentially had Hemospray failure and, ultimately, required transarterial embolization for spurting hemorrhage. Recurrent bleeding was found in seven of 18 (38.9%) patients and all developed within seven days of Hemospray application to lesions with spurting hemorrhage in two, oozing hemorrhage in three and no active bleeding in two. One of these patients required transarterial embolization and another required surgical oversewing. Repeat endoscopy was performed in seven (38.9%) patients and all occurred within seven days with the exception of one patient who received it at seven weeks. Four of these patients were found to have active bleeding of the previously treated lesion at repeat endoscopy, and Hemospray was reapplied to the one patient who only had minor oozing with acute hemostasis once again achieved.

Adverse events (Table 4)

Adverse events potentially related to Hemospray use were identified in two (10.5%) patients. One patient developed acute abdominal distension

TABLE 3
Hemostatic interventions

Patient	Hemospray*	Injection (volume)	Thermal	Mechanical (frequency)	Transarterial embolization	Surgical oversewing
1	Rescue modality	Epinephrine (8 mL)	—	Clips (× 3)	—	—
2	Monotherapy	—	—	—	—	—
3	Monotherapy	—	—	—	—	—
4	Rescue modality	Epinephrine (4 mL)	—	—	—	—
5	Rescue modality	Epinephrine (8 mL)	BICAP cautery	Clips (× 2)	Yes	—
6	Rescue modality	Epinephrine (16 + 9 mL)	Cautery	Clips (× 5)	—	—
7	Rescue modality	Epinephrine (12 mL)	—	—	—	—
8	Rescue modality	Epinephrine (15 mL × 2)	Gold probe	—	—	—
9	Rescue modality	Epinephrine (6 mL)	BICAP cautery	—	—	—
10	Rescue modality	Epinephrine (2 + 6 mL) Tromboject sclerosant (2.5 mL)	—	Bands (× 5)	—	—
11	Rescue modality	Epinephrine (4 mL)	—	Clips (× 4)	—	—
12	Rescue modality	—	—	Clips (× 2)	Yes	—
13	Rescue modality	Epinephrine (8 mL)	Gold probe	Clips (× 6)	—	—
14	Rescue modality	Epinephrine × 2	BICAP cautery	Clips (× 3)	—	Yes
15	Rescue modality	Epinephrine (3 mL)	—	—	—	—
16	Rescue modality	Epinephrine (3 mL)	Hot biopsy forceps	Clips (× 2)	—	—
17	First modality	Epinephrine (4.5 mL)	Hot cautery forceps	—	—	—
18	Rescue modality	Epinephrine (10 mL)	BICAP cautery	—	—	—
19	Rescue modality	Epinephrine (3 mL)	Cautery	—	—	—

BICAP Bipolar electrocoagulation; First modality (Hemospray [Cook Medical, USA] followed by conventional endoscopic therapy); Monotherapy (Hemospray only); Rescue modality (Conventional endoscopic therapy followed by Hemospray)

TABLE 4
Hemostatic outcomes

Patient	Acute hemostasis	Recurrent bleeding	Repeat endoscopy	Repeat Hemospray	Hemospray failure	Adverse event	Mortality
1	Yes	No	No	N/A	No	–	–
2	N/A*	No	No	N/A	No	? Visceral perforation (day 0)	Hemoperitoneum, hypovolemic shock (day 0)
3	Yes	Yes (day 3)	Yes (day 4)	No	No	–	–
4	Yes	No	No	N/A	No	–	–
5	N/A*	Yes (day 2)	No	N/A	No	–	–
6	Yes	Yes (day 5)	Yes (day 6)†	No	No	–	Hospital-acquired pneumonia (day 13)
7	Yes	No	Yes (day 3)	No	No	–	–
8	Yes	Yes (day 1)	Yes (day 3)†	No	No	–	–
9	Yes	No	Yes (day 48)	No	No	–	–
10	Yes	No	Yes (day 3)‡	Yes	No	–	–
11	Yes	No	No	N/A	No	–	–
12	No	N/A	No	N/A	Yes	–	AV fistula blockage, hemodialysis withdrawal (day 21)
13	Yes	Yes (day 4)	No	N/A	No	–	Acute renal failure, newly diagnosed cryptogenic cirrhosis (day 12)
14	N/A*	Yes (day 7)	No	N/A	No	–	MSSA bacteremia, ventilator-acquired pneumonia (day 74)
15	Yes	No	No	N/A	No	–	–
16	Yes	No	No	N/A	No	–	–
17	Yes	Yes (day 1)	Yes (day 2)†	No	No	–	–
18	Yes	No	No	N/A	No	? Splenic infarct (day 29)	–
19	N/A*	No	No	N/A	No	–	–

*Hemospray (Cook Medical, USA) was applied prophylactically to nonbleeding lesions; †Active bleeding of the previously treated lesion; ‡Minor oozing of the previously treated lesion. AV Arteriovenous; MSSA Methicillin-sensitive Staphylococcus aureus; N/A Not applicable

with hemoperitoneum on diagnostic paracentesis in the hours following Hemospray application; however, a coroner's autopsy was not performed to determine whether visceral perforation had occurred. This patient was admitted with severe mitral prosthetic paravalvular leak requiring percutaneous transfemoral closure. He had a history of hypertension, coronary artery disease, atrial fibrillation, congestive heart failure and chronic kidney disease. Another patient developed radiological evidence of new-onset splenic infarct on abdominal computed tomography scan after Hemospray use. This patient was admitted for a compound fracture of the left proximal tibia requiring open reduction and internal fixation. She had a history of hepatic steatosis, cholelithiasis, end-stage renal disease, gout and osteoporosis.

Mortality (Table 4)

Mortality occurred in five (26.3%) patients; however, with the exception of the patient who had developed hemoperitoneum and hypovolemic shock on day 0, the cause of death in the other four patients was not directly related to gastrointestinal bleeding. These included hospital-acquired pneumonia on day 13; hemodialysis withdrawal secondary to arteriovenous fistula blockage on day 21; acute renal failure and newly diagnosed cryptogenic cirrhosis on day 12; and methicillin-susceptible bacteremia and ventilator-acquired pneumonia on day 74.

DISCUSSION

Our study examined the use of Hemospray in UGIB (n=19), which originated from peptic ulcers in 63.2% of patients. Hemospray was frequently administered as a rescue modality (84.2%), with an overall rate of acute hemostasis in 93.3% and rebleeding in 38.9% of patients. In the largest four case series performed by Sung et al (3 [n=20]), Smith et al (4 [n=82]), Holster et al (6 [n=16]) and Leblanc et al (12 [n=17]), Hemospray was used as monotherapy in 50% to 95%, first modality in 0% to 19% and rescue modality in 0% to 33% of patients, with an overall rate of acute hemostasis in 81% to 100%, and recurrent bleeding in 11% to 31%. The higher rates of recurrent bleeding and Hemospray use

as a rescue modality in our study could be due to selection bias in the tertiary care setting, with frequent encounters of thrombocytopenia (47.4%), coagulopathy (38.9%), antiplatelet use (57.9%), anticoagulant use (52.6%) and spurting hemorrhage (21.1%).

Our finding that spurting hemorrhage was present in the one patient in whom acute hemostasis was not achieved with Hemospray is consistent with the experience of Sung et al (3) and Holster et al (6); however, Leblanc et al (12) reported effective control of pulsatile bleeding with Hemospray. Recurrent bleeding may be expected to occur because the hemostatic powder does not directly induce healing of the underlying lesion and is sloughed off from the mucosal wall within two to three days, leaving behind a clean remnant (10,11). The high rates of both acute hemostasis and recurrent bleeding suggest that Hemospray is probably best used as a bridge toward more definitive therapy such as transjugular intrahepatic portosystemic shunt in variceal bleeding (8) and radiation therapy in malignancy-related bleeding (11).

One patient in our study developed hemoperitoneum on day 0 and another developed splenic infarct on day 29, although it remained unclear whether these were directly related to Hemospray use. Perforation appears unlikely because the pressure of carbon dioxide is only 12 mmHg when the catheter is placed at 1 cm to 2 cm from the target lesion (10). Embolization also appears unlikely based on the safety study performed in a porcine model by Giday et al (17) using a sevenfold greater dose of Hemospray than that used in most clinical cases; the authors found no histological evidence of powder embolization in systemic tissues including the spleen. In addition, case reports and series in humans have not reported the theoretical risks of Hemospray including thromboembolism, bowel perforation, bowel obstruction, coagulopathy, allergic reaction and powder inhalation (3-13). Transient biliary obstruction has been reported after Hemospray use in postsphincterotomy bleeding (13). However, this did not occur in our patient, who received Hemospray for bleeding from an ampullectomy site because a biliary stent had been previously inserted. Despite its apparent safety from limited data in short-term

studies, Hemospray is contraindicated in variceal bleeding with low venous pressure and numerous collateral shunts due to the risk of thromboembolism (7), and in diverticular bleeding with thin mucosal wall and narrowed bowel lumen due to the risk of perforation and obstruction (10).

Conventional endoscopic therapies have been shown to be effective in decreasing the rates of recurrent bleeding, blood transfusion and surgical intervention in UGIB, but the mortality rate has remained at 7% to 10% in the past 30 years (18). It is, therefore, necessary to explore alternative methods of endoscopic hemostasis. Hemospray is a welcome addition to our current armamentarium given its many advantages. First, the ease of application without the need for advanced technical skills is desirable in emergency situations in which expert endoscopists are unavailable (12). Second, accurate localization and precise targeting are not necessary, making it useful in challenging anatomy compounded by endoscope angulation (10). Third, direct mucosal contact does not occur, reducing the risk of further tissue damage that could worsen bleeding and even result in perforation (11,12). Fourth, its ability to cover large areas with multiple bleeding points makes it a suitable choice for hemorrhagic gastritis, gastric antral vascular ectasia, radiation-induced mucosal injury and malignancy-related bleeding (3). Finally,

REFERENCES

- Giday SA. Preliminary data on the nanopowder hemostatic agent TC-325 to control gastrointestinal bleeding. *Gastroenterol Hepatol* 2011;7:620-2.
- Aslanian HR, Laine L. Hemostatic powder spray for GI bleeding. *Gastrointest Endosc* 2013;77:508-10.
- Sung JJY, Luo D, Wu JCY, et al. Early clinical experience of the safety and effectiveness of Hemospray in achieving hemostasis in patients with acute peptic ulcer bleeding. *Endoscopy* 2011;43:291-5.
- Smith LA, Stanley A, Morris J. Hemospray for non-variceal upper gastrointestinal bleeding: Results of the SEAL dataset (survey to evaluate the application of hemospray in the luminal tract). *Gut* 2012;62:A61-A62.
- Moosavi S, Barkun A. Case series: utility of Hemospray in management of benign upper and lower GI bleed of various etiologies: Preliminary experience. *Can J Gastroenterol* 2012;26:A081. (Abst)
- Holster IL, Kuipers EJ, Tjwa ET. Hemospray in the treatment of upper gastrointestinal hemorrhage in patients on antithrombotic therapy. *Endoscopy* 2013;45:63-6.
- Holster IL, Poley JW, Kuipers EJ, et al. Controlling gastric variceal bleeding with endoscopically applied hemostatic powder (Hemospray™). *J Hepatol* 2012;57:1391-402.
- Stanley AJ, Smith LA, Morris AJ. Use of hemostatic powder (Hemospray) in the management of refractory gastric variceal hemorrhage. *Endoscopy* 2013;45:E86-E87.
- Granata A, Curcio G, Azzopardi N, et al. Hemostatic powder as rescue therapy in a patient with H1N1 influenza with uncontrolled colon bleeding. *Gastrointest Endosc* 2013;78:451.
- Soulellis C, Carpenter S, Chen YI, et al. Lower GI hemorrhage controlled with endoscopically applied TC-325 (with video). *Gastrointest Endosc* 2013;77:504-7.
- 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 (with video). *Gastrointest Endosc* 2012;75:1278-81.
- Leblanc S, Vienne A, Dhooge M, et al. Early experience with a novel hemostatic powder used to treat upper GI bleeding related to malignancies or after therapeutic interventions (with videos). *Gastrointest Endosc* 2013;78:169-75.
- Moosavi S, Chen YI, Barkun AN. TC-325 application leading to transient obstruction of a post-sphincterotomy biliary orifice. *Endoscopy* 2013;45:E130.
- Barkun AN, Bardou M, Kuipers EJ, et al. International consensus recommendations on the management of patients with nonvariceal upper gastrointestinal bleeding. *Ann Intern Med* 2010;152:101-13.
- Sung JJY, Tsoi KK, Lai LH, et al. Endoscopic clipping versus injection and thermo-coagulation in the treatment of non-variceal upper gastrointestinal bleeding: A meta-analysis. *Gut* 2007;45:1364-73.
- Gralnek IM, Barkun AN, Bardou M. Management of acute bleeding from a peptic ulcer. *N Engl J Med* 2008;359:928-37.
- Giday SA, Van Alstine W, Van Vleet J, et al. Safety analysis of a hemostatic powder in a porcine model of acute severe gastric bleeding. *Dig Dis Sci* 2013 (Epub ahead of print).
- Giday SA, Kim Y, Krishnamurty 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;43:296-9.
- Barkun AN, Moosavi S, Martel M. Topical hemostatic agents: A systemic review with particular emphasis on endoscopic application in GI bleeding. *Gastrointest Endosc* 2013;77:692-700.

Hemospray can be used prophylactically or therapeutically and either alone or in combination with conventional endoscopic therapies depending on the risk of recurrent bleeding (19), with efficacy demonstrated in benign and malignant bleeding from the upper and lower gastrointestinal tract (3-13).

Limitations of our study included the small number of patients, the retrospective nature of data collection and the lack of documented information on the exact quantity of Hemospray applied. Future large-scale, prospective, randomized controlled trials should directly compare the relative efficacy of Hemospray with conventional endoscopic therapies, determine the exact duration of its hemostatic effect, establish its long-term safety in follow-up studies and characterize its optimal indications in mainstream endoscopy.

CONCLUSION

Hemospray appears to allow safe control of acute bleeding and may be used in high-risk cases as a temporary measure or a bridge toward more definitive therapy.

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