

Hemostatic spray powder TC-325 in the primary endoscopic treatment of peptic ulcer related bleeding: multicentre international registry

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Abstract

Introduction

Upper gastrointestinal bleeding (UGIB) is a leading cause of morbidity and associated with a 2-17% mortality in the United Kingdom (UK) and USA [1]. Peptic ulcers account for 50% of UGIB's. Endoscopic intervention in a timely manner can improve outcomes. Hemospray (Cook Medical, North Carolina, USA) is an endoscopic haemostatic powder for GI bleeding. This multicentre registry was created to collect data prospectively on the immediate Endoscopic haemostasis of GI bleeding in patients with peptic ulcer disease when Hemospray is applied as endoscopic monotherapy, dual therapy or rescue therapy.

Methods

Data were collected prospectively (January 2016 – March 2019) from 14 centres in the (UK, France, Germany and the USA). The application of Hemospray was decided upon at the endoscopist's discretion.

Results

202 patients with UGIB secondary to peptic ulcers were recruited. Immediate haemostasis was achieved in 178/202 (88%) of patients, 26/154 (17%) had a re-bleed, 21/175 (12%) died within 7 days, 38/175 (22%) died within 30 days (all-cause mortality). Hemospray combination therapy with other endoscopic modalities had an associated lower 30-day mortality (16%, $P < 0.05$) relative to Hemospray monotherapy or rescue therapy. There were high immediate haemostasis rates across all PUD Forrest classifications.

Conclusions

This is the largest case series of outcomes of peptic ulcer bleeds treated with Hemospray. There were high immediate haemostasis rates with Hemospray in oesophageal and peptic ulcer bleeds.

Key words

- Endoscopy
- Hemospray
- Peptic ulcer
- GI bleed

Introduction

Upper Gastrointestinal bleeding (UGIB) is one of the most common GI medical emergencies associated with significant mortality rates that have not significantly changed the past two decades [2,3].

Non-variceal bleeds account for approximately 89% of all UGIB [2], with peptic ulcers being the most common cause accounting for 50% of these [4]. Combination endoscopic therapy remains the gold standard for achieving haemostasis in peptic ulcer bleeds. The most commonly used modalities are epinephrine injection, thermal coagulation and mechanical therapy with endoscopic clips [5]. Despite advances in medical technology haemostasis is not achieved in 8-15% cases [6].

TC-325 (Hemospray; Cook Medical, Winston-Salem, North Carolina, USA) is a haemostatic mineral based powder. After application and contact with blood, it develops adhesive and cohesive properties forming a tamponade. Through absorption of blood fluid there is a concentration of clotting factors and activation of a clotting cascade [7]. Hemospray may be effective in the treatment of patients with peptic ulcer disease (PUD) (**Figure 1**), with haemostasis rates ranging from 76%-96%, but these data are from smaller, often retrospective, cohorts. Randomised trials have shown that Hemospray has a role in improving clinical outcomes compared with conventional techniques in variceal bleeds [8]. Other trials have shown higher re-bleed rates with Hemospray [9]. A metanalysis of 24 studies shows that hemostatic powders have a similar efficacy to conventional therapy for UGIB's [10].

Hemospray can be applied endoscopically with no requirement for direct contact. It is non-traumatic, non-thermal and nonspecific in terms of targeting. It is an attractive endoscopic alternative for treating UGIB'S [11] and tailors for various endoscopists skills.

The aim of this single arm, prospective, non-randomised multicentre international study is to assess the success of endoscopic haemostasis in patients presenting with UGIBs secondary to oesophageal and peptic ulcer disease treated endoscopically with Hemospray.

Methods:

Registration and ethics

This study was presented to the local research ethics committee (London - South East Research Ethics Committee). It concluded it should be classified as a service evaluation and development project in England (ISRCTN registry with study ID ISRCTN29594250). Centre's in other participating countries also obtained approval from their local authorities.

Risk stratification and peptic ulcer classification

The Rockall scoring system was used in the study as a predictor of re-bleeding and mortality [12]. The Blatchford scoring system was also used which helps determine need for urgent clinical intervention [13,14].

All endoscopists were asked to classify ulcers based on the Forrest classification which helps decide on what intervention is required and gives a prognosis for re-bleeding. It has been shown to be associated with requirement for surgery and mortality rates [15,16]. It divides ulcers into high risk lesions (Forrest Ia – spurting haemorrhage, Forrest Ib – oozing haemorrhage, Forrest IIa – non-bleeding visible vessel, Forrest IIb – adherent clots) and low risk lesions (Forrest IIc and III)[14].

Patient selection criteria and recruitment

Patients that were included all have stigmata of an acute UGIB (haematemesis, melaena, acute haemoglobin drop, haemodynamic instability). They all received Hemospray for the endoscopic management of an oesophageal and peptic ulcer related UGIB as a monotherapy, as part of a combination therapy or as a rescue therapy.

Patients with a Forrest IIc or Forrest III ulcer were excluded because these are lesions without signs of active or recent bleeding, where re-bleeding is rare and therefore endoscopic therapy provides no benefit [17].

Patients were recruited prospectively from January 2016 – March 2019 from 14 Centres in the United Kingdom, France, Germany and the USA. All participating endoscopists had training in the use of Hemospray. Consecutive patients were recruited presenting with GI bleeding at each centre, and the decision to use Hemospray was at the discretion of the endoscopist reflecting 'real world' clinical decisions.

An anonymised and customised online database was created to collect and securely store the data.

Device and procedure

Hemospray was applied at the time of endoscopy using a disposable delivery device. The device consists of a syringe containing the Hemospray powder, a 7Fr or 10Fr delivery catheter, and an introducer handle with a built-in carbon dioxide canister to help propel the Hemospray powder [18].

The accessory channel of the endoscope was flushed with air before inserting the catheter. The catheter was then advanced through the working channel and held 1-2cm from the site of bleeding [11]. Hemospray powder was delivered in short bursts under direct vision until there was complete coating of the lesion. The endoscopist would then observe the site for a minimum of 5 minutes to confirm immediate haemostasis or treatment failure requiring escalation of therapy

After treatment success the standard medical management of peptic ulcers is followed as per local protocols [19]. Any patients who had failed treatment were managed either conservatively, with surgery or interventional radiology.

Definition and study endpoints

The primary outcome was immediate overall endoscopic haemostasis rates following the Hemospray application. Secondary outcomes were haemostasis rates based on ulcer location and Forrest classification, re-bleeding rates, and 7- and 30-day all-cause mortality.

Immediate haemostasis was defined as observed cessation of bleeding within 5 minutes of application of Hemospray and no re-bleeding immediately. The haemostasis time of 5 minutes was decided upon in an investigator's consensus meeting at UEGW 2015. Re-bleeding was defined as a sustained drop in Hb (>2g/l), ongoing or new haematemesis or melaena with haemodynamic instability following index endoscopy. This is similar to the definition used in previous studies and consensus statements [18,20].

Monotherapy was when Hemospray was used alone following which the site is observed for 5 minutes for treatment failure/success. Combination therapy was when Hemospray was used in combination with conventional methods as an adjunct to a single or two other modalities and then the site is observed for 5 minutes. Rescue therapy is when Hemospray is used when all other conventional modalities have failed following the 5-minute observation time and there was ongoing bleeding. Hemospray was used as a primary therapy in cases where the ulcer was not amenable to standard therapy due to ulcer size or location. It was used as a rescue therapy when there was ongoing bleeding following standard endoscopic therapy.

Follow up

Patients were followed up for 30 days following index endoscopy. Follow-up was achieved by review on the ward, clinic review and telephone consultations. Patient records were reviewed. No patients were lost to follow up in the first 30 days.

Statistics

The analyses focussed on examining the association between key study factors (type of Hemospray, Forrest classification, ulcer location) and the outcomes. (haemostasis, re-bleeding, death).

Patients from the same centre may have more similar outcomes than from patients from different centres, and thus the analysis was performed using multilevel statistical methods. Two-level models were used with individual patients nested within centres. In order to give the analysis results as relative risks rather than odds ratios, a multilevel model was fitted, which assumed the data followed a Poisson distribution, and used a log link function, along with robust standard errors.

The association between various factors and outcomes were analysed using two sets of analysis. A direct, unadjusted, comparison of the groups for the key factors was first performed. Subsequently a second analysis adjusted for potentially confounding factors.

Potentially confounding variables were initially examined individually. Those showing some evidence of an association with each outcome ($p \leq 0.1$) were adjusted for in the second stage of the analysis. Both the Rockall and Blatchford score were also adjusted for, regardless of statistical significance, due to the clinical importance of these variables.

Statistical analysis was performed using the software package Stata, version 15.1 (Statacorp, Texas, USA).

Results

Between January 2016 and March 2019 202 patients were enrolled meeting inclusion criteria. They had a median age of 71 (IQR, 60-82). Most of the ulcers were Forrest 1b (58%) followed by Forrest 1a (19%) and were mostly located in the duodenum (62%).

(Table 1)

Overall haemostasis following the application of Hemospray was achieved in 88% of all patients, and in 85% of the Forrest 1 cohort of patients. The median Blatchford score was 12 (IQR, 10-14). The median Rockall score was 7 (IQR, 6-8). The overall re-

bleeding rate at 30 days following treatment with Hemospray was 17%. 7- and 30-day all-cause mortality rates were 12% and 22% respectively (**Table 2**).

Outcomes based on Hemospray utilization

50 patients (25%) received Hemospray as a monotherapy, 101 patients (50%) as part of a combination therapy and 51 patients (25%) as a rescue therapy. There was no difference between the three Hemospray groups for the haemostasis rate, re-bleeding rate or 7-day mortality. However, there was a significant difference in 30-day mortality rates in the combination group (Table 3). Further analysis was performed in the combination therapy subgroups (**Table 1s**). Re-bleed data was missing for 24 patients, and mortality data was missing for 27 patients.

Forrest classifications

Haemostasis rates were similar in the 1a (87%) and 1b (85%) Forrest groups. There was a significant difference in the rates of haemostasis between the different Forrest classifications ($P < 0.001$) (**Table 4**). 51% (20/39) of patients in the Forrest 1a group received Hemospray as part of a combination therapy and 5% (2/39) of patients received Hemospray monotherapy. 49% (57/117) of patients in the Forrest 1b cohort received Hemospray as part of a combination therapy. 48% (10/21) of patients in the Forrest 2b group received Hemospray as a monotherapy.

The occurrence of re-bleeding and death with both 7 and 30 days were not found significantly different between the four groups.

Peptic ulcer location

Highest haemostasis rates were achieved in the oesophagus (97%), and the lowest rates in the duodenum (85%). There was a slight evidence of a difference in haemostasis between the three groups ($P = 0.10$).

There was no difference between the three locations for the re-bleed rates or for 7-day mortality (**Table 5**).

Patients that failed to achieve immediate haemostasis

In the patients that did not achieve haemostasis following Hemospray treatment 10/24 (42%) had embolization in interventional radiology, 3/24 (13%) had surgery, 4/24 (17%) were stabilised and maintained with supportive care and 7/24 (29%) died. The cause of death was not documented.

Discussion

In acute PUD UGIBs endoscopic therapy is the first line treatment for achieving haemostasis. It reduces further bleeding, the need for surgery and mortality [21]. Success rates for primary haemostasis vary depending on the modality. There is a re-bleed rate of 8-15% [6] and mortality remains significant [2] despite endoscopic advances. There is a need to explore ways to improve outcomes.

To our knowledge, to date this is the largest study looking at outcomes of peptic ulcers treated with Hemospray, the next largest study had 75 patients [22]. Studies over the last 10 years reported varying haemostasis rates with Hemospray in peptic ulcer bleeds from 77% to 96% [15,23,24]. A larger targeted study was necessary.

There is a need to reduce re-bleed and mortality rates in UGIB. This is exacerbated by scenarios where there is a large ulcer size, high risk lesions and difficulty of access such as in the D1/D2 junction. Therefore, there is a need for a haemostatic device which has a short learning curve, quick to apply and is non-contact and therefore does not trigger further bleeding and is nonspecific in terms of targeting [18]. Hemospray has characteristics that can overcome all these challenges. Our study shows that Hemospray has high immediate haemostasis rates in Forrest 1 peptic ulcer UGIBs (85%). Therefore, Hemospray has a potential role to bridge this gap of complex peptic ulcers.

Patients with UGIBs can be risk stratified prior and after endoscopic intervention and our cohort of patients were high risk. This is evidenced by the high baseline median Rockall (7, IQR 6-8) and Blatchford scores (12, IQR 10-14). This reflects a higher risk cohort of patients from large teaching hospitals and explains the higher mortality rates. There have been similarly high Rockall scores in recent studies [7]. The re-bleed and mortality rate in the oesophageal and peptic ulcer cohort overall was lower or equal to predicted rates based on the Rockall score. The Rockall score is often criticised in studies as being a poorer predictor of mortality compared to the AIM65 and Blatchford score [25]. Other studies have shown it to be clinically useful in predicting re-bleeding, surgery and mortality [26]. Most societies recommend using the Blatchford score. We used both scoring systems.

The combination therapy cohort had high haemostasis rates (89%) and the lowest re-bleed rate (15%) however there was no significant difference relative to the other subgroups. Multivariable analysis showed a statistically significant lower chance of 30-day mortality when Hemospray was used in combination. Our re-bleed rates in the monotherapy cohort were lower than in previous studies (33.8%) [24] where the patient cohort was smaller. Most of the patients that received combination therapy had Forrest 1b peptic ulcers (57/101, 56%).

The combination of adrenaline and Hemospray showed good outcomes out of all groups. These should be analysed with caution and a larger cohort is required. Dual therapy with adrenaline injection is superior to adrenaline monotherapy for treatment of GI bleeds [27]. A previous study has shown a combination of Hemospray and adrenaline achieved a 100% initial haemostasis rate and 25% 7-day rebleeding rate in 8 patients. In our study there was high haemostasis rates of 89% and a lower re-bleed rate of 13% in 36 patients [22]

In our study Hemospray was used mostly in Forrest 1a and 1b ulcers (77%) showing high haemostasis rates. The re-bleed rate in these cohorts was lower than previously reported [7,24,28,29]. This may be related to Hemospray being applied in the majority of cases as part of a combination therapy. The Forrest Classification is globally used for classification of ulcers; however, the disadvantage is interobserver variability and therefore ulcers may be misclassified which can affect outcomes. Forrest classification IIc and III ulcers were excluded from the study because they do not have signs of active or recent bleeding [17]. Forrest classification 2 ulcers were included in the study as the use of Hemospray was at the discretion of the endoscopist and it was important to report the outcomes for this group of patients, particularly the re-bleeding rate.

The re-bleed and 7- and 30-day mortality rate in the Forrest 2 b cohort is higher than that of 1b. This can be explained by a higher proportion of these patients having Hemospray as a monotherapy (48%) relative to other Forrest classifications. There is possible selection bias as Hemospray use was at the endoscopists discretion and is a possible confounder when comparing re-bleeding rates between groups.

Most of the peptic ulcers in the study were in the duodenum. There was a higher haemostasis rate in the oesophagus relative to the duodenum and this is likely due to the complex anatomy and higher risk vessels. The oesophagus is a long narrow tube with better access and visibility which explains the better outcomes.

A national UK audit showed that only 38% of patients received dual endoscopic therapy for an UGIB [30]. This can be due to challenging anatomy, local resources or endoscopists experience. Our data shows that Hemospray can help bridge this gap due to its ease of use as its non-contact and non-specific in terms of targeting [11]. High haemostasis rates were achieved in the more complex part of the upper GI tract in the duodenum. In smaller units with limited resources, low case volumes or limited expertise Hemospray can be used in high risk lesions to achieve haemostasis and patient stability, and bridge towards a second look endoscopy or surgery/radiological intervention.

There are other second line treatments being investigated for UGIB's. This includes over the scope clips which studies have shown to be more effective than standard

therapy for patients with recurrent bleeding peptic ulcers [31]. A head to head comparison with Hemospray is required to compare effectiveness.

Our study has some important limitations. One such limitation of this study is non-intentional selection bias. Hemospray was administered at the discretion of the endoscopist. This is reflected by the high Rockall and Blatchford scores suggesting higher risk patients were selected. This may lead to higher mortality rates and reduced overall haemostasis rate compared to a standard patient cohort. Another limitation is this was not a randomised control trial and there isn't head to head comparisons with conventional therapy. A study power calculation was not done. Another limitation is the exact cause of death was not documented. The majority of deaths would have been likely secondary to co-morbidities in this high-risk cohort. The total number of patients with peptic ulcer bleeding was not recorded. It would have been interesting to note the proportion of all patients treated with Hemospray. An important limitation is that there can be interobserver variability in the classification of ulcers and the definition of immediate haemostasis of bleeding. Another limitation is the justification for use of Hemospray was not documented to understand why it was used rather than standard of care. An important limitation was treatment following endoscopy was not documented on the database following each procedure which would help explain variations in re-bleeding rates. We will improve the registry by including a comments section for the Endoscopist after each Hemospray use and a question regarding treatment protocol following the endoscopy.

The results suggest Hemospray may play a current role to achieve immediate haemostasis in high risk bleeding oesophageal and peptic ulcers to achieve control and bridge towards a second look endoscopy with conventional methods or surgery/radiological intervention. The ideal role for Hemospray would be as part of a combination or rescue therapy to optimise control. Use as a monotherapy should be avoided unless there is difficulty in applying standard therapy due to access or surface area of bleeding. In this scenario a repeat endoscopy should be arranged in 24-48 hours. Randomised controlled trials are required to validate results.

Acknowledgements

This work was undertaken at UCL/UCLH which received a proportion of funding from the Department of Health's NIHR Biomedical Research Centres funding scheme. The views expressed in this publication are those of the authors and not necessarily those of the department of health. This work was also supported by the Wellcome/EPSRC centre for interventional and surgical sciences (WEISS) at UCL. Dr Rehan Haidry (Chief Investigator) has received research grant support from Cook Endoscopy to support research infrastructure.

Table 1: Baseline demographics and peptic ulcer characteristics/locations

Demographic parameter (N =202)	Value
Median age, Years (IQR)	71 (60-82)
Sex	
Male (%)	136/202 (67%)
Female (%)	66/202 (33%)
Medication use	
Antiplatelets (%)	40/192 (21%)
Anticoagulants (%)	39/191 (20%)
NSAIDs (%)	14/202 (7%)
Peptic ulcer characteristics (N=202)	
Median lesion size,mm (IQR)	15 (10-20)
Forrest classification	
Forrest Ia	39/202 (19%)
Forrest Ib	117/202 (58%)
Forrest IIa	25/202 (12%)
Forrest IIb	21/202 (10%)
Ulcer location	
Oesophagus	30/202 (15%)
Gastric	47/202 (23%)
Duodenum	125/202 (62%)

Table 2: Outcomes in overall ulcer bleed cohort

	Ulcers (N =202)	Rockall score	Blatchford score
Haemostasis rate	178/202 (88%)	7 (IQR, 6-8)	12 (IQR, 10-14)
Re-bleeding rate	26/154 (17%)	7 (IQR, 6-8)	13 (IQR, 12-14)
7-day mortality	21/175 (12%)	8 (IQR, 7-8)	15 (IQR, 13-17)
30-day mortality	38/175 (22%)	8 (IQR, 7-8)	14 (IQR, 10-16)

Table 3: Analysis of outcomes in Hemospray subgroups

Outcome	Analysis	Monotherapy (N=50)	Combination (N=101)	Rescue (N=51)	P-value (+)
Haemostasis rate	Summary	44/50 (88%)	90/101 (89%)	44/51 (86%)	
	Unadjusted	1	1.01 (0.91, 1.13)	0.98 (0.85, 1.13)	P = 0.82
	Adjusted(*)	1	0.93 (0.81,1.06)	0.90 (0.72, 1.12)	P = 0.50
Re-bleeding rate	Summary	5/32 (16%)	12/81 (15%)	9/41 (22%)	
	Unadjusted	1	0.95 (0.36, 2.48)	1.41 (0.70, 2.81)	P = 0.16
	Adjusted(**)	1	1.52 (0.51, 4.54)	2.21 (0.79, 3.196)	P = 0.31
7-day mortality	Summary	5/38 (13%)	9/89 (10%)	7/48 (15%)	
	Unadjusted	1	0.77 (0.30, 1.94)	1.11 (0.45, 2.75)	P = 0.50
	Adjusted(#)	1	0.85 (0.26, 2.81)	1.48 (0.30, 7.17)	P = 0.36
30-day mortality	Summary	12/38 (32%)	14/89 (16%)	12/48(25%)	
	Unadjusted	1	0.49 (0.27, 0.89)	0.79 (0.34, 1.85)	P = 0.01
	Adjusted(##)	1	0.51 (0.28, 0.93)	1.56 (0.44, 5.59)	P <0.001

Figures are number (percentage) of patients with each outcome, plus relative risks (95% confidence interval)

(*) Adjusted for Forrest classification, blood pressure, Hb, NSAIDs, Rockall and Blatchford score

(**) Adjusted for Forrest classification, lesion size, Rockall and Blatchford score

(#) Adjusted for Forrest classification, blood pressure, Rockall and Blatchford score

(##) Adjusted for Forrest classification, Hb, Rockall and Blatchford score

(+) P-value indicating the significance of the overall difference between the 3 Hemospray groups

Table 4: Analysis of Hemospray treatment outcomes based on Forrest classification

Outcome	Analysis	Ia (N=39)	Ib (N=117)	IIa (N=25)	IIb (N=21)	P-value (+)
Haemostasis	Summary Unadjusted	34/39(87%) 1	99/117(85%) 0.97 (0.84, 1.12)	25/25 (100%) 1.15 (0.99, 1.33)	20/21 (95%) 1.09 (0.94, 1.27)	P < 0.001
	Adjusted(*)	1	0.96 (0.80, 1.16)	1.17 (0.91, 1.50)	1.07 (0.86, 1.33)	P = 0.08
Re-bleeding	Summary Unadjusted	7/29(24%) 1	13/84 (15%) 0.64 (0.14, 2.97)	2/23(9%) 0.36 (0.06, 2.27)	4/18(22%) 0.92 (0.38, 2.23)	P = 0.69
	Adjusted(**)	1	1.57 (0.39, 6.32)	0.46 (0.04, 5.14)	1.46 (0.49, 4.31)	P = 0.26
7-day mortality	Summary Unadjusted	6/34(18%) 1	11/99 (11%) 0.63 (0.34, 1.16)	1/23(4%) 0.25 (0.03, 1.93)	3/19(16%) 0.89 (0.30, 52.70)	P = 0.28
	Adjusted(#)	1	-	-	-	
30-day mortality	Summary Unadjusted	9/34(26%) 1	21/99 (21%) 0.79 (0.40, 1.54)	3/23(13%) 0.49 (0.22, 1.08)	5/19(26%) 1.0 (0.55, 1.83)	P = 0.37
	Adjusted(###)	1	1.45 (0.58, 3.62)	1.04 (0.43, 2.52)	1.87 (0.47, 7.46)	P = 0.77

Figures are number (percentage) of patients with each outcome, plus relative risk (95% confidence interval)

(*) Adjusted for method of Hemospray therapy, lesion size, Rockall and Blatchford score

(**) Adjusted for method of Hemospray therapy, lesion size, Rockall and Blatchford score

(#) Unable to perform adjusted analysis due to zero deaths in one group in the patient group with data on all factors

(###) Adjusted for method of Hemospray therapy, Hb, Rockall and Blatchford score

(+) P-value indicating the significance of the overall difference between the 4 ulcer categories

Table 5: Analysis of Hemospray treatment outcomes based on peptic ulcer location

	Analysis	Oesophagus (n =30)	Gastric (n=47)	Duodenum (n=125)	P-value
Haemostasis	Summary Unadjusted	29/30 (97%) 1.14 (1.00, 1.30)	43/47 (91%) 1.08 (0.91, 1.28)	106/125(85%) 1	P = 0.1
	Adjusted (*)	1.20 (1.03, 1.40)	1.15 (1.00,1.33)	1	
Re-bleed	Summary Unadjusted	2/23 (9%) 0.45 (0.17, 1.20)	6/38 (16%) 0.82 (0.37, 1.20)	18/93 (19%) 1	P = 0.4
	Adjusted (**)	0.31 (0.05, 1.87)	0.97 (0.44, 2.12)	1	
7-day mortality	Summary Unadjusted	4/24 (17%) 1.40 (0.64, 3.07)	4/42 (10%) 0.80 (0.21, 3.01)	13/109 (12%) 1	P = 0.7
	Adjusted (#)	1.20 (0.56, 2.55)	0.95 (0.30, 3.01)	1	

Figures are number (percentage) of patients with each outcome, plus relative risks (95% confidence interval)

(*) Adjusted for blood pressure, Hb, NSAIDs, Rockall and Blatchford score

(**) Adjusted for blood pressure, Rockall and Blatchford score

(#) Adjusted for blood pressure, Rockall and Blatchford score

(+) P-value indication the significance of the overall difference between the ulcer location categories

Supplementary material

Table 1s: Outcomes in the combination therapy subgroups

	Hemospray + adrenaline injection (n = 36)	Hemospray + clips (n=12)	Hemospray + adrenaline + clips (n =31)	Hemospray + adrenaline + thermal (n = 13)	Hemospray + adrenaline + thermal + clips
Haemostasis	32/36 (89%)	11/12 (92%)	28/31 (90%)	10/13 (77%)	7/7 (100%)
Median Rockall score (IQR)	7 (6-8)	7 (6-8)	7 (6-8)	8 (6-8)	7 (6-8)
Median Rockall score (IQR)	13 (10-14)	15 (12-16)	11 (8-14)	13 (11-14)	12 (12-15)
Re-bleeding	4/30 (13%)	2/9 (22%)	4/26 (15%)	1/10 (10%)	1/6 (17%)
7- day mortality	2/33 (6%)	3/10 (30%)	2/28 (7%)	1/10 (10%)	1/6 (17%)
30-day mortality	5/33 (15%)	0	4/28 (14%)	0	0

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