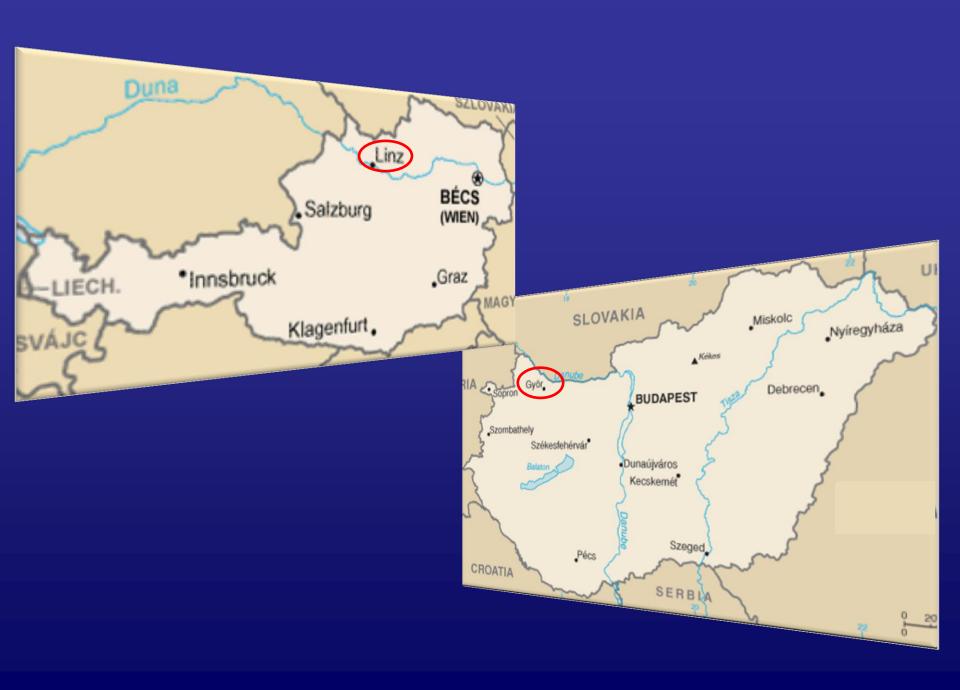
BLUTUNGEN Gastrointestinal bleeding

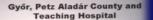
István Rácz, MD
Petz Aladár County and Teaching Hospital
Győr, Hungary





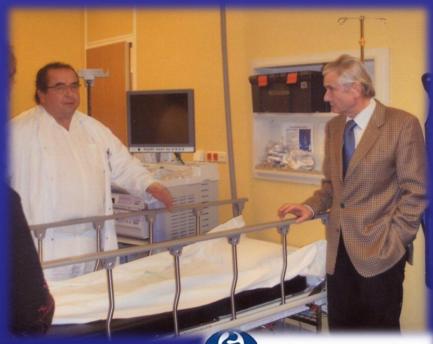






Course Directors: István Rácz, Rainer Schöfl

15 & 16 November 2007, International Workshop Bartók Béla Centre, Győr, Hungary



ESGE

International Live Endoscopy Workshop Budapest

14-15 September 2012

Military Hospital, Budapest, HUNGARY

under the auspices of Csaba HENDE – Minister of Defense



Marion De PATER Éva FARKAS Stefan KOHLMANN

IN THIND FOR



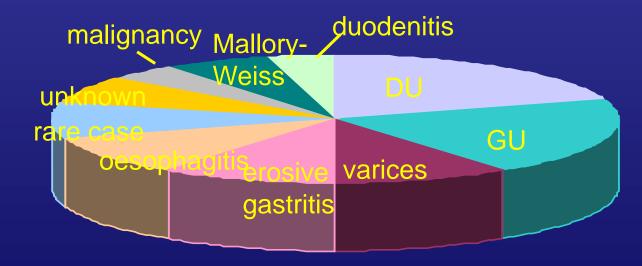
Epidemiology

Acute upper GI bleeding

Ulcer bleeding: 40-60 %

70-100/100.000 patients annually

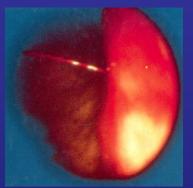
Győr, Hungary UGIB pts. 148 in 2013



AGA data

Ulcer bleeding

Endoscopic hemostasis indicated



Forrest la



Forrest Ib

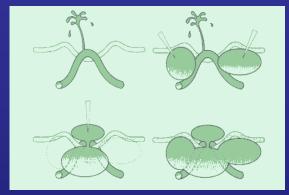


Forrest IIa

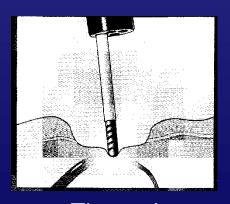


Forrest IIb (?)

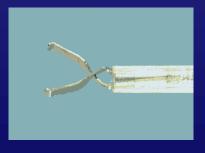
Hemostatic methods



Injection



Thermal



Hemoclip

Available endoscopic hemostatic methods (2013)

Techniques	ulcer	tumor	varix
1.) Injection (epinephrine-NaCl)	+	-	-
2.) Thermo probe (HPU)	+	-	-
3.) Hemoclip	+	-	-
4.) Endo-loop	-	-	+
5.) Aethoxysclerol	-	-	+
6.) Band ligation	-	-	+
7.) Argon-plasma coag. (APC)	+	+	-
8.) Cyanoacrylate (Histoacryl)	-	-	+
9.) Fibrin glue (fibrinogen+thrombin)	+	-	-
10.) Oesophageal metal stent	-	+	-
11.) "Over the scope" clip (OVESCO)	+	-	-
12.) Hemospray	+	+	-

Available endoscopic hemostatic methods (2013)

Techniques	ulcer	tumor	varix
1.) Injection (epinephrine-NaCl)	+	_	-
2.) Thermo probe (HPU)	+	-	-
3.) Hemoclip	+	-	-
4.) Endo-loop	-	-	+
5.) Aethoxysclerol	-	-	+
6.) Band ligation	-	-	+
7.) Argon-plasma coag. (APC)	+	+	-
8.) Cyanoacrylate (Histoacryl)	-	-	+
9.) Fibrin glue (fibrinogen+thrombin)	+	-	-
10.) Oesophageal metal stent	-	+	-
11.) "Over the scope" clip (OVESCO)	+	-	-
12.) Hemospray	+	+	-

Rescue endoscopic bleeding control for nonvariceal upper gastrointestinal hemorrhage using clipping and detachable snaring Endoscopy 2013; 45: 489-492

Authors

J. H. Lee¹, B. K. Kim², D. C. Seol¹, S. J. Byun², K. H. Park², I. K. Sung¹, H. S. Park¹, C. S. Shim¹

Institutions

Digestive Disease Center, Department of Internal Medicine, Konkuk University Medical Center, Seoul, Korea

² Digestive Disease Center, Department of Internal Medicine, Hong Ik Hospital, Seoul, Korea

- rescue endoscopic therapy in 7 out of 100 pts (Forrest la,b or lla)
- initial endo-Rx (inj.+clipping or coag.) was failing
- multiple clips fixed by detechable snare
- sucess: all









Endoscopic hemostasis of bleeding gastric ulcer with a combination of multiple hemoclips and endoloops

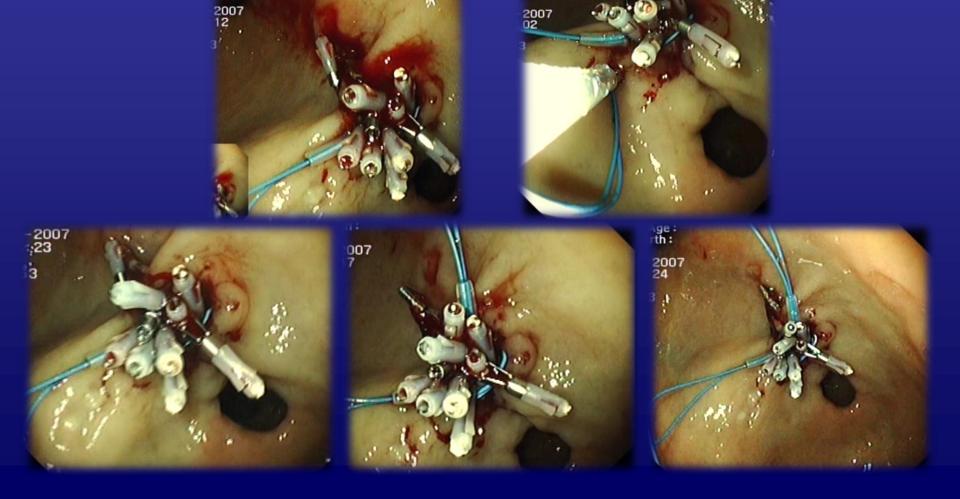
István Rácz, MD, PhD, Tibor Kárász, MD, Hussam Saleh, MD

Gyor, Hungary

rth:

GASTROINTESTINAL ENDOSCOPY Volume 69, No. 3: Part 1 of 2: 2009

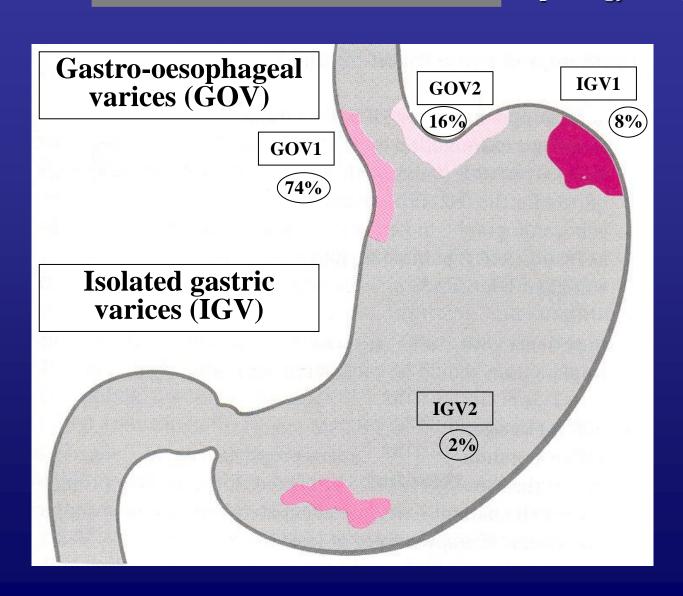
www.giejournal.org



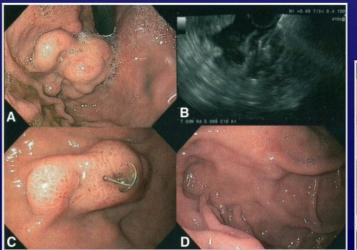
Age: rth:

Gastric Varices

Saurin SK et al. Hepatology 1992, 16, 1343



N-butyl 2-cyanoacrylate (enbucrilate) (Histoacryl, add. Lipiodol, polymer. time 10 sec) bucrilate C ocrilate, polymerisation time: 45-60 sec



TECHNICAL REVIEW

Cyanoacrylate applications in the GI tract

Rees Cameron, MD, Kenneth F. Binmoeller, MD

It has the transfer of the tra

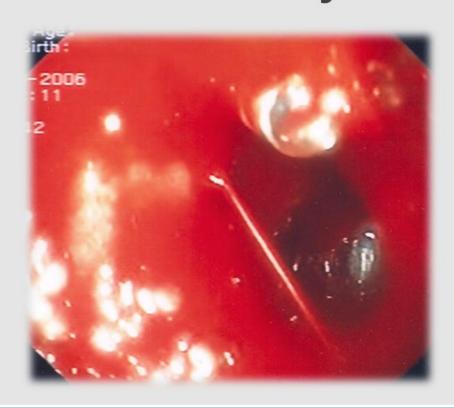
GASTROINTESTINAL ENDOSCOPY Volume 77, No. 6: 2013

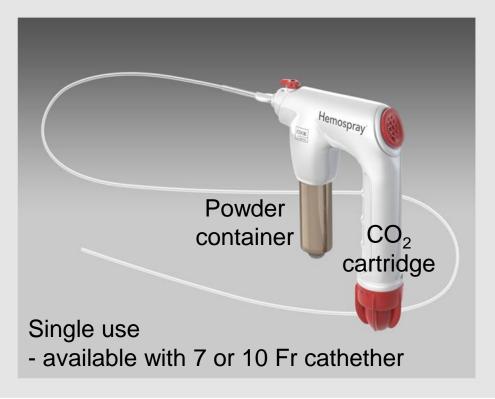
San Francisco, California, USA

- gastric varices: well-established
- varix obliteration 70-90%
- rebleeding < 30%
- secondary prophylaxis of bleeding
- primary prophylaxis for varices > 10 mm
- EUS monitoring
- to find the main "perforating" feeding vein (Romero-Castro)



Hemospray[™] Endoscopic Hemostat: A New Modality for Endoscopic Hemostasis





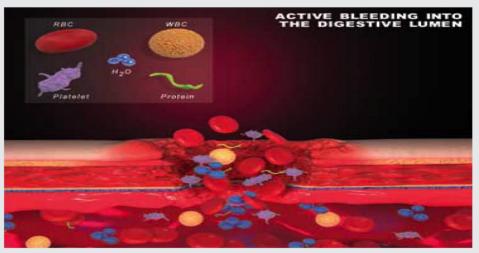


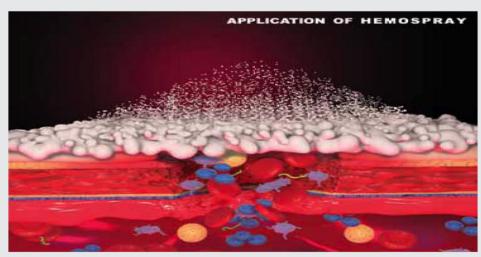
What is Hemospray?

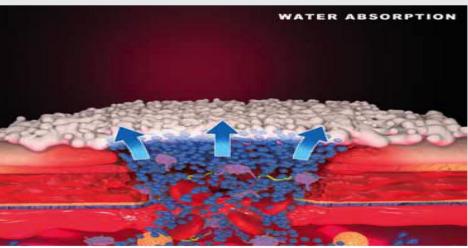
- Hemospray is a proprietary <u>mineral blend powder</u> developed specifically for endoscopic hemostasis.
- It contains <u>no human or animal proteins</u> or botanicals and has <u>no known allergens</u>.
- Hemospray is metabolically inert and deemed <u>nontoxic</u>, systemically or otherwise.

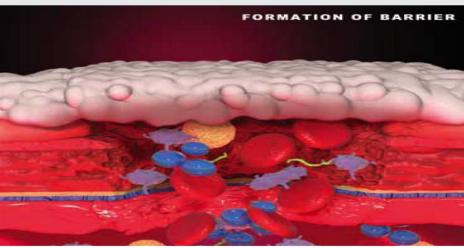
How does Hemospray work?

When Hemospray comes in contact with blood, the powder <u>absorbs water</u>, then acts both cohesively and adhesively, forming a <u>mechanical barrier</u> over the bleeding site.











Studies & Publications

Giday/Animal Study

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

Authors

S. A. Giday^{1,2}, Y. Kim^{1,3}, D. M. Krishnamurty¹, R. Ducharme⁴, D. B. Llang¹, E. J. Shin¹, X. Dray^{1,5}, D. Hutcheon¹, K. Moskowitz⁴, G. Donatelli¹, D. Rueben⁶, M. I. Canto¹, P. I. Okolo¹, A. N. Kalloo¹

nstitutions

Institutions are listed at the end of article.

2010



Sung/PU Study

Acute Hemostasis: 19/20 patients ‡

No Recurrent Bleeding: 17/19 patients †

Procedural Adverse Events: None

Device-related SAE: None

Mortality/SAE at 30-day follow-up: None

(20 patients)

Early clinical experience of the safety and effectiveness of Hemospray in achieving hemostasis in patients with acute peptic ulcer bleeding J. J. Y. Sung¹, D. Luo¹, J. C. Y. Wu¹, J. Y. L. Ching¹, F. K. L. Chan¹, J. Y. W. Lau¹, S. Mack², R. Ducharme¹, P. Okolo⁴, M. Canto⁴, A. Kalloo⁴, S. A. Giday⁴ Institute of Digestive Disease, The Chinese University of Hong Kong, Hong Kong

Cook Medical, Winston-Salem, North Carolina, USA

MED Institute, West Lafayette, Indiana, USA

Department of Medicine, Johns Hopkins Institute, Baltimore, USA 2011

emains chal-

copic devices.

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nimal model.

ospray for he-

eding in hu-

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Conclusion: These pilot results indicate that Hemospray is safe in humans. Hemospray was effective in achieving acute hemostasis in active peptic ulcer bleeding.

Vice-Councilour & President University Administration Building The Chinese University of Hong Kong Shatin, New Territories Hong Kong Fax: +852-26037301 joesung@cuhk.edu.hk

or lb), who had all given informed consent to par-

ticipation, underwent upper gastrointestinal endoscopy and application of Hemospray within 24 hours of hospital admission once hemodynamically stable. Up to two applications of Hemospray. not exceeding a total of 150 g were allowed. Bleeding recurrence was monitored post proce-

durally, by second-look endoscopy (72 hours post treatment), and by phone at 30 days. Rate of hemostasis, recurrent bleeding, mortality, need powder with for surgical intervention, and treatment-related bleeding site. complications were assessed. Results: 20 patients were recruited (18 men. 2

women; mean age 60.2 years). Acute hemostasis was achieved in 95% (19/20) of patients; 1 patient had a pseudoaneurysm requiring arteria embolization. Bleeding recurred in 2 patients within 72 hours (shown by hemoglobin drop); neither had active bleeding identified at the 72-hour endoscopy. No mortality, major adverse events, or treatment- or procedure-related serious adverse events were reported during 30-day follow-up.

Conclusion: These pilot results indicate that Hemospray is safe in humans. Hemospray was effective in achieving acute hemostasis in active peptic ulcer bleeding.

Introduction

Endoscopic hemostasis has been widely recognized as the first-line treatment for peptic ulcer bleeding. However some 5% - 10% of patients still experience recurrence of bleeding after initial hemostasis with combined endoscopic therapy including injection, thermal coagulation, or mechanical hemostasis [1]. In patients with severe active bleeding and challenging anatomy, endoscopic treatment can be difficult and a higher level of technical expertise is often required. A simple and effective method of endoscopic hemostasis would have a significant impact on the treatment of active gastrointestinal bleeding.

The Hemospray powder is highly adsorptive with a multimodal mechanism of action. When in contact with moisture (e.g. blood and tissue) in the gastrointestinal tract, the powder becomes cohesive and adhesive, and forms a stable mechanical barrier which adheres to and covers the bleeding tract.

site to achieve hemostasis. The Hemospray pov der is not absorbed or metabolized by mucosal tissue and therefore appears to have no risk of systemic toxicity. The covering formed by the powder sloughs from the lesion of the digestive tract wall and is naturally eliminated from the gastrointestinal tract. Endoscopic application of Hemospray for the treatment of acute arterial bleeding in the gastrointestinal tract has been explored recently in an animal model. In a randomized controlled swine model study in which arterial bleeding in the gastrointestinal tract was induced to test the hemostasis effect of Hemospray (TC-325), Giday et al. [2] reported 100% initial cessation of bleeding with the use of Hemospray versus 0% in the control group which did not receive any treatment. Hemospray was found to be eliminated from the stomach of animals within 48 hours with no complication associated with passage of the powder through the gastrointestinal

Sung JJY et al. Safety and effectiveness of Hemospray for hemostasis in acute peptic ulcer bleeding: early clinical experience ... Endoscopy 2011; 43: 291 – 295

SEAL Product Evaluation



Survey to Evaluate the Application of Hemospray[™] in the Luminal Tract

Objective: To gain clinical experience with Hemospray in Europe and Canada

97 patients

Gastroduodenal ulceration	58% (n=41)
Tumours	7% (n=5)
Oesophageal ulceration	4% (n=3)
Dieulafoy lesion	4% (n=3)
Post EMR	3% (n=2)
GAVE	3% (n=2)
Other causes	21%(n=15)

SEAL-Clinical Outcomes

	Hemospray Monotherapy	Hemospray + Additional endoscopic therapy	Standard endoscopic therapy + Hemospray
Number of Patients	39	8	24
Rockall Score	5.5	7	6.5
(median)	(range 3-10)	(range 5-10)	(range 5-7)
Primary	38/39	6/8	16/24
Haemostasis	(97%)	(75%)	(67%)
Rebleed	6/38	1/6	6/16
(7 days)	(16%)	(17%)	(38%)
Mortality	3/39	0	2/24
(7 days)	(8%)		(8%)

.

Hemospray indications (FDA)

- non-variceal acute upper GI bleeding
- lower GI bleeding (Canada)

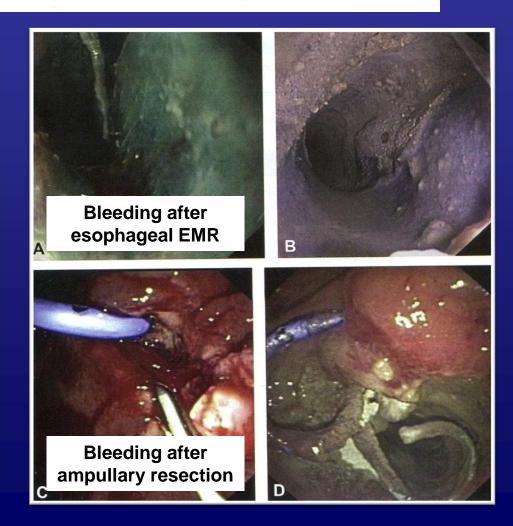
Early experience with a novel hemostatic powder used to treat upper GI bleeding related to malignancies or after therapeutic interventions (with videos)

Sarah Leblanc, MD, Ariane Vienne, MD, Marion Dhooge, MD, Romain Coriat, MD, PhD, Stanislas Chaussade, MD, PhD, Frédéric Prat, MD, PhD

Paris, France

Volume 78, No. 1: 2013 GASTROINTESTINAL ENDOSCOPY

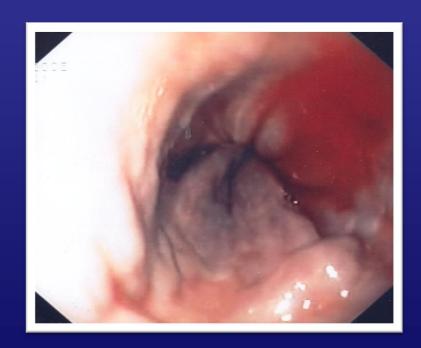
- 12 tumor cases (1 pulsatile,
 11 oozing bleeding)
- Hemospray application
- Immediate hemostasis in all 12 pts. after Hemospray (in 8 pts. first line treatment)



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

Ibrahim Mostafa et al. UEGW abstract 2013

- Bi-centric prospective trial (Cairo-Brussels)
- Aim: to control acute oe. variceal bleeding
- Patients: 9 cirrhotic with variceal (oe/cardia) bleeding
- ITN narcosis
- Mean hemospray volume: 21 g/ pts.
- Results: Initial hemostasis: all No rebleeding, no mortality (15 days)



Lower GI hemorrhage controlled with endoscopically applied TC-325 (with videos)

Constantine A. Soulellis, MD,¹ Stephanie Carpentier, MD,¹ Yen-I Chen, MD,¹ Carlo A. Fallone, MD,¹ Alan N. Barkun, MD, MSc^{1,2}

GASTROINTESTINAL ENDOSCOPY Volume 77, No. 3: 2013

Montreal, Quebec, Canada

- 4 cases
- indications:
 - post-polypectomy bleeding
 - post-irradiation proctitis
 - anticoagulant, clopidogrel treatment
- successfull hemostasis in all cases
- CO₂ pressure

12 mmHg (1-2 cm)

55 mmHg! (in contact with the tissue)

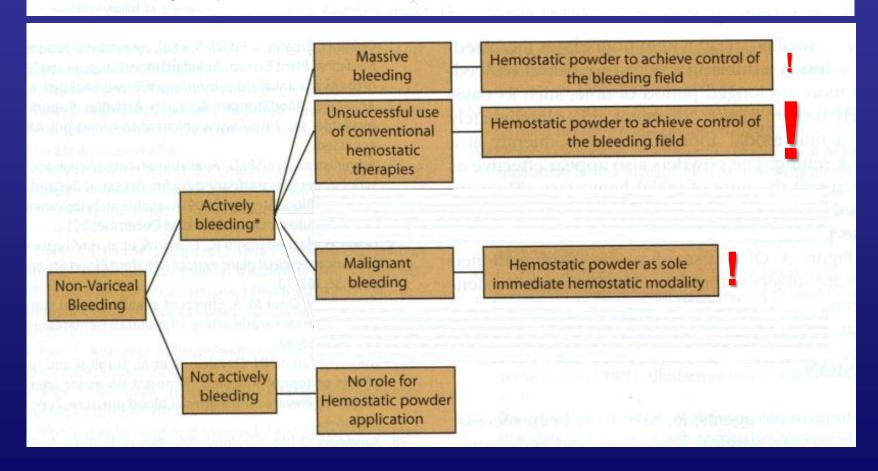


Topical hemostatic agents: a systematic review with particular emphasis on endoscopic application in GI bleeding (CME)

Alan N. Barkun, MD, MSc, 1,2 Sarvee Moosavi, MD, Myriam Martel, BSc1

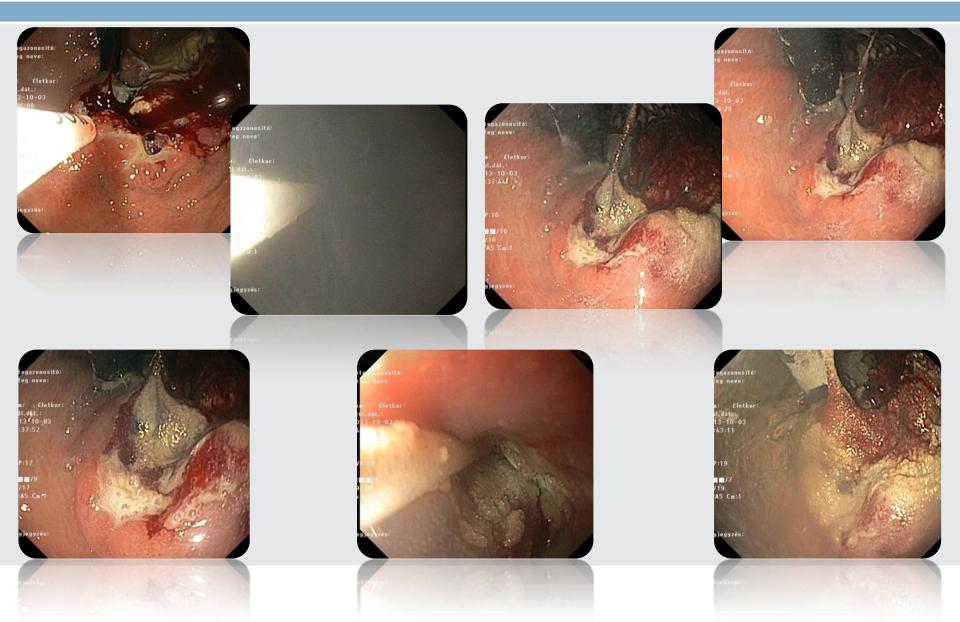
Montreal, Quebec, Canada

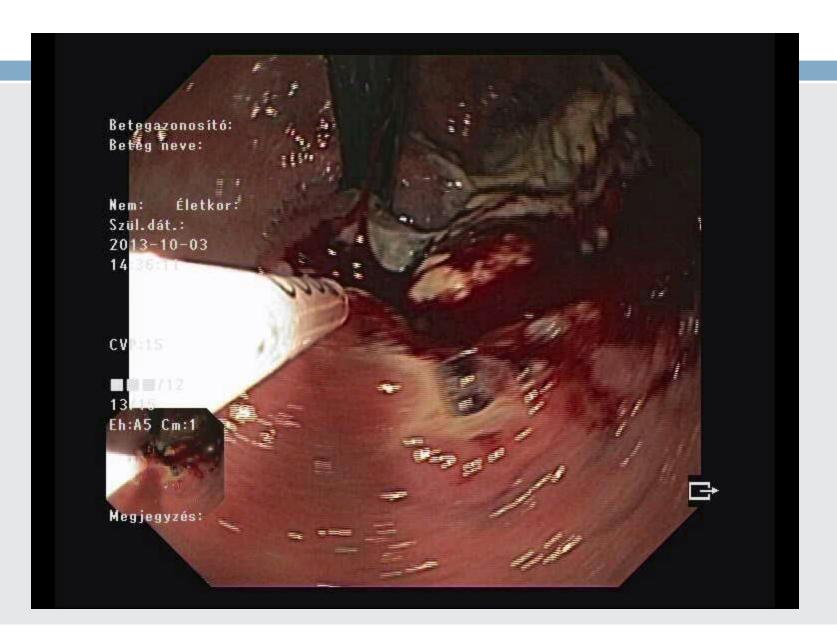
GASTROINTESTINAL ENDOSCOPY Volume 77, No. 5: 2013





Own results: 75 year old female – subcardial gastric cancer Endoscopic hemostatic therapy with hemospray











- Hemospray first conventional endoscopic
 hemostasis afterwords?
- Hemospray embolism?
- Hemospray in bleeding varices?
- Hemospray and surgery?
- Hemospray and endoscope damage?
- and ...?