

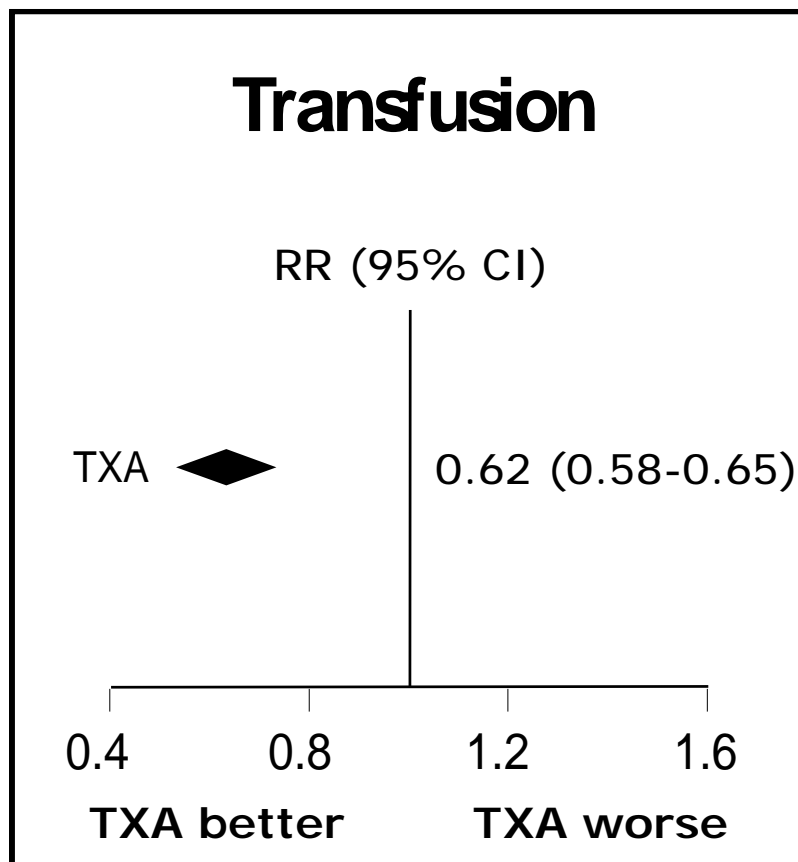
# HALT-it

Tranexamic acid for gastrointestinal  
haemorrhage:

A randomised placebo controlled trial

# TXA use in surgery

TXA reduces bleeding in surgery



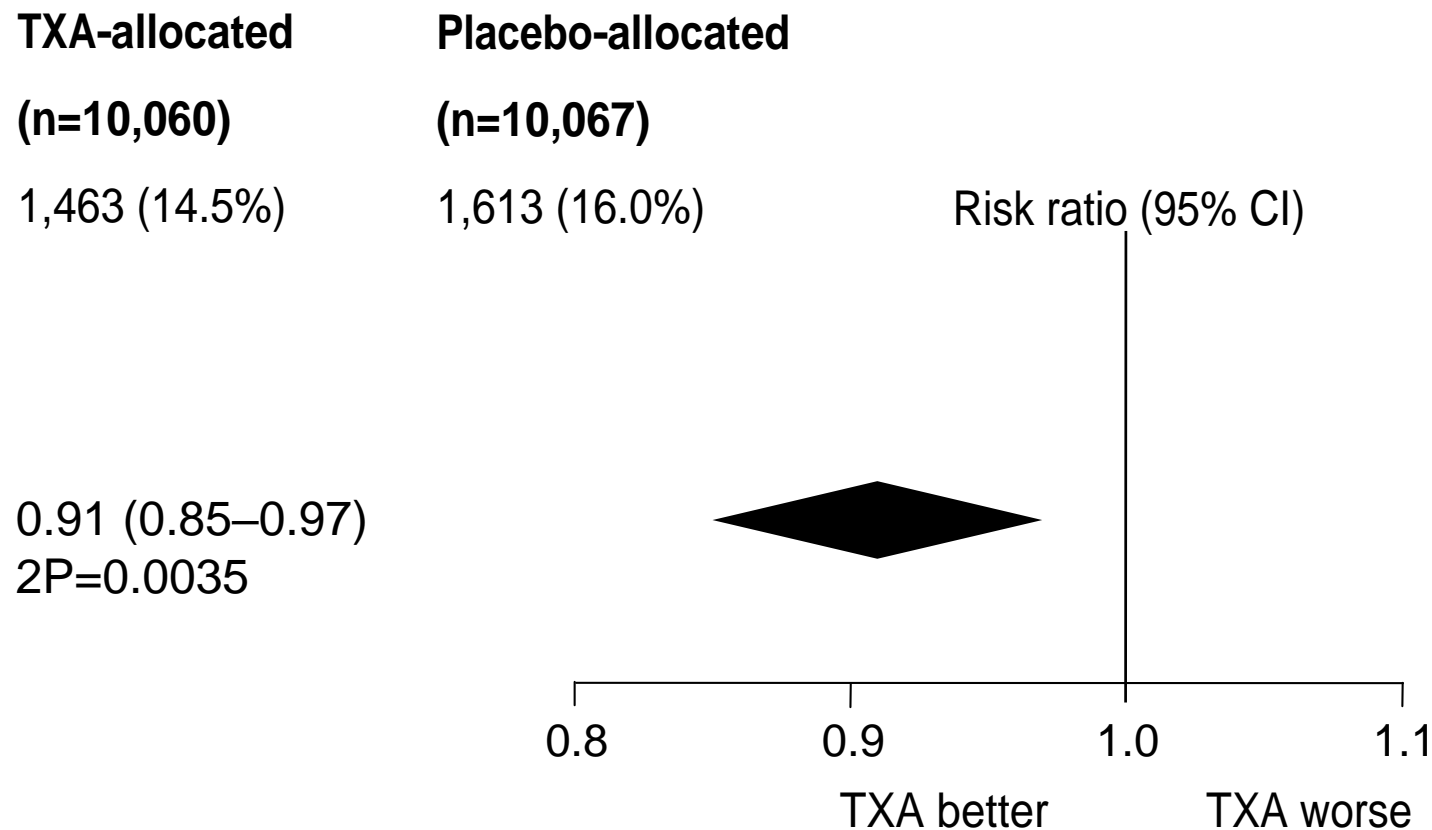
95 trials



72 trials

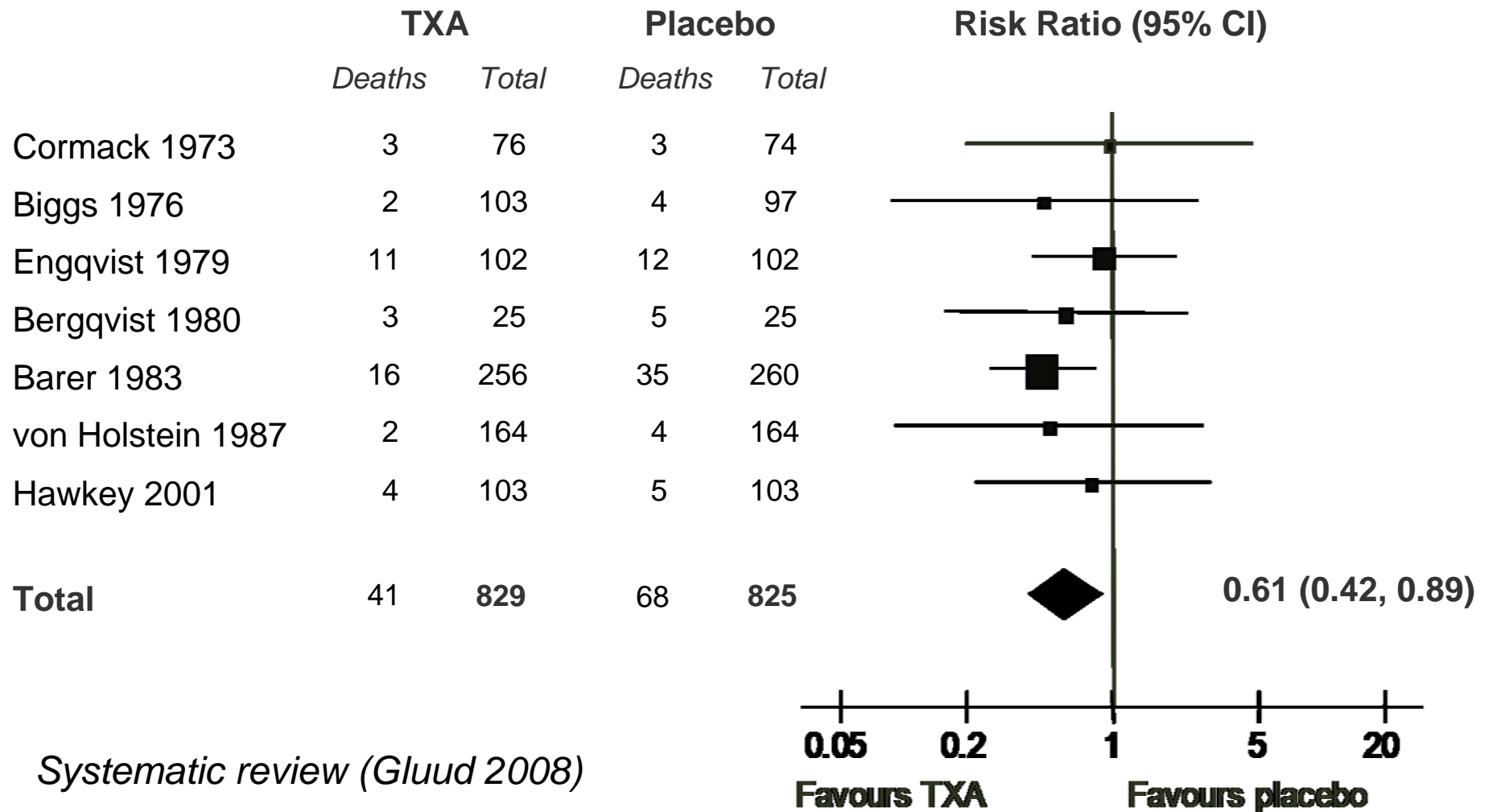
# CRASH-2 trial results

TXA reduced deaths in trauma patients with significant haemorrhage



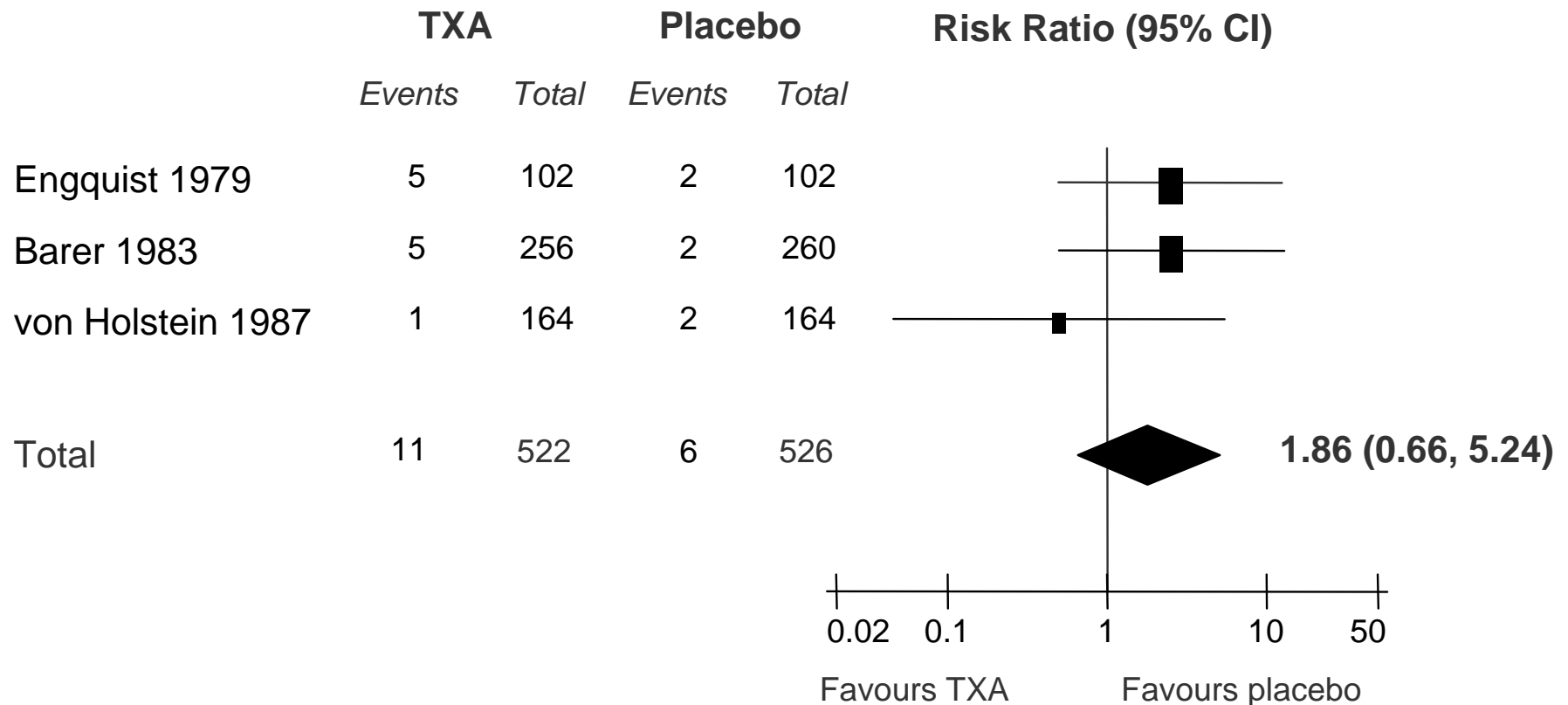
# TXA in upper GI bleeding

TXA may reduce death in GI bleeding but the quality of the trials is poor



# TXA in upper GI bleeding (2)

Trials are too small to assess the effect of TXA on thromboembolic events



# Trial design

- Randomised double blind placebo controlled

# Target sample size

- 8000 adults with acute significant bleeding
  - upper and lower GI

# Where

- UK and worldwide

# Aims

- To quantify the effect of TXA on mortality and morbidity

# Outcomes

- Primary
  - death in hospital within 28 days of randomisation (cause-specific mortality will also be recorded)
- Secondary
  - Re-bleeding
  - Need for surgery or radiological intervention
  - Blood product transfusion
  - Thromboembolic events
  - Other adverse medical events
  - Patient's self care capacity
  - Days spent in ICU or HDU
  - Patient status (death, hospital readmission) at 12 months



# Simple Trial Procedures

## 1. Entry Form – assess eligibility; randomisation data

Randomise *anyone* with GI bleeding in whom you are not sure TXA will help

## 2. Trial treatment:

- **Loading Dose:** 1 g TXA/placebo via IV over 10 min
- **Maintenance Dose:** 3 g TXA/placebo in 1,000 mL of isotonic intravenous solution over 24 hrs

Haltit		ENTRY	
PLEASE COMPLETE 1-19 BEFORE RANDOMISING THE PATIENT			
<b>ABOUT THE HOSPITAL</b>			
1. Country			
2. Hospital code (to enter Study ID)			
<b>ABOUT THE PATIENT (please ensure all information below is contained in the medical records)</b>			
3. Patient's initials	first	last	
4. Sex (circle)	MALE	FEMALE	
5. Do you know the date of birth? (circle)	YES	day	month year
6. Time since onset of GI bleed symptoms	hours	in relation to 1st acute episode only	
7. Suspected location of GI bleed (circle one)	UPPER	LOWER	
8. Haematemesis/g coffee-ground vomitus (circle)	YES	NO	
9. Melena/gg fresh blood per rectum (circle)	YES	NO	
10. Suspected variceal bleed? (circle)	YES	NO	
11. Systolic blood pressure	mmHg	Blood recent measurement prior to randomisation	
12. Heart rate	beats per minute	Blood recent measurement prior to randomisation	
13. Signs of shock present? (circle)	YES	NO	
14. Suspected current active bleeding? (circle)	YES	NO	
15. Other co-morbidities? (circle all that apply)	CARDIOVASCULAR	RENAL	OTHER MAJOR CO-MORBIDITY
16. On anti-coagulant therapy? (circle)	YES	NO	
17. Emergency admission? (circle)	YES	NO	
<b>RANDOMISATION INFORMATION</b>			
18. Eligible? (circle)	YES	NO	
19. Consent for entry obtained from (circle)	WAVES	OTHER REPRESENTATIVE	
20. Treatment pack number	BOX	PACK	
21. Date of randomisation	day	month	year
22. Time of randomisation (24 hour clock)	hours	minutes	
23. a) Name of person randomising patient	first name	last name	
b) Signature			
PLEASE SEND THESE DATA TO THE COORDINATING CENTRE IMMEDIATELY AFTER RANDOMISATION – SEE GUIDANCE OVERLEAF			
Protocol Code: Page 1 of 2 Draft Version 0.3c Entry Form			

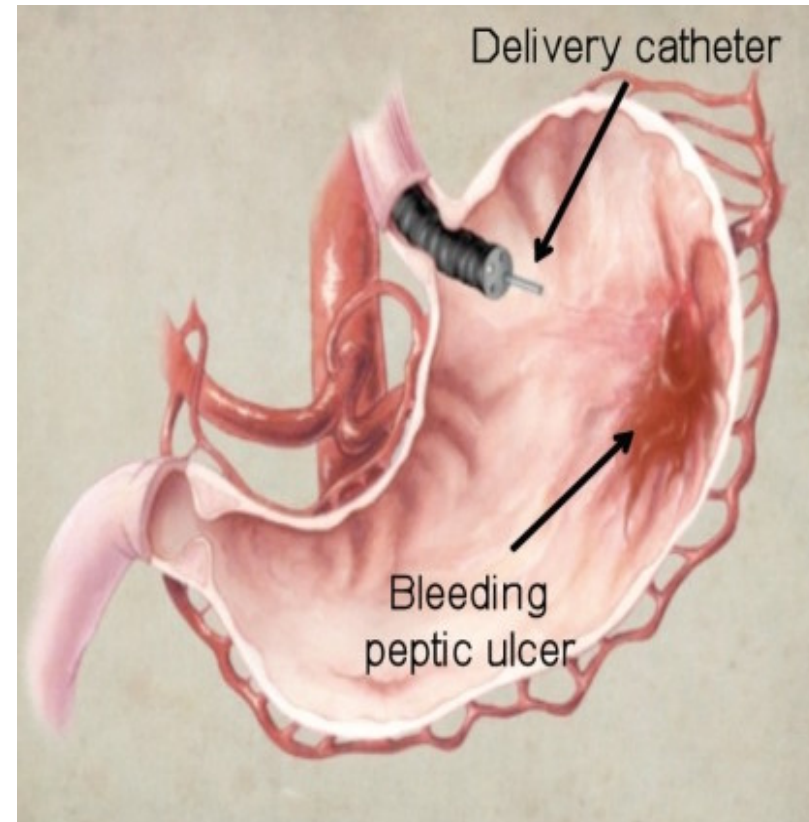
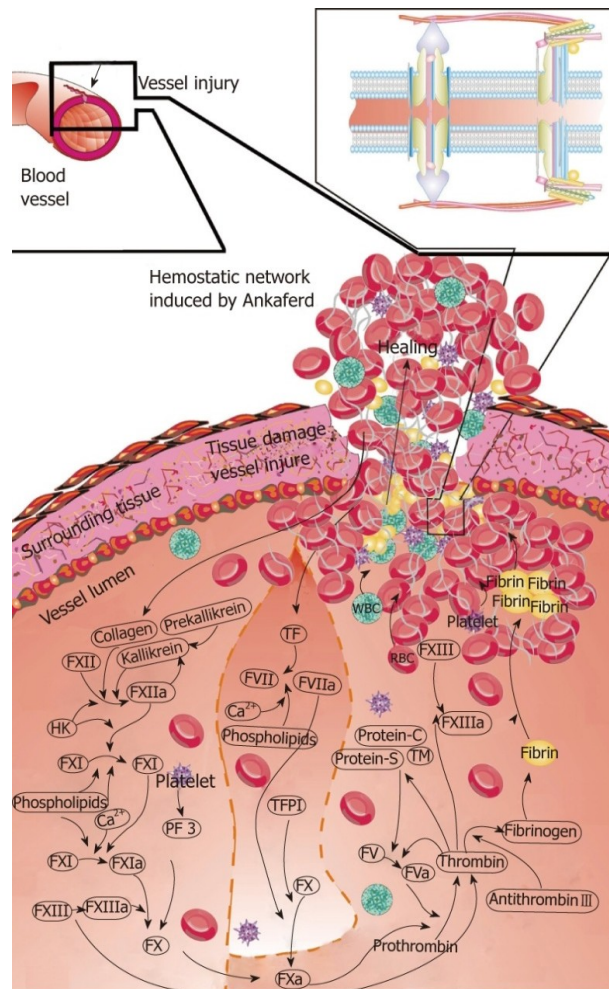
## 3. Record outcome at 28 days on one page Outcome Form

# Haemospray

- Novel treatment for GI bleeding first used in military injuries
- Via endoscope – indicated in those for whom other endotherapies failed or not possible
- No clinical trials as yet – lots of case reports and retrospective data

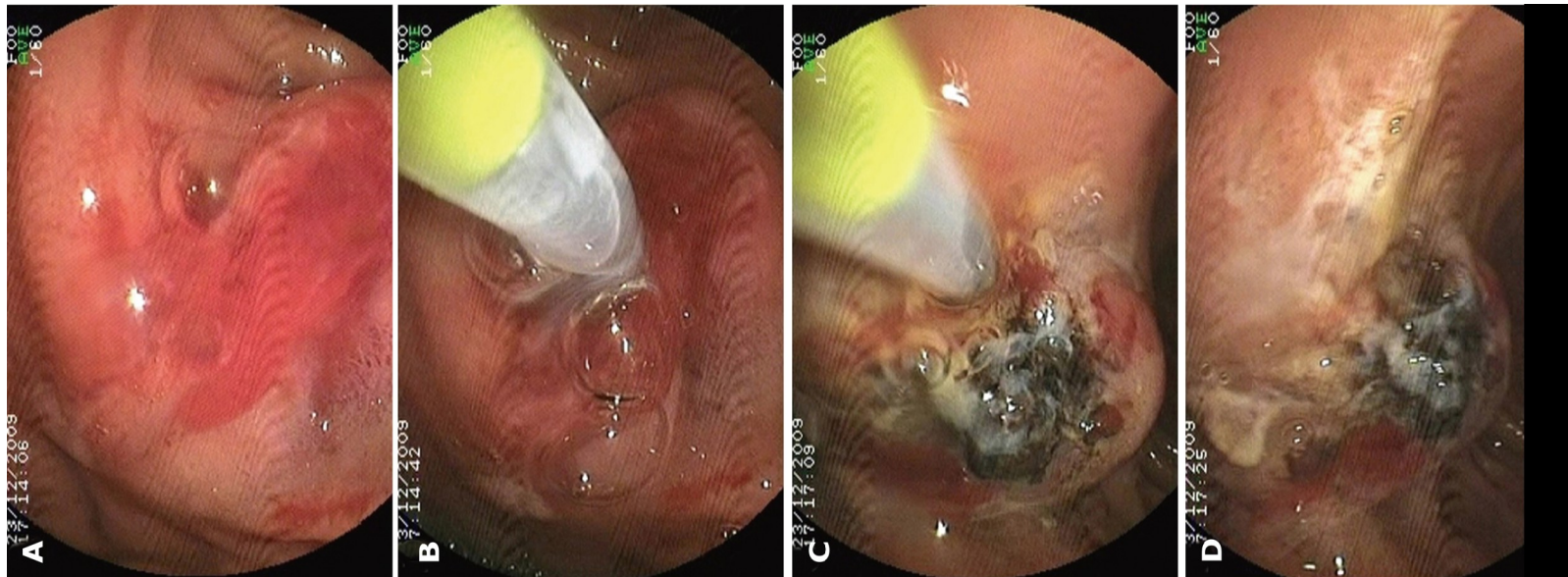
- Proprietary inorganic powder
- Single-use device delivered through the endoscope
- Sprayed toward the source of a bleed
- When powder contacts blood, it absorbs water and forms a gel
- Acts cohesively and adhesively creating stable mechanical barrier
- Adheres to and covers the bleeding site.
- Non-thermal, non-traumatic treatment modality for achieving haemostasis
- Need repeat OGD and further definitive treatment

# Hemospray



# Hemospray

95% acute hemostasis



Sung JJ Endoscopy. 2011 Apr;43(4):291-5. Epub 2011 Mar 31.