

# **A New Approach to the Diagnosis and Management of Non-hematemesis Gastrointestinal Bleeding**

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# Disclosures

- Olympus – research support and consultant

# Concept

- Concept from 1970s – present: Upper and lower GI bleeding
- New concept: Hematemesis v 'the rest'
- Rationale: we now have the tools to examine the entire GI tract

# Hypothesis: based on the new concept

- Fundamental paradigm
  - Improve patient care
  - Cut cost of care
- Since we do not know accurately the origin of melena or hematochezia, can we use video capsule endoscopy to reduce the time to diagnosis and or improve the detection rate of active bleeding ? If so are there other benefits ?

Randomized controlled trial of video capsule endoscopy as first procedure versus standard of care for diagnosis and management of non-hematemesis gastrointestinal bleeding: an interim analysis.

Neil Marya, Jawaid, Salmaan; Foley, Anne; Patel, Krunal; Rupawala, Abbas; Han, Samuel; Marshall, Christopher; Kaufman, Daniel; Bhattacharya, Kanishka; Tennyson, Joseph, and Cave, David.

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# Background

- For 40 years the diagnosis and management of gastrointestinal bleeding has remained unchanged.
- Upper GI bleeding / hematemesis requires endoscopy. LOS 2-3 days
- Lower GI bleeding / melena or hematochezia: usually requires EGD, colonoscopy and uncommonly video capsule endoscopy and enteroscopy. Sequence requires an educated guess. LOS 4-5 days

# Introduction:

- Feasibility study with 24 patients 2003-4. Randomized comparison of VCE v Standard of Care at Caritas St Elizabeth's Hospital. Brighton MA
- Epidemiology of GI bleeding at UMass: 120 hematemesis: 235 NHGIB per year: Jawaid et al 2013
- The earlier a VCE is deployed the higher the diagnostic and therapeutic yield Singh et al 2013
- Randomized trial of VCE first v standard of care 2015 [Supported by Olympus Tokyo]

# Epidemiology of GI Bleeding 2013-4

Site : UMass Memorial ER; tertiary referral center 120,000 visits/pa

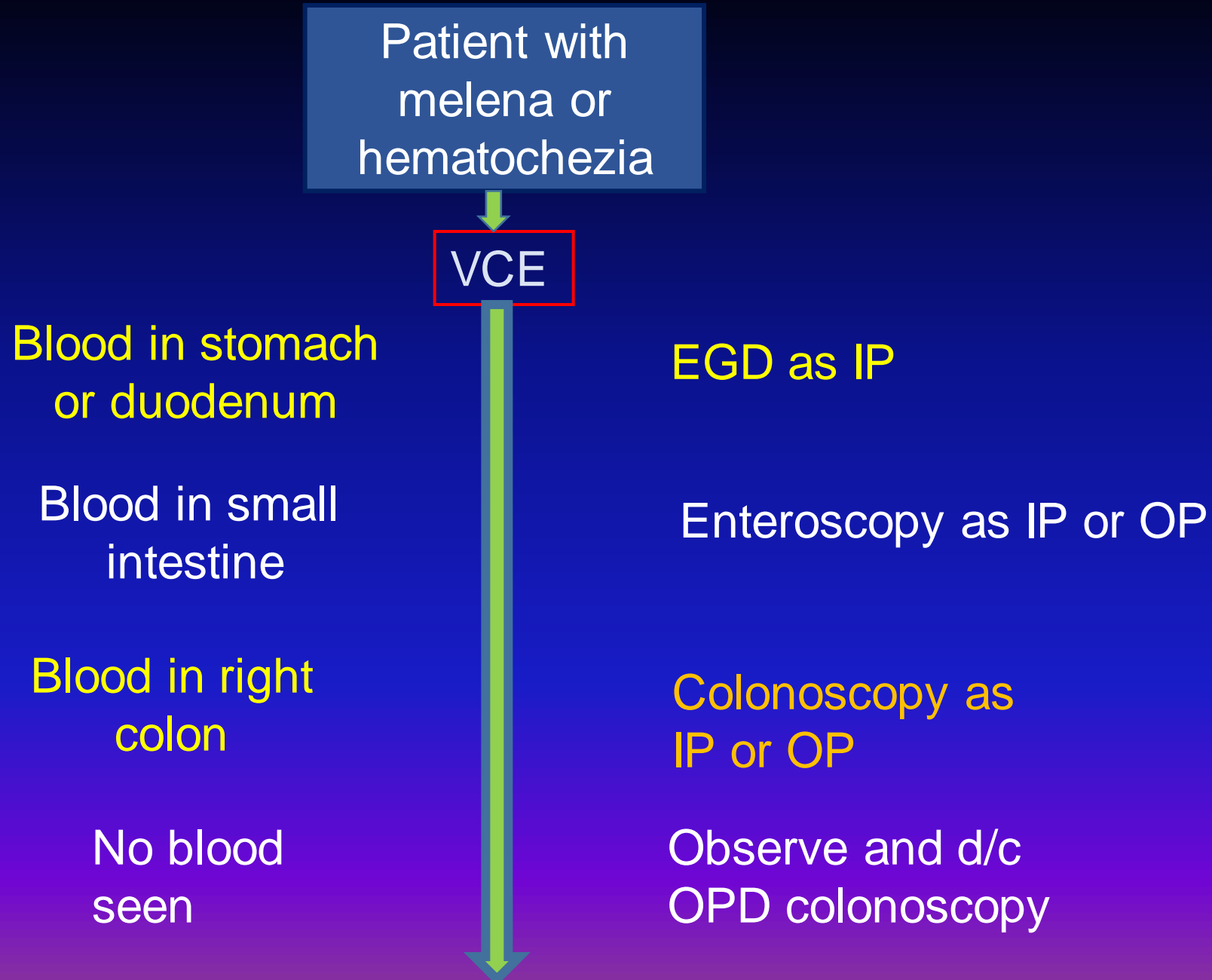
	<b>Hematemesis</b>		<b>Non Hematemesis</b>
• Number	105	• N	231
• Male	62%	• M	53%
• NSAIDs, anticoags etc	42%	• NSAIDs etc	75%
• Hemodynamics:		• Hemodynamics:	
• stable	59%	• stable	65%
• Unstable	33%	• Unstable	30%
• Shock	7%	• Shock	4%
• Admitted	96%	• Admitted	100%



# Methods: Trial design

- Randomized, single center, 2 arm
- Standard of care versus video capsule as the first procedure
- Sample size: 80 patients in each arm
- Consent obtained as soon as patient identified as eligible

# Early Capsule Group Algorithm



# Olympus EndoCapsule EC 10



## Physical characteristics

Size: 11 x 26 mm

Image frequency: 2/sec

1 Camera

6 LED light source

Battery life: 20 hours

Images transferred by RF

Real time viewer

# Methods: Inclusion criteria

- Age 18 years or older
- Patients have either melena or hematochezia
- Able to sign consent
- Vital signs: BP 100/60 or greater or pulse  $<110$  at consent
- Needs admission to hospital or CDU

# Methods: exclusion criteria

- Unable or unwilling to sign consent. Unable to speak English
- Massive bleeding
- IBD, presumed infectious colitis and ano-rectal bleeding
- Pregnancy, prisoners
- Pacemaker ICD
- Dysphagia
- Gastroparesis
- Previous gastric or small intestinal surgery.
- Resuscitation status DNR/DNI

# Results: patient population to date

- >130 patients were screened
- 36 included in this analysis
- 2 technical failures

# Table 1 Demographics of study population

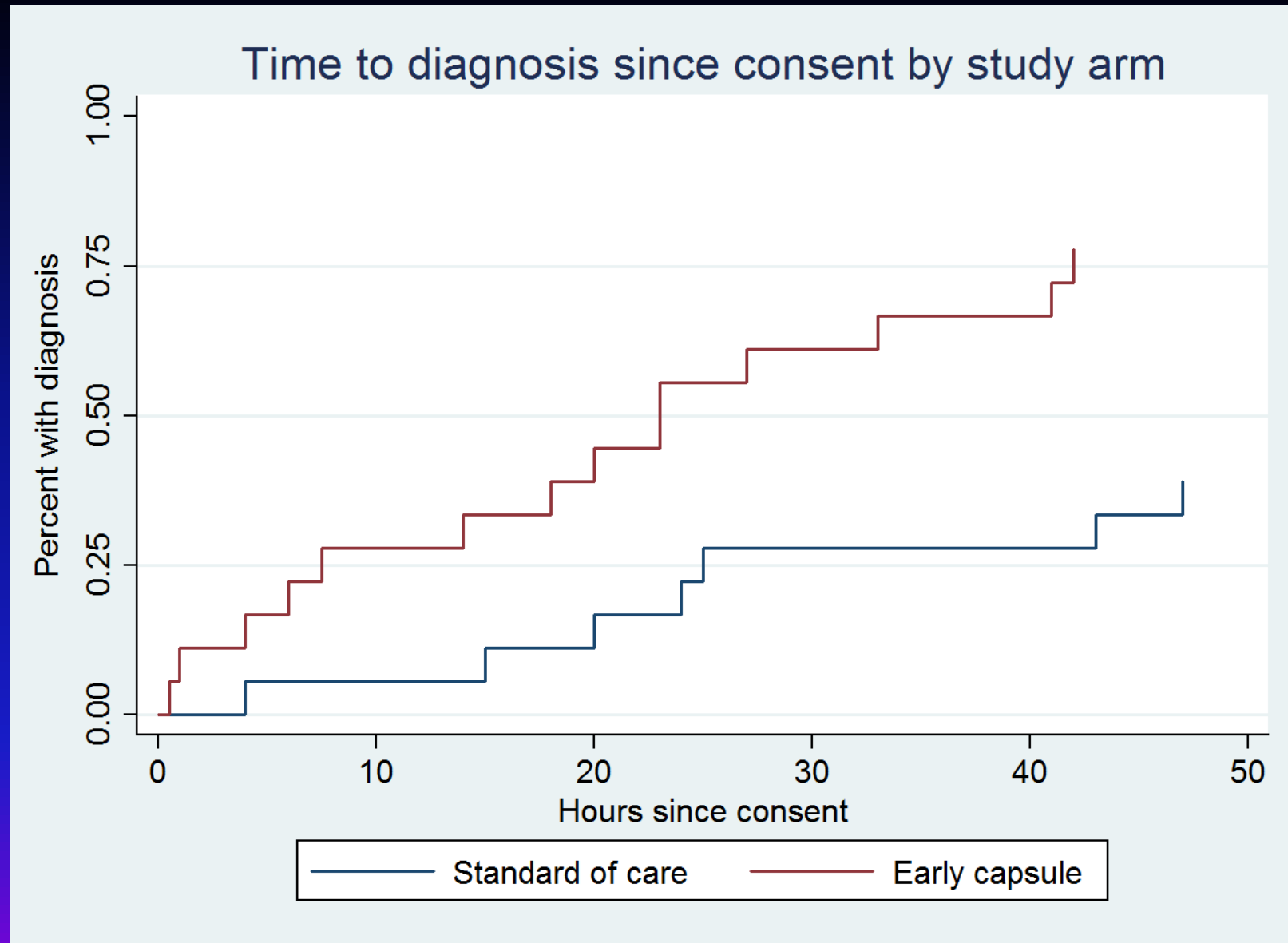
	Standard of care (n = 18)	Early capsule (n = 18)	
Male, n (%)	11 (61)	8 (44)	
Age (years), mean ± SD	73.6 ± 13.1	64.6 ± 9.6	
Antiplatelet agents	10 (55.6)	5 (38.5)	
Anticoagulation agents	7 (38.9)	4 (28.6)	
NSAID agents	2 (11.1)	4 (22.2)	
Guaiac positive stool and/or unexplained anemia	1 (5.6)	4 (22.2)	
Hematochezia and unexplained anemia	4 (22.2)	5 (27.8)	
Melena	13 (72.2)	9 (50)	

## Table 1 cont: Demographics of study population

Heart rate at consent (beats per minute), mean $\pm$ SD	75.9 $\pm$ 10.8	77.0 $\pm$ 11.5	
Systolic blood pressure at consent (mm Hg), mean $\pm$ SD	127.8 $\pm$ 19.3	122.3 $\pm$ 17.9	
History of heart failure, n (%)	3 (16.7)	0 (0)	
History of liver failure, n (%)	2 (11.1)	3 (16.7)	
Recent syncope, n (%)	0 (0)	2 (11.1)	
Glasgow-Blatchford score, mean $\pm$ SD	9.0 $\pm$ 3.6	8.3 $\pm$ 4.5	
Blood urea nitrogen (mg/dL)	29.6 $\pm$ 21.2	26.8 $\pm$ 20.5	
Prothrombin time (seconds)	22.0 $\pm$ 16.9	14.8 $\pm$ 6.5	
Hemoglobin (g/dL)	9.1 $\pm$ 1.9	9.7 $\pm$ 3.3	



# Results



Kaplan – Meier plot: comparing time to diagnosis between study arms. Statistical analysis using log rank tests shows that the curves are statistically different ( $p=0.009$ )

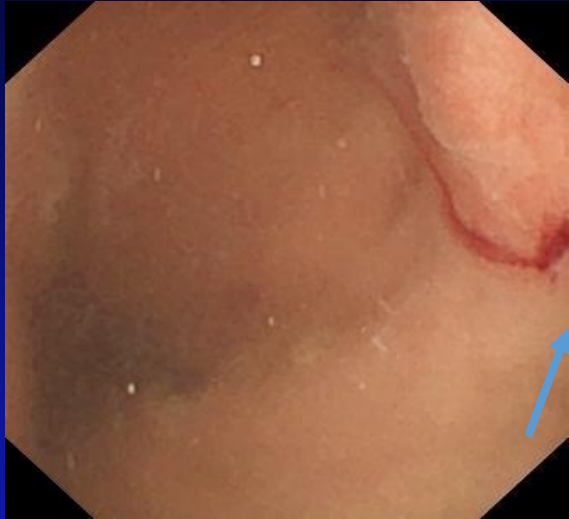
## Results: primary and secondary aims

	Early VCE %		SOC %	p value
Detection of active bleeding	72		17	p= 0.001
Rate of diagnosis	78		39	p=0.018

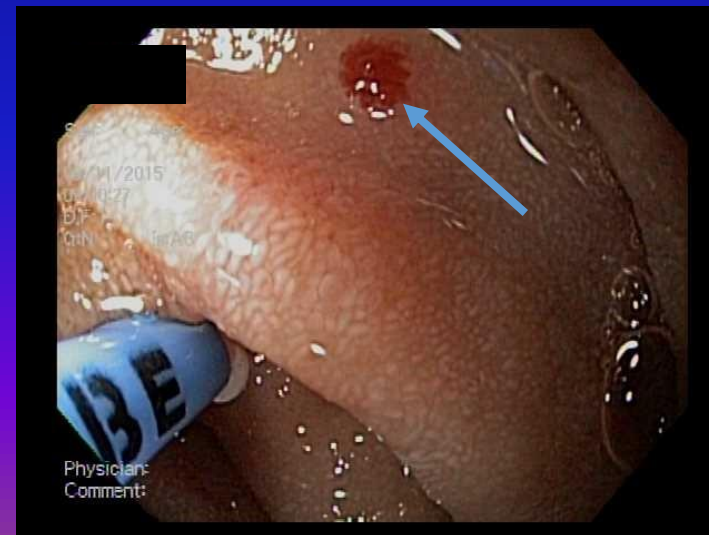
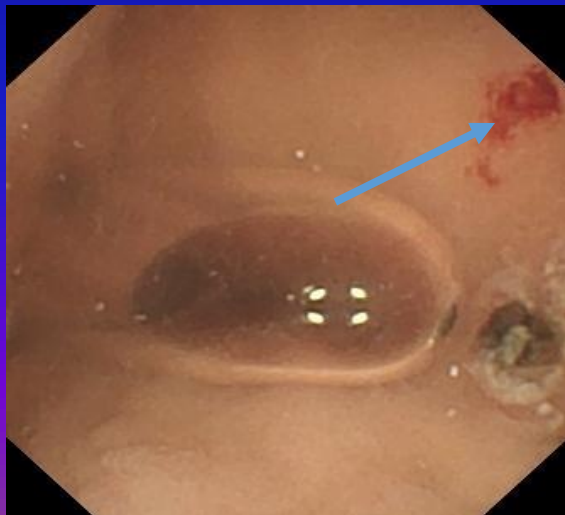
# Results: secondary aims

	Early capsule group	Standard of Care group	p value
Therapeutic intervention#	33	17	0.248
Total # of procedures	0.89	1.06	0.452
Length of stay: hours	113	101	0.779
Recurrence/ readmitted #	0	4	0.062

# Case 1: 65 yr. old WM with melena requiring transfusion: Dx. Dieulafoy lesion and lipoma



Mass



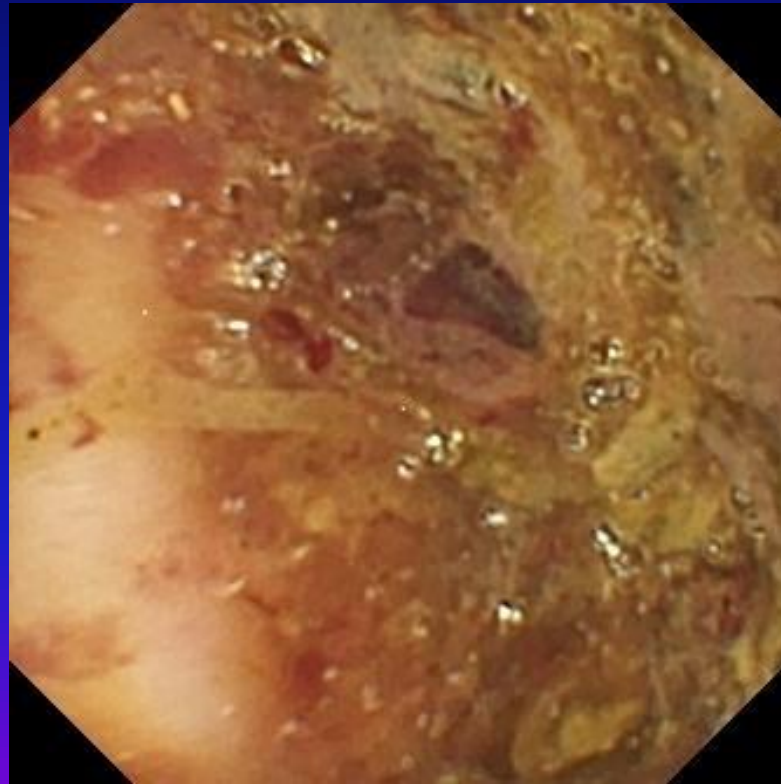
Case 2 Angioectasia

Case 3 Cecal bleed

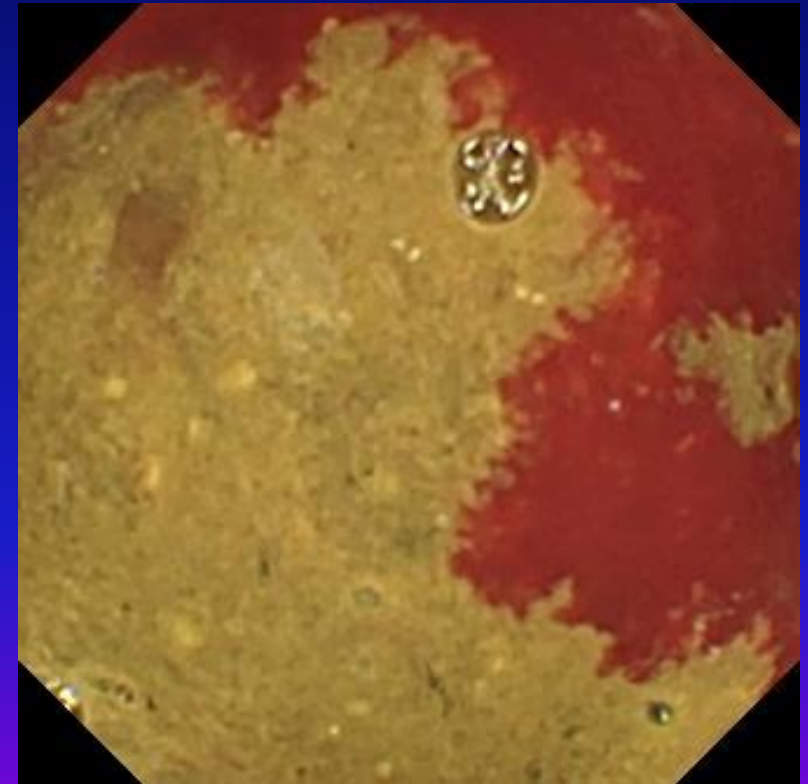
Case 4: Right Colon bleed at 17 hrs



2



3



4

# Complications

- 2 technical failures of recorder / capsule
- No cases of capsule retention in small intestine
- No cases of gastric retention – 1 required prokinetic at about 1 hour

# Conclusions

- Primary aim already achieved
- Secondary aims need more patients to clarify if significant.
- Improved patient care? Patients like VCE since it is non- invasive and more accurate as a diagnostic tool.
- Cost containment? LOS unchanged, but this may be real, a behavioral problem. Many procedures could be safely moved to OP. Reduced re admission rate?





# Safety and efficacy FDA trial of the Power Spiral enteroscope:

K.Bhattacharya, D. Cave and C. Marshall

- Device has the potential to traverse the entire small intestine with both diagnostic and therapeutic capabilities and is complementary to capsule endoscopy
- This is a disruptive technology that is likely to replace double, single balloon and hand driven
- UMMHC is one of 3 sites in the USA to start using the device. It will greatly enhance our New England wide referral base for deep enteroscopy if FDA approved

# Summary of studies in clinical gastroenterology

- Funded trials = 8: 2 device trials, 6 pharmaceutical trials
- Pending trials = 4: pharmaceutical trials 3, 1 device trial
- Unfunded studies 18: 1 randomized trial, 16 chart reviews, 1 survey
  - These involve interns, residents and students and 7 faculty

# Pathology of bleeding

