The Usefulness of Capsule Endoscopy

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PillCam™ SB 3 system

INDICATIONS FOR USE

• The PillCam™ SB 3 capsule is intended for visualization of the small bowel mucosa and:
  – May be used in the *visualization and monitoring of lesions that may indicate Crohn’s disease* not detected by upper and lower endoscopy.
  – May be used in the *visualization and monitoring of lesions that may be a source of obscure bleeding* (either overt or occult) not detected by upper and lower endoscopy.
  – May be used *in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA)* not detected by upper and lower endoscopy.

• The PillCam™ SB 3 capsule may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults and children from two years of age.

• The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas.
Contraindications for PillCam™ SB 3 capsule include:

- Patients with known or suspected GI obstructions, strictures or fistulas based on the clinical picture or pre-procedure testing and profile.
- Patients with cardiac pacemakers or other implanted electromedical devices.
- Patients with swallowing disorders.
Small Bowel Capsule Endoscopy:

- Suspected small intestinal tumors and surveillance in patients with polyposis syndromes
- Suspected or refractory malabsorptive syndromes (celiac disease)
Obscure Gastrointestinal Bleeding
AGA Medical Position Statement on Bleeding

Raju GS, et al. (AGA Institute) Gastroenterology 2007; 133:1694-1696.
Capsule Endoscopy or Angiography in Patients With Acute Overt Obscure Gastrointestinal Bleeding: A Prospective Randomized Study With Long-Term Follow-Up

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OBJECTIVES: Both capsule endoscopy (CE) and angiography have been recommended as first investigation for patients with acute overt obscure gastrointestinal bleeding (OGIB). However, no studies have directly compared the diagnostic yield and long-term outcomes of patients with overt OGIB randomized to CE or angiography.

METHODS: Consecutive patients presented with acute melena or hematochezia, but not data from both upper and lower endoscopy, were immediately randomized to receive small-bowel CE or angiography. All patients were monitored for rebleeding and anemia for up to 5 years. Primary outcomes included rebleeding, readmission for bleeding or anemia, and mortality.

RESULTS: A total of 60 patients with overt OGIB were randomized. The mean follow-up was 45.5 months. The diagnostic yield of immediate CE was significantly higher than angiography (P = 0.016). The cumulative risk of rebleeding in the angiography and CE group was 16.7%, respectively (P = 0.10, log-rank test). There was no significant difference between the two outcomes in terms of rebleeding, readmission, hospitalization, or mortality.

CONCLUSIONS: In patients with overt OGIB, immediate CE has higher diagnostic yield and comparable outcomes when compared with angiography.

Diagnostic yield of small-bowel capsule endoscopy in patients with iron-deficiency anemia: a systematic review

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Background: Iron-deficiency anemia (IDA) is the most common cause of anemia worldwide. Current guidelines recommend the use of small-bowel capsule endoscopy (SBCE) in IDA. Evidence of the validity of SBCE in patients with IDA alone is still limited.

Objective: To assess the diagnostic yield (DY) of SBCE in IDA by pooling data from relevant studies.

Design: Systematic review and meta-analysis. Fixed-effects or random-effects models were used as appropriate.

Setting: Studies that estimated the DY of SBCE in IDA were identified. Two investigators independently conducted the search and data extraction.

Patients: A total of 24 studies enrolling 1960 patients with IDA who underwent SBCE were included.

Main Outcome Measurements: Per-patient DY, with 95% confidence intervals. Subgroup analysis was also performed.

Results: The pooled DY of SBCE in IDA, evaluated by a random-effects model, was 47% (95% CI, 42%-52%), but there was statistically significant heterogeneity among the included studies (inconsistency index [I2] = 78.8%, P < .0001). The pooled DY of SBCE in studies focused solely on patients with IDA (subset 1, 4 studies) was 66% (95% CI, 61.0%-72.3%; I2 = 44.3%); conversely, that of studies not focusing only on IDA patients (subset 2, 20 studies) was 44% (95% CI, 39%-48%; I2 = 64.9%). In particular, more vascular (31% vs 22.6%, P = .007), inflammatory (17.8% vs 11.5%, P = .009), and mass/tumor (7.9% vs 2.2%, P < .0001) lesions were detected with SBCE in patients participating in the studies in subset 1.

Limitations: Heterogeneity of studies, retrospective design, and selection bias.

Conclusions: This analysis demonstrates the validity of SBCE in the investigation of patients with IDA and negative findings on a previous diagnostic workup, although certain factors such as heterogeneity and quality of the included studies should be taken into account. (Gastrointest Endosc 2022;86:983-92.)
**PillCam® Endoscopy in OGIB**

**Title**

*Does Timing of Video Capsule Endoscopy Relative to Obscure Overt Gastrointestinal Bleed Alter Diagnostic Yield?*

Singh A, Chandhury B, Marshall CA, Okoli CI, Foley A, Bhattacharya K, Cave DR.

*Gastrointest Endosc 2011;73(4):A4 Supp AB103.*

**Key Points**

1. A retrospective study was performed to analyze the diagnostic yield of capsule endoscopy (CE) in patients who underwent the procedure for obscure overt gastrointestinal (GI) bleeding, within 3 days of admission as compared to patients who underwent CE in a timeframe greater than 3 days after admission.

2. A total of 144 patients were included in the analysis. Overall, positive findings were detected in 65.9% of patients, including active bleeding, AVMs, ulcers, red spots, tumors, and non-small bowel findings.

3. In patients who underwent CE within three days of admission, the diagnostic yield for active bleeding or an AVM was found to be 44.4%. In patients who underwent CE after three days of admission, the diagnostic yield for active bleeding or an AVM was found to be 27.8%.

4. Therapeutic intervention was successful in 18.9% of patients evaluated within three days, as compared to 7.4% of patients evaluated after three days.

5. The average length of stay in patients evaluated within three days of admission was 6.1 days, as compared with 10.3 days in the group evaluated after three days of admission.

6. Timing of video capsule endoscopy is important for patients presenting with GI bleeding, with optimal diagnostic yields and therapeutic outcomes when the procedure is done sooner rather than later.
Crohn’s Disease
“In a blinded study of 35 patients with suspected Crohn’s disease, a diagnosis was made in 77% by using a capsule study versus 23% by small bowel follow-through and 20% by CT scan.”

“In a recent study in 39 patients, the majority of whom had known Crohn’s disease, the estimated sensitivity and specificity of capsule endoscopy was determined to be 89.6% and 100%, respectively.”
• Prospective, blinded, multicenter study comparing the accuracy of CE, CTE and MRE in patients with newly diagnosed Crohn’s disease
• CE could be a new gold standard for detection of small bowel CD beyond the reach of the colonoscope

<table>
<thead>
<tr>
<th>Method</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<tbody>
<tr>
<td>CE</td>
<td>100%</td>
<td>91%</td>
</tr>
<tr>
<td>CTE</td>
<td>76%</td>
<td>85%</td>
</tr>
<tr>
<td>MRE</td>
<td>81%</td>
<td>86%</td>
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</table>
• Retrospective review of 124 patients with Crohn’s, 15 with indeterminate colitis, 23 with pouchitis to determine if CE findings result in management changes.

• 61.6% had a change in current medication, 39.5% initiated a new medication.

• CE findings result in medical management in symptomatic patients with CD, IC and pouchitis with princonclusive work.
Impact of CE on Reclassification of IBD

• CE may lead to reclassification of IBD from ulcerative colitis (UC) or indeterminate colitis (IC) to Crohn’s disease (CD)¹
  – 4/5 UC patients and 1/2 IC patients had their disease reclassified to CD based upon newly diagnosed small bowel mucosal lesions¹
  – 50% of patients with presumed UC/IBDU had a change in diagnosis to CD²

• Disease reclassification based upon CE findings appeared to impact patient management³
  – Improved medical decision-making (60%)
  – Tailoring pharmacological management to improve patient outcomes (40%)

• 13/21 (62%) CD patients were found to have more extensive small disease as result of CE exam¹

Capsule endoscopy may be particularly beneficial in the investigation of Crohn’s disease (CD) in four different clinical situations:

1. In patients with clinical and/or biological suspicion of CD, but who have normal results of radiological and traditional endoscopic procedures.
2. In the diagnosis of disease recurrence after surgery.
3. In the evaluation of the extent of small bowel lesions in patients with known CD and to assess mucosal healing.
4. To further diagnose indeterminate colitis by detection of intestinal lesions, thus directing double-balloon enteroscopy with biopsies.

Delvaux M, Gay G. Inflammatory Bowel Disease 2007;7(3):99-104
Small Bowel Tumors
Small bowel tumors

• Capsule endoscopy detects more polypoid lesions than barium examinations, such as small bowel follow through.

• Several studies have suggested the benefits of performing capsule endoscopy in patients with known or suspected polyposis syndromes.
Small bowel tumors

- Data from 562 patients who underwent CE for a variety of indications were reviewed (retrospectively).
- 8.9% (50 patients) diagnosed with SBT.
- 48% of the tumors were malignant.
- This data suggests an important role for CE in the workup of patients with suspected small intestinal lesions.
- CE may lead to earlier detection and treatment of SBT and an improved prognosis for patients.
Why VCE for celiac disease?

• Unexplained diarrhea/malabsorption

• Patient unwilling or unable to have endoscopy

• Positive celiac serology (TTG or EMA) and normal duodenal histology

• History of celiac disease with warning signs or refractory disease (RCD Type II)
CE and complicated CD

• 47 patients with persistent symptoms despite GFD
• Findings:
  ▪ Ulcerations (n=21)
  ▪ Carcinoma (n=1)
  ▪ Polyp (n=1)
  ▪ Stricture (n=1)
  ▪ Intussception (n=1)

• CE helpful patients with refractory symptoms +/- alarm symptoms, especially RCD Type II

*GIE 62:55;2005.*
Do preps make a difference?

- Meta-analysis
- 12 studies (6 prospective, 6 retrospective)
- Purgative preparation versus clear liquid diet alone
- Diagnostic yield significantly better \((p=0.002)\) with preparation
- Visualization improved
- Completion rates unchanged

Rokkas et al. AJG 2009;104:219
Electromagnetic interference (EMI): electrical signals of non-physiologic origin that may affect pacemaker or ICD function.

There is a concern that CE signals could cause EMI and alter CP or ICD function.
  - Concern that there may be loss of CE images.

CE is currently contraindicated in patients with CP and/or ICD.

The PillCam® video capsule is contraindicated in patients with cardiac pacemakers or other implanted electromedical devices.
Swallowing Difficulties

• Swallowing disorders and intestinal transit difficulties
  • Mechanical such as congenital rings / webs, Zenker’s diverticulum, achalasia, strictures or prior surgery
  • Oropharyngeal such as dementia, pediatric or elderly patient
  • Gastroparesis, intestinal transit issues due to narcotics and psychotropic drugs
Endoscopic Devices Used To Place Capsules In Patients with Swallowing Difficulties

- Endoscopic devices that aid in the placement of PillCam video capsule directly into the small bowel include:
  - AdvanCE™
  - Roth Net™
  - Snares
  - ERCP Baskets
Capsule is preloaded into endoscope
- Holder is attached to catheter
- Capsule snaps into holder
- Guidewire ejects capsule when in position
PillCam Capsule Delivery
Retention

The Problem:
Retention may lead to surgery / additional endoscopy in a patient who otherwise may have been treated medically, or may have remained asymptomatic from their stricture.
ICCE Consensus Statements

• Rate of capsule retention appears to be dependent upon CE indication (summary of studies):

<table>
<thead>
<tr>
<th>Condition</th>
<th>Rate</th>
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<tbody>
<tr>
<td>Obscure GI Bleeding</td>
<td>1.5%</td>
</tr>
<tr>
<td>Known Crohn’s Disease</td>
<td>2.6%</td>
</tr>
<tr>
<td>Suspected Crohn’s Disease</td>
<td>1.4%</td>
</tr>
<tr>
<td>Normal Volunteers</td>
<td>0%</td>
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</tbody>
</table>

• Obtaining a good medical history is essential to avoiding capsule retention.

• Patients with abdominal pain, distention, and nausea, or those with known Crohn’s disease, should be suspected of having potential for capsule retention.
PillCam® Patency Capsule

Day 0: Liquid diet from noon
NPO at 10 PM

↓

Day 1: Morning ingestion

↓

Day 2: Scanning*
(close to but not later than 30 hours)

- Patency proven
  (capsule not detected in patient’s body)
- Patency NOT proven
  (capsule detected in patient’s body)

Capsule disintegrates after 30 hours
NPO = nothing by mouth.
PillCam® Patency Capsule Disintegration and Terminology Post-excretion

Intact Capsule
Body and Plugs are virtually intact.

Intact Body
Body is intact and hard. Plugs have eroded.

Disintegrating Body
Body is losing its original dimensions and becomes soft.

Empty Shell and Tag
Capsule contents have disintegrated.

Patency Confirmed

Patency Not Confirmed
Colon Capsule.....
CONTRAINDICATIONS

- Patients with known or suspected GI obstruction, strictures or fistulas based on the clinical picture or pre-procedure testing and profile.
- Patients with cardiac pacemakers or other implanted electro-medical devices.
- Patients with swallowing disorders.
- In patients with allergies or known contraindications to the medications and preparation agents used in the procedure as described in the relevant instructions for use.
Next Generation
PillCam® COLON 2 Views

PillCam COLON 2 has received CE MARK, but it is not cleared for marketing or available for commercial distribution in the USA.
PillCam® COLON 2: Indications for Use

• The PillCam COLON 2 capsule endoscopy system is intended to provide visualization of the colon. It may be used for detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.

• Intended for the detection of colon polyps in patients with evidence of gastrointestinal bleeding of lower GI origin. This applies to patients with major risks for colonoscopy or moderate sedation, but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.
PillCam® COLON 2:
Features

- 2 Cameras
- Adaptive Frame Rate
- Advanced Optics/3 Lenses
- Advanced Automatic Light Control
- Extra-wide Angle of View - 172°
- 11.6 mm x 31.5 mm
- Depth of Field 0-30 mm
Prep Used in the US Registration Study For PillCam® COLON 2

Before ingestion of PillCam COLON:
- 4 (12mg) Senna tablets - 2 days prior to the procedure
- 2 liters PEG the evening prior to the procedure
- 2 liters PEG the morning of the procedure

After ingestion of PillCam COLON:
- Reglan: If necessary during procedure for gastric emptying*
- 2 boosts of SUPREP® - to enhance capsule propulsion and maintain adequate cleansing
  - 6 oz. SUPREP** solution
  - 3 oz. SUPREP** solution*
- Suppository, if needed*
- Light meal, if needed*

* Indicates potential procedure requirements
** SUPREP © Braintree Laboratories Inc., Braintree, MA.
<table>
<thead>
<tr>
<th>Colonoscopy</th>
<th>PillCam® COLON 2</th>
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<tbody>
<tr>
<td>![Colonoscopy Image]</td>
<td>![PillCam® COLON Image]</td>
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> 10 mm polyp at right colon

> 10 mm polyp at sigmoid
<table>
<thead>
<tr>
<th>Colonoscopy</th>
<th>PillCam® COLON 2</th>
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<tbody>
<tr>
<td>![Colonoscopy Image]</td>
<td>![PillCam® COLON Image]</td>
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<tr>
<td>&gt; 10 mm tumor at right flexure</td>
<td></td>
</tr>
<tr>
<td>![Colonoscopy Image]</td>
<td>![PillCam® COLON Image]</td>
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<tr>
<td>&gt; 10 mm tumor at sigmoid-rectum</td>
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Game plan for capsule reading....

• Check to see if the capsule reached the cecum
• Identify the landmarks (first gastric image, first duodenal image, and first cecal image).
• Review SBI images
• Read the study **at rate and in mode most comfortable** for you
• Make thumbnails of potential abnormal findings to review at the end of the study.
• Share images with consultants via email.
• Interpret the findings in the appropriate clinical context.
QUESTIONS?

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