Capsule Endoscopy
Overview

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Anatomy of Small Intestines

- Specialized Tubular Structure that is Continuous Proximally with the Stomach and Distally with the Colon
- 6 Meters in Length
  - Average Length of SI is approximately 3 Times the Height of a Standing Adult
- Duodenum is the most Proximal Portion of the Small Intestines
- Jejunum is 40% of the Mobile Small Intestines
- Ileum is 60% of the Mobile Small Intestines
Brief History of Small Bowel Imaging

- Radiological Evaluation
  - Plain Films of Abdomen
  - Barium Studies
  - Gastrograffin Studies
  - Enteroclysis
- Push Enteroscopy
- Small Bowel Capsule Endoscopy
- Balloon Enteroscopy
Procedure Consists of 3 Steps

1. Ingest the PillCam video capsule.

2. Capsule transmits images to DataRecorder.

3. Images are reviewed using RAPID software, and physician makes diagnosis.
• The premier non-invasive diagnostic tool for visualizing the entire small bowel
• >750,000 ingestions to date
• >800 Peer reviewed journal articles published
• Produces 55,000+ images per study
• 30 to 60 minute reading time per study
Types of Capsule Endoscopy

- Small Bowel Capsule - SB
- Esophageal Capsule - ESO
PillCam Platform Components

- PillCam ESO or SB
- DataRecorder
- Given Workstation
- RAPID Software
Patient Selection/Screening

- **Taking a complete medical history is CRUCIAL.**
- **Screen for the following:**
  - Gastric motility disorders can cause delayed capsule passage to small intestine; i.e., diabetics or use of certain medications
  - Swallowing disorders
  - Prior abdominal surgery; may cause adhesions and strictures
  - Prior radiation therapy; may cause adhesions and strictures
- **Contraindications include:**
  - Patients with known or suspected GI obstruction, strictures, or fistulas based on clinical presentation or pre-procedure testing
  - Patients with cardiac pacemakers or other implanted electro-medical devices
  - Patients with swallowing disorders
Patient Preparation

- Provide a copy of the Patient Instructions.
- Patients should wear loose-fitting, two-piece opaque or dark clothing.
- Patients should refrain from applying lotions or powders on the abdomen.
- For small bowel procedure: Patients must be on a liquid diet from lunchtime the day before the examination and a complete food and liquid fast for at least 6 hours prior.
- For esophageal procedure: Patients must not eat any solid food for 2 hours prior.
- No medications should be taken during the 2 hours before the exam.
Primary Indications for Capsule Endoscopy of the Small Bowel

- Occult Gastrointestinal Bleeding and Iron Deficiency Anemia (OGIB)
- Small intestine inflammatory bowel disease
- Small bowel tumors and polyposis syndromes
- Malabsorptive syndromes and celiac sprue
Ingestion
In approximately eight hours, the patient will return to the clinic for removal of equipment.

9:00 am 5:00 pm
Improved Diagnostic Confidence: RAPID Atlas

- All images reviewed and labeled by physician advisory panel.
- Enables side-by-side comparison of case image to known pathology.
- Searchable by Capsule Endoscopy Structured Terminology (CEST), findings, and diseases.
Capsule Endoscopy
Retention
Retention

Definition - what is it?

• Capsule retained proximal to an intestinal narrowing for at least TWO WEEKS.
• Untreated, may be permanent.
• Capsule removal requires medical, endoscopic or surgical intervention.
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.
Retention

- Causes
  - NSAIDs
  - Crohn’s disease (CD)
  - Tumors
- Radiation enteritis
- Surgical anastomotic strictures
Rate of capsule retention appears to be dependent upon CE indication (summary of studies):

<table>
<thead>
<tr>
<th>Obscure GI Bleeding</th>
<th>1.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known Crohn’s Disease</td>
<td>5%</td>
</tr>
<tr>
<td>Suspected Crohn’s Disease</td>
<td>1.4%</td>
</tr>
<tr>
<td>Normal Volunteers</td>
<td>0%</td>
</tr>
</tbody>
</table>

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

Patients with abdominal pain, distension, and nausea, or those with known Crohn’s disease, should be suspected of having potential for capsule retention.

Endoscopy 2005;37(10):1065-1067
Retention: How do we treat it?

- **Medical therapy**
  - Purges
  - Stop NSAIDs
  - Steroids / Remicade
- **Endoscopic retrieval**
  - Double-balloon endoscopy (DBE) if necessary and available
- **Surgical therapy**
  - Stricturoplasty
  - Resection

Endoscopy 2005;37(10):1065-1067
Push Enteroscopy

- Using pediatric colonoscope (135-165cm)
  - 40-60 cm past ligament of Treitz
- Enteroscope (210-250cm)
  +/- overtube
  - 100 cm past ligament of Treitz
Double-Balloon Endoscopy
DBE for Capsule Retrieval

Retention: Take Home Messages

- Retention risk is low
- Retention occurs at site of pathology
- Include possible retention in consent form
- If colon visualized - no follow-up
- X-ray in two weeks if colon is not reached to confirm passage
- Management of retention depends on finding
The Agile patency capsule is a simple and convenient accessory to PillCam video capsules that is intended to verify functional patency of the GI tract in patients with known or suspected strictures prior to administration of the PillCam SB or the PillCam ESO capsule.
Agile 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**
**Unexpected Patency**

Patency Capsule passed intact in patient who had SBFT indicative of stricture – functional patency

- **Stricture detected**
- **Patency Capsule ingested 3 months later**
- **Patency Capsule excreted after 35 hours following ingestion**
Image Spectrum: PillCam Capsule Endoscopy

Bleeding

Suspected Crohn's

Tumors

Celiac Disease
“In a recent evaluation of obscure GI bleeding after a negative initial workup, 47 consecutive patients underwent both capsule and intraoperative enteroscopy.”

“Compared with intraoperative enteroscopy, the sensitivity, specificity, and positive and negative predictive value of capsule endoscopy were 95%, 75%, 95%, and 86%, respectively.”
Image Spectrum – NSAID Enteropathy
Image Spectrum - GI Bleeding & Tumors

GI Bleeding

SB Tumors
Bleeding

• In a meta-analysis of 14 studies n=396 the yield for CE and push enteroscopy was 63% and 28%, respectively.

• The yield of CE to small bowel barium radiology (SBFT) was 42% and 6%, respectively, for any clinically relevant finding.

• In study populations the incremental yield for clinically significant findings is ≥30%, (number needed to test = 3) primarily due to visualization of additional vascular and inflammatory lesions by CE.
**Approach to the Patient with Obscure GI Bleeding**

- Capsule endoscopy is the preferred test for visualizing the mucosa of the entire small bowel.
- CE should be the next diagnostic tool in patients with obscure bleeding for whom there is no suspected obstruction.
- The diagnostic yield of CE is high and has the potential to produce an earlier diagnosis.

Faigel, DO and Cave, DR. Capsule Endoscopy. 2008 Elsevier Inc:71-90
ASGE Technology Status Evaluation Report: Efficacy and Comparative Studies 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.”

Gastrointestinal Endoscopy 2006;63(4):539-545
Image Spectrum - Crohn’s Disease
The incremental yield for capsule endoscopy was found to be significantly higher when compared with small bowel follow through, CT enterography, and colonoscopy with ileoscopy.

- CE vs. SBFT for recurrent Crohn’s: incremental yield 51% (p=0.001, 95% CI 0.31-0.70)
- CE vs. CT enterography in established Crohn’s (diagnostic yield 68% vs. 38%, respectively): incremental yield 30% (p< 0.001, 95% CI = 0.12-0.48) in determining pathology in the proximal and mid-small bowel
- CE vs. colonoscopy with ileoscopy for recurrent Crohn’s (diagnostic yield was 86% vs. 60%, respectively): incremental yield 26% (p= 0.002, 95% CI- 0.09-0.43)
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.
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
Various Ulcerations - Crohn’s Disease
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
ICCE Consensus - SB Tumor High Probability

- Adenocarcinoma
- GIST
- Adenocarcinoma
- B-cell lymphoma
ICCE Consensus - SB Tumor

Key points of the consensus for treatment:

**High or intermediate probability** lesions may lead to double-balloon endoscopy (DBE) or surgery.
Small Bowel Tumors (SBT)

- 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.

Capsule endoscopy is able to identify villous atrophy and other endoscopic findings suggestive of celiac disease.

“Evaluation of the entire small intestine is of significant importance in complicated or refractory cases. In this subgroup, capsule studies have documented unexpected findings in up to 45% of cases, such as neoplasms, ulcerations, and strictures.”
Image Spectrum – Celiac Disease
Approach to the Patient with Celiac Disease

- There is emerging evidence for the role of capsule endoscopy in patients with celiac disease.
- CE may be used in cases of unexplained, recurring symptoms suggestive of celiac disease after inconclusive radiologic studies.

Faigel, DO and Cave, DR. Capsule Endoscopy. 2008 Elsevier Inc:191-198
Esophageal Disease

Normal Z-line

Suspected Barrett’s

Esophagitis

Varices

Varices

Suspected Barrett’s
Esophageal Varices

Background

- Esophageal varices (EV) are a serious consequence of portal hypertension (PHT).
- In patients with cirrhosis, the incidence of EV increases 5% per year and the rate of progression from small to large varices is 5-10%.
- Increasing size of varices is associated with increased wall tension leading to rupture and bleeding.
- AASLD/UK guidelines recommend endoscopic screening of patients with cirrhosis for varices and treatment of patients with medium/large varices to prevent bleeding.

Esophageal Varices Background

cont.

- Recommended endoscopic screening intervals are 1-3 years, depending on presence/absence of varices and whether patient has compensated/decompensated liver disease.
- Endoscopic surveillance is performed in patients after obliteration of varices.
- This patient population could benefit from a non-invasive diagnostic test that does not require sedation.
- These recommendations/practices represent a potentially large endoscopic burden.

Among 106 patients who underwent both a PillCam ESO study and standard endoscopy, the capsule study was found to have positive and negative predictive values of 97% and 88%, respectively, and sensitivity and specificity of 92% and 95% for all findings.

In a pilot study of 32 patients with esophageal varices, the overall concordance between PillCam ESO and EGD was 96.9% for the diagnosis of esophageal varices and 90.6% for portal hypertensive gastropathy.

This preliminary data shows an excellent diagnostic yield in cases of erosive esophagitis, Barrett’s esophagus, and esophageal varices.
Approach to the Patient with Esophageal Disease

- Esophageal capsule endoscopy (ECE) is safe and more acceptable to patients, providing an alternative to traditional upper endoscopy.
- As GERD and chronic liver disease pose a significant clinical and economic burden in the U.S., ECE has the potential to improve outcomes in patients at risk and reduce associated healthcare costs.
Case Study
Iron Deficient Anemia

- History: 49-year old with progressive iron deficient anemia, post prandial abdominal pain, and diarrhea. Maintained on iron supplementation to keep Hb at 10 gms. No rectal bleeding, no change in menses. Weight has remained stable. No extraintestinal manifestations of IBD. No medications, or NSAID use. Family history unremarkable.

- Physical Exam: Unremarkable, guaiac negative stool.

Previous Exams

- Colonoscopy with right-sided biopsies - negative
- EGD – mild gastritis. Duodenal biopsies - normal, without villous atrophy
- SBFT/CT scan - negative
- Patient referred for capsule endoscopy to further evaluate diarrhea, iron deficient anemia, and to rule out occult Crohn’s disease.
Capsule Findings
Villous Atrophy
Conclusions

- Capsule revealed classic findings of celiac disease – villous atrophy, fissures, mosaiac mucosal pattern in proximal small bowel.
- Celiac disease serologies obtained, post-capsule, revealed marked elevation of tTG.
- Review of duodenal biopsies - normal villous architecture.
Conclusions

- Duodenal biopsy, the “gold standard” in celiac disease may be negative (celiac disease may be patchy proximally).
- Capsule endoscopy, along with positive serology, diagnosed celiac disease in this patient.
- Anemia, pain, and diarrhea resolved on gluten-free diet.
Future Directions of CE

- RAPID® REAL TIME VIEWER
  - Remote Patient Check-in
  - Real-time viewing
  - Data Transfer to GDS
  - PillCam ESO Viewing
Future Directions of CE

- PillCam Colon
  - Potential utility
    - CRC screening
    - Patients unable or unwilling to undergo standard colonoscopy
    - Incomplete colonoscopy
    - Monitoring colonic IBD treatment
  - Clinical status and timeline
    - Initial comparative studies underway
      - 5 centers (Israel, Europe, U.S.)
      - >100 patients currently enrolled
    - Multi-center study for FDA to commence soon

*Investigational Device. Not yet cleared for marketing.*
PillCam™ COLON Views

PillCam™ COLON is not cleared for marketing or available for commercial distribution in the USA [510(k) pending].
Future Directions: PillCam Colon

Investigational Device. Not yet cleared for marketing.