# Wireless video capsule endoscopy

**Author**
David Cave, MD, PhD

**Section Editor**
John R Saltzman, MD, FACP, FACG, FASGE, AGAF

**Deputy Editor**
Anne C Travis, MD, MSc, FACG, AGAF

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**INTRODUCTION** — Wireless video endoscopy or video capsule endoscopy (VCE) is a noninvasive technology designed primarily to provide diagnostic imaging of the small intestine, an anatomic site that has proven peculiarly difficult to visualize. Limited views of the esophagus, stomach, and cecum may also be acquired. Images acquired are of excellent resolution and have a 1:8 magnification, which is higher than that of conventional endoscopes. This magnification allows visualization of individual villi. VCE approaches the concept of physiological endoscopy since the capsule moves passively, does not inflate the bowel, and images the mucosa in the collapsed state. More recently, double-ended wireless video capsules have been developed for the examination of the esophagus and colon.

This topic will review the use of wireless video capsule endoscopy for evaluation of the esophagus, small bowel and the colon. The approaches to patients with occult and/or obscure gastrointestinal bleeding are discussed in detail elsewhere. (See "Evaluation of occult gastrointestinal bleeding" and "Evaluation of obscure gastrointestinal bleeding".)

**AVAILABLE CAPSULES** — There are three small bowel capsules (PillCam SB, EndoCapsule, and MiRo capsule) and one esophageal capsule (PillCam ESO) that are available. A colonic capsule is also available in Europe, the United States, and Japan (PillCam Colon). (See 'Colon capsule endoscopy' below.)

The US Food and Drug Administration (FDA) approved the original capsule (Given Imaging, Ltd, Yoqneam, Israel) in August 2001 [1,2]. It was subsequently replaced by the M2A Plus capsule, which has now been renamed the PillCam (PillCam SB). The PillCam is now in its third generation (PillCam SB3). This version has an improved resolution and a variable frame rate. The frame rate increases to six frames per second when it is moving quickly, as in the duodenal sweep, and slows to two frames per second when moving slowly or when stationary. It has a "suspected blood indicator," which may facilitate identification of bleeding sites, although the clinical value of this feature is unclear since the sensitivity and specificity are poor [3-5]. The latest version of the PillCam software has discontinued the ability to track the location of the capsule within the abdominal cavity because of poor accuracy.

In October 2007, the FDA approved a second small bowel capsule (EndoCapsule, Olympus Corporation, Allentown, PA). It has similar characteristics to the PillCam SB but has a charge-coupled device (CCD) chip instead of a complementary metal-oxide-semiconductor (CMOS) chip. FDA approval was based upon a study of 51 patients with obscure gastrointestinal bleeding who swallowed both the PillCam SB and the EndoCapsule 40 minutes apart in randomized order [6]. The devices were similar, based upon the detection of normal versus abnormal and in diagnostic capability. This study also demonstrated that a capsule does not always travel axially, but may tumble. Furthermore, non-axial movement implies incomplete mucosal visualization, one of the limitations of the technology. The original EndoCapsule has been superseded by the EndoCapsule 10, which has also received FDA approval. This device has increased resolution and 3D location software.

Both the PillCam SB3 and the EndoCapsule 10 have combined the battery, recorder, and real time viewer into a single cell phone-like device. In addition, both are 11 x 26 mm in size. Both capsules now have extended battery life lasting

more than 12 hours.

An esophageal PillCam (PillCam ESO) with double-ended imaging up to 37 fps (11 x 26 mm) has been approved for detection of mucosal disease and varices in the esophagus. A double-ended colon capsule (11 x 31 mm) for colorectal cancer screening is available but its role is still uncertain [7,8]. (See 'Colon capsule endoscopy' below.)

The MiRo capsule became available in many countries between 2007 and 2009 and was approved by the FDA in 2013. This device uses a novel mode of transmission called electric field propagation, which uses the human body as a conductive medium to transmit images [9]. This technology uses less energy, which increases the operation time of the capsule and allows for the acquisition of more image data. A trial that compared the MiRo capsule with the EndoCapsule in 50 patients found they were similar with regard to complete small-bowel examination rates and diagnostic yield, though the findings on the two studies were concordant in only 68 percent (kappa = 0.50) [10]. This discordance is another demonstration that while the capsule passes the length of the small bowel in most patients, imaging of the mucosa with current devices is still far from complete [6].

**SMALL BOWEL CAPSULE ENDOSCOPY**

**Indications** — The indications for video capsule endoscopy (VCE) of the small bowel are evolving. The primary indications are for diagnosis of the site of obscure gastrointestinal bleeding in adults (including iron deficiency anemia), suspected Crohn disease, and small bowel tumors. Its role in the assessment of mucosal healing in patients with small bowel Crohn disease is beginning to evolve. In addition, VCE is being used to detect small bowel injury associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDs), evaluate abdominal pain of unclear etiology, to screen for polyps in patients with familial polyposis syndromes such as Peutz-Jeghers syndrome and familial adenomatous polyposis, and possibly in the assessment of celiac disease (picture 1) [11-16]. There is also growing experience in children over the age of 10 years for the above indications [17], and these indications are now approved for children as young as two years of age. (See "Evaluation of obscure gastrointestinal bleeding".)

**Procedure** — The procedure can be performed in ambulatory or hospitalized patients.

**Preparation** — It is generally agreed that patients should fast at least overnight (12 hours). Whether additional patient preparation or prokinetics are needed is controversial and a consensus on their use has not yet been achieved [18,19]. We use only a 12-hour fast without preparation. In addition, there is still no objective measurement of what constitutes a well-prepared small bowel.

In addition to a period of fasting, some investigators have advocated using a full colonoscopy preparation (with a gallon of polyethylene glycol) [20,21]. The rationale is to minimize the amount of dark bile, which can reduce visibility in the distal small bowel. A controlled trial suggested that ingestion of 2L of polyethylene glycol 16 hours before the procedure was associated with significantly increased visibility and a higher diagnostic yield [21]. A meta-analysis of 12 studies comparing VCE with and without a purgative concluded that purgative bowel cleansing before VCE improved the quality of visualization and diagnostic yield [22]. However, there is a great deal of heterogeneity between studies [23], mainly due to the subjective assessment of what constitutes a "good prep." (See "Bowel preparation for colonoscopy and flexible sigmoidoscopy in adults".)

A randomized trial with 291 patients published after the meta-analysis found no benefit from a preparation with aqueous sodium phosphate or polyethylene glycol compared with a clear liquid diet and an overnight fast [24].

Other investigators have examined the use of mannitol with or without simethicone. In a randomized trial, 200 patients were assigned to one of four groups [25]:

- A – Clear liquid diet after lunch the day prior to the procedure, followed by overnight fasting
- B – 250 mL of 20 percent mannitol and 1 L of 0.9 percent saline at 5:00 am the day of the procedure

- C – Same regimen as in B, but given at 8:00 pm the day prior to the procedure and at 5:00 am the day of the procedure
- D – Same regimen as in C along with 20 mL of simethicone 30 minutes prior to capsule endoscopy

Overall, adequate small bowel cleansing was more common in group D compared with groups A, B, and C. There were no differences in adequate small bowel cleansing in pairwise comparisons of groups A, B, and C. Pathologic lesions were found in the proximal small bowel more often in group D (46 percent) and in the distal small bowel in groups C and D (34 and 38 percent, respectively).

Other studies have suggested that simethicone increases visibility. Two controlled trials suggested improved visibility with bowel preparation involving bowel cleansing and simethicone [26,27]. However, another trial found that bowel preparation with magnesium citrate was superior to simethicone for improving small bowel fluid transparency and hence diagnostic yield [28].

The use of prokinetic agents, such as metoclopramide, is also controversial. One study of 150 patients suggested it increased the likelihood of complete small bowel examination compared with patients who did not receive metoclopramide (97 versus 76 percent) [29]. However, a randomized trial of 95 patients assigned to either metoclopramide 15 minutes prior to the examination or no metoclopramide did not show a benefit. In that study, there were no differences between those who received metoclopramide and those who did not with regard to the rate of complete small bowel examinations (81 versus 77 percent), median gastric transit time (26 versus 28 minutes), mean small bowel transit time (221 versus 256 minutes), or mean number of findings (4.5 versus 4.7) [30].

**Sensor array** — For the PillCam SB2, the original 8 lead sensor array has been replaced with a three-part sensor array contained in a belt worn by the patient, thereby eliminating adhesives. In addition, the belt containing the sensors is washable, reducing the risk of transfer of nosocomial infection. However, when the belt is used, localization of the capsule within the abdomen using diagnostic software is no longer possible.

The EndoCapsule continues to use an eight-lead sensor array that is fastened to the abdomen by adhesive pads. A template defines the correct position of the array. The EndoCapsule 10 has a belt-type sensor array.

For both systems, the array is connected to a solid state recorder and battery pack worn on a belt.

**Capsule ingestion** — The video capsule is swallowed with water. Following capsule ingestion, clear liquids may be taken after two hours, and food and medications may be taken after four hours. The sensor arrays are removed after 8 to 12 hours and the recorded images are downloaded and processed on workstations. The capsules are disposable and are excreted with bowel movements.

A device (AdvanCE capsule endoscopy delivery device: US Endoscopy) is available for endoscopic introduction of a capsule into the small bowel in patients who cannot swallow the capsule, who have gastroparesis, or who have some other impediment that may prevent passage of the capsule into the small bowel in a reasonable time [31].

**Image acquisition and review** — Both the PillCam SB2 and the EndoCapsule take two images per second, which are transmitted digitally to the recorder using radio frequency transmission. The recorders acquire up to 55,000 images over approximately eight hours. The field of view is about 150 degrees for both devices that have a camera at one end. This limitation has implications for incomplete imaging of the small bowel mucosa.

Review of the video, selection of representative images, and generation of a report can take 30 to 90 minutes. Algorithms in the software allow for quick preliminary screening of the videos, but do not replace careful review of the study. Clinically important abnormalities may be represented on only one or two frames out of 55,000; thus, significant concentration is required during the review of images. The video may be reviewed as slowly as one frame at a time up to 25 frames per second (standard video speed) when viewed singly. Images can be viewed singly or in groups of two or

four. The latter arrangements permit a further reduction in viewing time. Anecdotally, the author uses a rate of 25 to 30 frames per second in the four-view mode.

With recent versions of the Given Imaging and Olympus software, an optional mosaic view is also provided to facilitate rapid viewing of the video for pathological lesions. As is the case with the algorithms for preliminary review, review of the images in mosaic view is not a replacement for careful review of the study in one of the standard viewing modes, since abnormalities may be visible on a single frame that could easily be missed using mosaic view.

Both capsules now have a real time viewing device that can be plugged into the recorder. The role for these devices remains to be defined. They have the potential to be helpful for detecting active bleeding by intermittent real time review of images, rather than waiting for a full eight hours of recording, video processing, and review time.

**Efficacy** — VCE has several possible advantages compared to other means of visualizing the small bowel. It is noninvasive and permits examination of the majority of the small bowel mucosa, which is not possible with push enteroscopy [32-41]. The main disadvantage of VCE is that it does not permit tissue sampling or therapeutic intervention. In addition, the capsule does not reach the cecum within recording time in about 16 percent of cases [42]. One study found that an incomplete exam was more likely in patients who had undergone small bowel surgery, were hospitalized, had moderate or poor bowel cleaning, or had a gastric transit time of longer than 45 minutes [43].

The overall detection rate (ie, the percentage of studies which yield a diagnosis) is approximately 60 percent [42], and VCE has been shown to have an impact on the management of patients with a variety of small bowel disorders. An illustrative study included 40 clinicians who were interviewed before and after VCE examinations in 98 patients [44]. Clinicians changed overall management plans in 67 percent of patients. Of these clinicians, 74 percent reported that they changed their plan directly as a result of the VCE findings.

**Obscure bleeding/iron deficiency anemia** — The most common indication for VCE is the evaluation of obscure gastrointestinal bleeding (including iron deficiency anemia) [42]. However, even with VCE it can be difficult to identify bleeding sources within the small bowel. (See "Evaluation of obscure gastrointestinal bleeding".)

VCE was able to identify causes of obscure bleeding more often than push enteroscopy in most reports (picture 2) [32-34,36,45-48]. The overall yield of VCE for obscure gastrointestinal bleeding has been reported to be in the range of 30 to 70 percent [32-34,37,41,42,45,49-56]. A large meta-analysis included 227 studies with 22,840 procedures, 66 percent of which were done for obscure gastrointestinal bleeding. In that analysis, the detection rate for VCE in patients with obscure gastrointestinal bleeding was 61 percent [42].

In a study of 911 patients with obscure gastrointestinal bleeding published subsequent to the meta-analysis, 509 patients (56 percent) had a lesion identified on capsule endoscopy that was thought to be responsible for the bleeding [53]. The findings included:

- Small bowel angioectasia – 22 percent
- Small bowel ulcerations – 10 percent
- Small bowel tumors – 7 percent
- Small bowel varices – 3 percent
- Blood in the small bowel with no lesion identified – 8 percent
- Esophagogastric lesions (eg, esophagitis, gastritis) – 11 percent
- Colonic angioectasia – 2 percent

A meta-analysis of 14 observational studies compared capsule endoscopy with other tests for obscure bleeding. They estimated that the overall yield (ie, the yield of VCE for any small bowel findings) of VCE (63 percent) was significantly higher than for push enteroscopy (26 percent), and barium studies (8 percent) [54]. Comparison of the published reports

is somewhat limited since the definition of a bleeding site was variable. In some cases, active bleeding was identified, while in others, bleeding was presumed to originate from an ulceration or mass.

The diagnostic yield of VCE (ie, the percentage of studies that provided a clear-cut explanation for the bleeding) is highest when it is performed as close as possible to the bleeding episode and in patients with overt, rather than occult, bleeding [53,55,57]. One study included 100 consecutive patients with obscure bleeding [55]. Patients were categorized into three groups; the diagnostic yield of VCE was highest in the group with ongoing overt bleeding (92 percent), compared with those with previous overt bleeding (13 percent) or guaiac positive stools and iron deficiency anemia (44 percent). The most common findings were angioectasia (29 percent) and Crohn disease (6 percent). Sixty-two patients underwent further examination that led to independent verification of the diagnosis in 56. Sensitivity, specificity, positive, and negative predictive values were 89, 95, 97, and 83 percent, respectively. The authors concluded that VCE is effective for evaluation of obscure bleeding and that the best candidates appear to be patients with ongoing obscure-overt bleeding or obscure-occult bleeding.

Other factors associated with an increased yield of VCE include older age, male sex, current hospitalization, increasing transfusion requirements, and the presence of connective tissue disease [53,58].

VCE appears to be more accurate for identifying small bowel pathology than barium small bowel radiography [35,50,59]. Two of the studies that have looked at this showed the following:

- One series included 22 patients suspected of having small bowel pathology who underwent both VCE and a standard upper gastrointestinal series with small bowel follow-through [35]. VCE was considered diagnostic in 45 percent compared with 20 percent for barium studies. VCE was significantly more sensitive for causes of obscure bleeding (31 versus 5 percent).

- In a randomized trial, 136 patients with occult or overt obscure gastrointestinal bleeding were assigned to either VCE (n = 66) or dedicated small bowel barium radiography (n = 70) [50]. The diagnostic yield was higher for VCE compared with barium radiography (30 versus 7 percent). However, the improved diagnostic yield did not result in a significant difference in subsequent diagnostic or therapeutic interventions for bleeding (26 percent for VCE versus 21 percent for barium radiography). Additionally, patients who underwent VCE did not differ from patients who underwent barium radiography with regard to subsequent hospitalizations for bleeding (12 versus 6 percent) or the need for subsequent blood transfusions (8 versus 6 percent).

At least one randomized controlled trial (involving a total of 89 patients) suggested that performing VCE before push enteroscopy was a more effective strategy than beginning with push enteroscopy in patients with obscure gastrointestinal bleeding [60]. The VCE first strategy reduced the percentage of patients needing the push enteroscopy study (25 versus 79 percent). Twelve months after evaluation, the strategy based upon VCE first (followed by push enteroscopy as necessary) had a similar diagnostic yield, clinical outcome and therapeutic impact compared with a strategy of push enteroscopy first (followed by VCE as needed).

A 2004 study was the first to note that early deployment of the VCE enhances the diagnostic yield of capsule endoscopy [55]. A more recent retrospective study in 2013 expanded on this observation in an inpatient population and showed that deployment within 72 hours of admission enhanced the detection rate of active bleeding, the rate of therapeutic intervention, and significantly reduced the length of stay by 40 percent. Capsule deployed after 72 hours had the same diagnostic yield as that of an outpatient population [57]. Thus, there is increasing support for early use of VCE, particularly in patients with obscure-overt bleeding.

**Crohn disease** — VCE can be useful in diagnosing Crohn disease in patients with symptoms suggestive of Crohn disease or in patients with indeterminate colitis. It can also be used in patients with known Crohn disease to detect active disease (picture 3) and to evaluate responses to therapy. The overall detection rate by VCE in patients with known or suspected Crohn disease was 55 percent in a large meta-analysis [42].

VCE should not be used in patients with known or suspected strictures without careful consideration and pre-procedure evaluation [61-65]. A small bowel follow-through that does not reveal strictures does not necessarily exclude strictures. Capsule retention has been described in up to 13 percent of patients who underwent a capsule study for Crohn disease, even after performing an initial small bowel study [62]. In most reports, retention was more likely in patients in whom the capsule study was being performed for known Crohn disease compared with those with suspected Crohn disease (5 to 13 versus 1 to 2 percent) [62,66]. This has led to the recommendation that patients with known small bowel Crohn disease have small bowel imaging or a patency study prior to VCE. (See 'Patency capsule' below.)

A patency study should also be obtained in patients without Crohn disease who are at high risk for having strictures (eg, known strictures that have not been treated or symptoms of recurrent small bowel obstructions). In patients at lower risk (eg, patients with a history of small bowel Crohn disease who are asymptomatic), evaluation with a computed tomographic (CT) or magnetic resonance imaging (MRI) enterography is an acceptable alternative to patency capsule.

Studies have been done comparing VCE with other modalities for small bowel Crohn disease. A meta-analysis of 12 studies found that capsule endoscopy had an overall yield of 50 to 70 percent for findings of Crohn disease [67]. The yield was higher than the yield for barium radiography (22 percent), ileo-colonoscopy (48 percent), push enteroscopy (8 percent), or CT enterography/CT enteroclysis (31 percent). In patients with known Crohn disease who were being evaluated for a suspected recurrence, the yield for VCE was 66 to 71 percent. The yield was lower for patients with suspected Crohn disease (33 to 68 percent).

A subsequent study compared VCE with CT enterography and MR enterography in patients without small bowel strictures [68]. Using ileoscopy or surgery as the gold standard, VCE had a sensitivity of 100 percent for detecting terminal ileal Crohn disease, which was significantly higher than that for CT enterography (76 percent) and showed a trend toward being higher than the sensitivity for MR enterography (81 percent). The specificities of the three studies were similar (91, 85, and 86 percent, respectively). Overall, the diagnostic yield of VCE for Crohn disease in any portion of the small bowel did not differ significantly from the other studies (30 versus 33 and 28 percent, respectively), but it did detect more cases of Crohn disease proximal to the ileum (18 versus 6 and 2 cases, respectively).

VCE findings may also help identify patients who are likely to have a disease relapse. In a study of 108 patients with Crohn disease, the presence of jejunal lesions on capsule endoscopy was associated with an increased risk of relapse (adjusted hazard ratio 1.99, 95% CI 1.10-3.61) [69].

**Small bowel tumors, polyps, and other pathology** — A variety of small intestinal lesions have been detected with VCE, including small intestinal varices, tumors and polyps, and intestinal graft-versus-host disease [14,38,39,63,64,70-78]. VCE is comparable to EGD for the diagnosis of celiac disease when there are overt villous changes. In a study of 43 patients with suspected celiac disease, VCE had a sensitivity of 88 percent and a specificity of 91 percent for detecting celiac disease [79]. However, VCE was less sensitive in a study of patients with known celiac disease [80]. The study included 42 patients with refractory celiac disease, 84 patients without celiac disease, and 30 patients with uncomplicated celiac disease. Using histology as the gold standard, VCE was 56 percent sensitive and 85 percent specific for detecting villous atrophy. Importantly, VCE detected complications of celiac disease in two of the patients with refractory celiac disease, finding one case of ulcerative jejunitis and one adenocarcinoma.

VCE appears to be less sensitive for detecting small bowel tumors than CT enterography. In a study that included 17 patients with small bowel tumors who underwent both CT enterography and capsule endoscopy, CT enterography was more sensitive than capsule endoscopy for detecting small bowel tumors (94 versus 35 percent) [81]. Lesions in the duodenum and proximal jejunum are easily missed because of the rapid transit of the capsule through these areas. One problem encountered with VCE is that transient bulges into the small bowel lumen may appear to be submucosal masses [82,83]. Factors associated with true submucosal masses include a well-defined boundary with the surrounding mucosa, a lesion that is taller than it is wide, visible lumen in the frame with the lesion, ulceration, attenuation of folds, and visualization of the lesion for more than 10 minutes of the capsule's recording time.

VCE may have a role in surveillance of patients with polyposis syndromes [71-75]. However, at least one report found that VCE underestimated the number of small bowel polyps and did not reliably detect large polyps in persons with familial adenomatous polyposis compared with push enteroscopy and lower endoscopy [84]. Given that VCE frequently fails to identify the ampulla of Vater [85,86], it should not be used for ampullary surveillance in patients with familial adenomatous polyposis. (See "Familial adenomatous polyposis and MUTYH associated polyposis: Screening and management of patients and families", section on 'Surveillance for upper intestinal tumors'.)

Occasionally, a small number of small, benign-appearing polyps are detected by capsule endoscopy in a patient without a polyposis syndrome. There are no clear guidelines on the management of such polyps. We typically will repeat the capsule endoscopy in one year to ensure there has been no change in the polyps.

**Risks** — VCE is an extremely safe technology. No deaths have been attributed to the device, despite more than a million ingestions. One of the main risks associated with VCE, although not inherently serious, is retention of the capsule. In addition, in some patients the battery runs out before the capsule passes through the ileocecal valve, making it unclear if the capsule has been retained until it is passed with a bowel movement. However, not all patients will note passage of the capsule in their stool. If there is clinical concern regarding capsule retention, it is generally recommended to obtain a plain abdominal x-ray to confirm passage.

**Capsule retention** — Capsule retention generally occurs in three forms:

- Long-term retention, which may be first suspected in patients in whom the capsule does not pass the ileocecal valve before the battery runs out. In a meta-analysis that included 22,840 procedures, retention occurred in 1.4 percent of patients [42]. The capsules were removed surgically in 59 percent and endoscopically in 16 percent. However, with the increasing use of deep small bowel enteroscopy (eg, double balloon enteroscopy), the frequency with which capsules are being removed endoscopically is likely increasing.

  In a study of 904 patients, capsule retention occurred in eight (0.9 percent) [87]. In all cases, the capsule was removed with double balloon enteroscopy. Five patients subsequently underwent elective surgery to treat the underlying cause of the retention, and one patient required emergency surgery because of multiple small bowel perforations.

  In general, surgical intervention to remove the capsule should also address the underlying cause of the retention. Long-term retention is always associated with underlying pathology (eg, stricture, tumors). The most common cause of long-term retention is Crohn disease [42].

- Incomplete transit of the capsule during its recording time, often with transient retention at the ileocecal valve. This occurs in approximately 16 percent of procedures and is of no clinical consequence [42].

- Transient retention at a stricture or mass (picture 4). The patient is rarely aware of this, but in this situation it is recommended that an abdominal plain film be taken two weeks after the procedure to confirm excretion of the capsule.

As a general rule, a retained capsule does not cause obstruction but tumbles around above the narrowed segment, where it may remain for as long as several months to years. It is not yet known how long the capsule can be safely left above a stricture. The development of pain usually heralds passage through a tight stricture.

Careful consideration must be given before performing VCE on any patient in whom there is the potential for capsule retention. Examples include patients with known Crohn disease (up to a 13 percent retention rate) [66], patients with intermittent small bowel obstruction secondary to adhesions, patients with radiation enteritis, patients with severe motility disorders, and patients with a Zenker's diverticulum. Patients with suspected Crohn disease have a much lower risk of retention (about 1 percent retention rate) [66]. In these settings, decisions to proceed with VCE should be made in

conjunction with a surgeon, who may be left with the problem of retrieving the capsule and treating the underlying problem. A normal small bowel barium study or CT scan does not exclude the possibility of retention, particularly in NSAID-associated diaphragm disease, which is nearly impossible to pick up radiologically because the diaphragms are the same width as normal small bowel folds.

In a significant number of patients with a retained capsule, surgery would have been indicated for the underlying condition, even in the absence of retention (eg, in a patient whose retention is due to a small bowel tumor). A collaborative approach may enable the team to use the capsule to both visualize and localize an obstructive lesion [55,66]. Palpation by the surgeon of the capsule retained above a stricture may be helpful in localizing the stricture, which may have no serosal signs, thus avoiding the need for intraoperative enteroscopy. However, there is a risk of incorrect localization if the capsule migrates proximal to the stricture during surgery. This can be avoided by having the surgeon "milk" the capsule distally until further progress is prevented by the stricture.

There are situations where a laparotomy and enterotomy to retrieve the capsule may not be in the patient's best interest (eg, a patient with Crohn disease who has a capsule retained at an asymptomatic stricture). In these cases, removal of the retained capsule by double balloon enteroscopy may be an option [87,88].

**Patency capsule** — A capsule system to determine small bowel patency has been developed (Agile Patency Capsule, Given Imaging, Ltd, Yoqneam, Israel). The patency capsule is used in patients who are at high-risk for having small bowel strictures, such as those with symptoms suggesting small bowel obstruction, imaging findings suggesting stricturing, a history of small bowel strictures, previous small bowel surgery, abdominal radiation for intestinal or gynecological malignancy, or heavy NSAID consumption.

The system is based upon a capsule (the same size as the PillCam SB2) composed of lactose and barium enclosed in a thin plastic envelope that contains a radiofrequency identification tag that can be detected by a scanning device placed on the abdominal wall or by a plain abdominal film. The biodegradable plugs at each end start to dissolve after 30 hours, and fully dissolve 40 to 80 hours after ingestion, allowing the capsule to pass even in the presence of a stricture. The patency capsule does not have any image acquisition capability.

The patency capsule is used as follows:

- The patient is instructed to ingest a liquid diet starting at noon and to not eat or drink anything after 10 pm.
- The patient ingests the capsule the following morning (we suggest 7 or 8 am). Following capsule ingestion, liquids may be taken after two hours, and food and medications may be taken after four hours.
- The patient is assessed at as close to 30 hours as possible, without exceeding 30 hours (if the capsule is ingested at 7 am, the assessment should be done prior to 1 pm). This can be done using the scanning device or a plain abdominal film. Our practice is to use a plain film. If the scanning device indicates the capsule is in the abdomen, then follow-up imaging (also performed less than 30 hours after capsule ingestion) is used to localize the capsule to the small bowel or colon. The radiologist needs to understand the difference in the radiological appearance of the patency capsule compared with the video capsule, which is more radiologically opaque. The patency capsule is sometimes difficult to see if it overlays the spine.
- Patency is suggested if at or before 30 hours:
    - The capsule is not present in the abdomen (determined either with the scanning device or radiographic evaluation)
    - The capsule is in the abdomen, but imaging indicates that it is in the colon
    - The patient sees the capsule pass fully intact

The capsule is used to assure small bowel patency before VCE and can also be used as a diagnostic test for suspected small bowel strictures that might retain the video capsule and that cannot be identified by standard radiographic means [89-91]. Passage of the patency capsule into the colon by 30 hours suggests that there are no obstructions likely to impede passage of the video capsule. However, VCE retention following a patency study that suggested no significant strictures has been reported when capsule localization was determined using a plain abdominal film (presumably due to inaccurate interpretation of the patency capsule location) [92].

In a report of 106 patients with known strictures, the patency capsule suggested the gastrointestinal tract was sufficiently patent in 59 patients. All subsequently underwent VCE with no cases of capsule retention [93].

Adverse events related to patency capsule ingestion were common with an earlier version of the patency capsule. The earlier version had a single dissolvable plug, leading to incomplete dissolution of the device, allowing it to become lodged within a stricture as it dissolved to the dimensions of the stricture. In one study, about 25 percent of patients with strictures developed abdominal pain [89]. In some of the patients the pain was severe and two patients required emergency surgery.

**Magnetic resonance imaging** — Patients should not undergo magnetic resonance imaging (MRI) until passage of the capsule has been confirmed due to concern that it could result in damage to the gastrointestinal tract.

**Contraindications** — The procedure may be contraindicated in patients with the following conditions, albeit these contraindications may not be absolute:

- Dementia (in patients who cannot cooperate with swallowing of the capsule or who may inadvertently damage the equipment)
- Gastroparesis (the capsule can be placed in the duodenum by endoscopy to avoid this problem)
- An esophageal stricture, swallowing disorders that could prevent passage of the capsule (eg, Zenker's diverticulum) (the capsule can be placed in the duodenum by endoscopy to avoid this problem)
- Partial or intermittent small bowel obstruction (unless a surgeon is involved, the patient understands the risks, and the patient has been cleared for surgery)
- Those patients who are inoperable or refuse surgery
- Patients who have defibrillators or pacemakers (this is a recommendation in the package insert, but does not appear to be a significant clinical problem)
- Women who are pregnant

**ESOPHAGEAL CAPSULE ENDOSCOPY** — An esophageal capsule (the PillCam ESO2) with imaging systems at both ends is available for the detection of mucosal disease of the esophagus in patients complaining of heartburn [94]. Its role is still being determined (particularly since very few patients have been studied), although it is being proposed as a minimally invasive screening tool for esophageal disease other than Barrett's esophagus (since it cannot provide histology, which is the "gold standard" for diagnosing Barrett's esophagus).

The patient swallows the capsule in the right lateral position and drinks 15 mL sips of water every 30 seconds. The device captures images at 18 frames per second from each end and records for approximately 30 minutes. Thus, a large number of images of the mucosa can be obtained, even if esophageal transit is fast. Images of the stomach and small bowel may be seen if gastric transit is rapid.

Its approval was based upon a study that included 73 patients with gastroesophageal reflux disease and nine patients with known Barrett's esophagus who underwent the capsule study followed by standard endoscopy [94]. A positive

esophageal finding was found in 55 patients, of which 51 were seen on capsule endoscopy. The sensitivity, specificity, positive, and negative predictive values for Barrett's esophagus were 97, 100, 100, and 98 percent, respectively. For esophagitis these values were 98, 100, 100, and 95 percent, respectively. However, sensitivity and specificity were only 67 and 84 percent, respectively in another study of 96 patients [95].

A subsequent meta-analysis involving nine studies (with a total of 618 patients) estimated that the pooled sensitivity and specificity for diagnosis of Barrett's esophagus were 77 and 86 percent, respectively [96]. The authors concluded that upper endoscopy remains the modality of choice for evaluation of suspected Barrett's esophagus. In addition, two economic analyses concluded that screening for Barrett's esophagus with the PillCam ESO was not cost-effective compared with standard screening with upper endoscopy [97,98].

Ongoing studies are evaluating accuracy in other clinical settings. Initial studies suggest that it may provide an accurate alternative for screening for the presence of esophageal varices in patients with cirrhosis [99,100]. It may also have a role in identifying patients in the emergency department with active upper gastrointestinal bleeding [101-105]. In a study of patients with suspected upper gastrointestinal bleeding, esophageal capsule endoscopy was performed prior to upper endoscopy in 83 patients. Upper gastrointestinal bleeding was identified in 62 patients (75 percent) overall [103]. Capsule endoscopy was positive in 41 of the patients with upper gastrointestinal bleeding (66 percent) and negative in 21 (34 percent). Among the 21 patients with bleeding missed by capsule endoscopy, failure to visualize the duodenum was a contributing factor in 7 (33 percent). In a second study of 25 patients with upper gastrointestinal bleeding, esophageal capsule endoscopy had a sensitivity of 88 percent and a specificity of 64 percent for detecting bleeding [101]. Failure of the capsule to enter the duodenum prior to the battery expiring contributed to missing a postpyloric bleeding lesion in one patient. These studies suggest that esophageal capsule endoscopy may be helpful for identifying patients with upper gastrointestinal bleeding, but that bleeding cannot be reliably excluded if the duodenum is not visualized during the recording time of the capsule.

**COLON CAPSULE ENDOSCOPY** — A colon capsule for colorectal cancer screening has been approved by the EMA in Europe and by the US Food and Drug Administration, but its role is still uncertain [7,8]. In the United States, it is approved for use in patients who have had an incomplete colonoscopy. Guidelines issued by the European Society for Gastrointestinal Endoscopy suggest that colon capsule endoscopy is a reasonable alternative to colonoscopy for colorectal cancer screening in average-risk patients [106]. However, the guidelines do not recommend it for patients at increased risk for colon cancer (eg, those with a family or personal history of colon cancer) or for those with alarm symptoms (eg, anemia, rectal bleeding, weight loss).

Like optical colonoscopy, a preparation is given prior to colon capsule endoscopy. One regimen that has been used consists of the patient taking a clear liquid diet following a light breakfast the morning prior to the procedure [107]. The evening prior to the examination, patients take 3 liters of polyethylene glycol (PEG). The morning of the procedure, the patient drinks another liter of PEG between 6:00 and 7:00 am and the capsule is ingested at 8:00 am. Additional medications (phosphosoda and bisacodyl) are then given during the procedure to increase transit of the capsule. Of note, phosphosoda has been associated with renal dysfunction and is not currently recommended in the United States. (See "Bowel preparation for colonoscopy and flexible sigmoidoscopy in adults", section on 'Sodium phosphate preparations'.)

Colonic capsule endoscopy does not allow for biopsy or polyp removal, so patients with lesions detected during the examination typically require subsequent colonoscopy for further evaluation and/or treatment.

Studies looking at the efficacy of colon capsule endoscopy compared with standard colonoscopy have reached variable results [8,108-111].

- A meta-analysis that included 626 patients found that for detecting "significant polyps" (a polyp >6 mm in size or three or more polyps), colonic capsule endoscopy had a sensitivity of 69 percent with a specificity of 86 percent.

When all polyps (not just "significant polyps") were included, the sensitivity was 73 percent and the specificity was 89 percent [110].

- A subsequent study examined 545 patients who underwent colonic capsule endoscopy followed by standard colonoscopy [112]. The patients were all asymptomatic and undergoing the studies for either screening or surveillance for colonic neoplasia. Colon cancer was detected in five patients on standard colonoscopy. Two of the cancers were missed on colonic capsule endoscopy. With regard to polyp detection, the sensitivity of colonic capsule endoscopy for detecting polyps that were 6 mm in size or larger was 39 percent and the specificity was 88 percent.
- A study of a newer capsule (PillCam Colon 2) that has a wider angle of view (172 degrees per camera) and an adaptive frame rate that preserves battery life included 109 patients [113]. For detecting polyps that were 6 mm or larger, the capsule had a sensitivity of 84 percent and a specificity of 88 percent. For polyps 10 mm or larger, the sensitivity and specificity were 88 and 95 percent, respectively. Three of the patients had invasive cancer, all of which were detected by the capsule.
- Another study that used the PillCam Colon 2 capsule looked at colon capsule for identifying patients with polyps 6 mm or larger in 50 patients with positive fecal occult blood tests [114]. The sensitivity and specificity of the colon capsule for detecting individuals with at least one polyp ≥6 mm in size were both 88 percent.

**ADJUNCTIVE DEVICES** — Both of the US Food and Drug Administration approved capsules have plug-in devices that permit real time viewing of the lumen of the intestine via a laptop or a hand held device. Until recently, these devices had attracted little interest. However, one study suggests that such a device can be used to improve completion rates and increase diagnostic yields. By real time imaging the capsule at one hour, the position of the capsule was assessed; if the capsule was already in the small intestine, 500 mL of polyethylene glycol (PEG) was given; if the capsule was still in the stomach, PEG plus metoclopramide was given. This group was compared with a conventional no-prep group. Completion rates increased from 73 to 90 percent, as did image quality [115,116].

**INFORMATION FOR PATIENTS** — UpToDate offers two types of patient education materials, "The Basics" and "Beyond the Basics." The Basics patient education pieces are written in plain language, at the 5$^{th}$ to 6$^{th}$ grade reading level, and they answer the four or five key questions a patient might have about a given condition. These articles are best for patients who want a general overview and who prefer short, easy-to-read materials. Beyond the Basics patient education pieces are longer, more sophisticated, and more detailed. These articles are written at the 10$^{th}$ to 12$^{th}$ grade reading level and are best for patients who want in-depth information and are comfortable with some medical jargon.

Here are the patient education articles that are relevant to this topic. We encourage you to print or e-mail these topics to your patients. (You can also locate patient education articles on a variety of subjects by searching on "patient info" and the keyword(s) of interest.)

- Basics topics (see "Patient information: Angiodysplasia of the GI tract (The Basics)")

**SUMMARY AND RECOMMENDATIONS**

- Video capsule endoscopy (VCE) is most commonly used for the diagnosis of small bowel disorders.
- Available capsules include the PillCam SB2 and SB3, and the EndoCapsule and the EndoCapsule 10 for evaluation of the small bowel, and the PillCam ESO2 for evaluation of the esophagus. A colon capsule has also been developed and is available in Europe, the United States, and Japan. (See 'Available capsules' above.)
- VCE may be used for diagnosing sites of obscure gastrointestinal bleeding in adults, evaluating patients with suspected Crohn disease, and detecting small bowel tumors. In addition, VCE is being used to detect small bowel injury associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDs). (See 'Indications' above and

'Obscure bleeding/iron deficiency anemia' above and "Evaluation of obscure gastrointestinal bleeding" and 'Crohn disease' above.)

- Additional applications for VCE continue to be described, but experience with some is limited. These include diagnosing celiac disease or evaluating patients with complicated celiac disease (picture 1), detecting rejection following small bowel transplantation, detecting graft–versus-host disease after bone marrow transplantation, and performing surveillance in patients with hereditary polyposis syndromes. The evaluation of patients with abdominal pain of unclear etiology has been reported as a low-yield indication. (See 'Small bowel tumors, polyps, and other pathology' above.)
- The esophageal PillCam has not been approved for screening for Barrett's esophagus but is approved for screening for esophageal varices and diagnosing esophagitis. (See 'Esophageal capsule endoscopy' above and "Cirrhosis in adults: Overview of complications, general management, and prognosis".)



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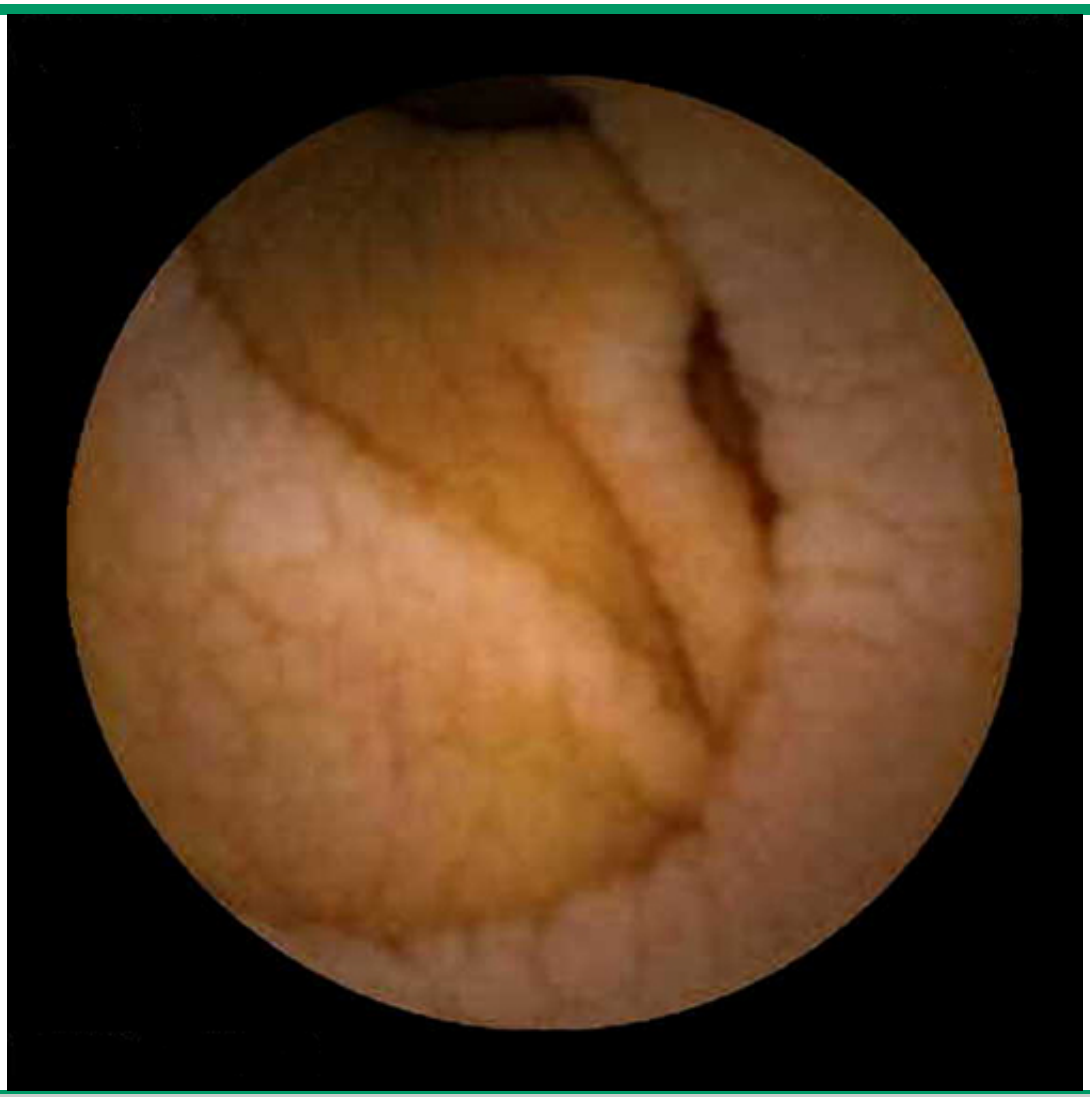
## GRAPHICS

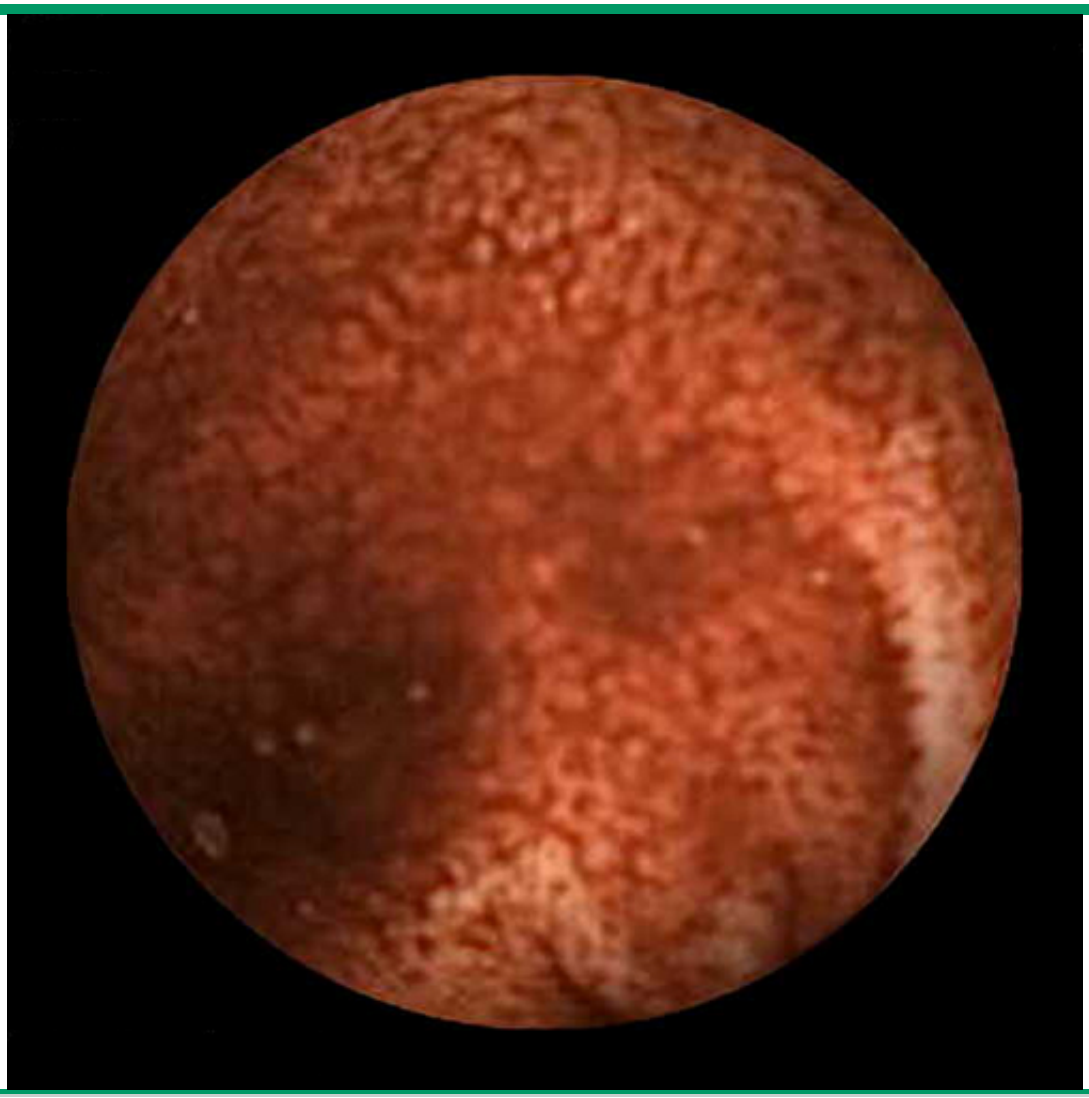
### Celiac disease



Capsule endoscopy image in a patient with celiac disease. The findings are notable for villous blunting, leading to a scalloped mucosal appearance.

Graphic 83586 Version 1.0

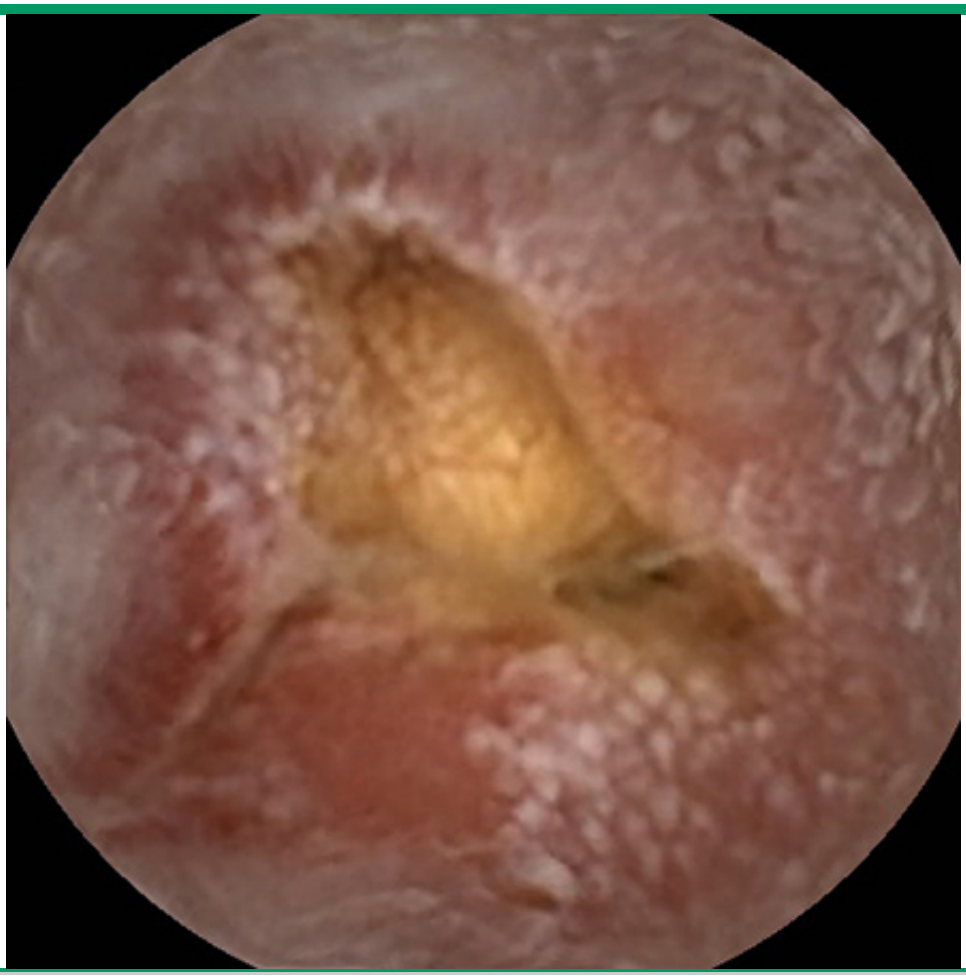
## Bleeding in the ileum



Capsule endoscopy image showing bleeding in the ileum.

Graphic 83585 Version 1.0

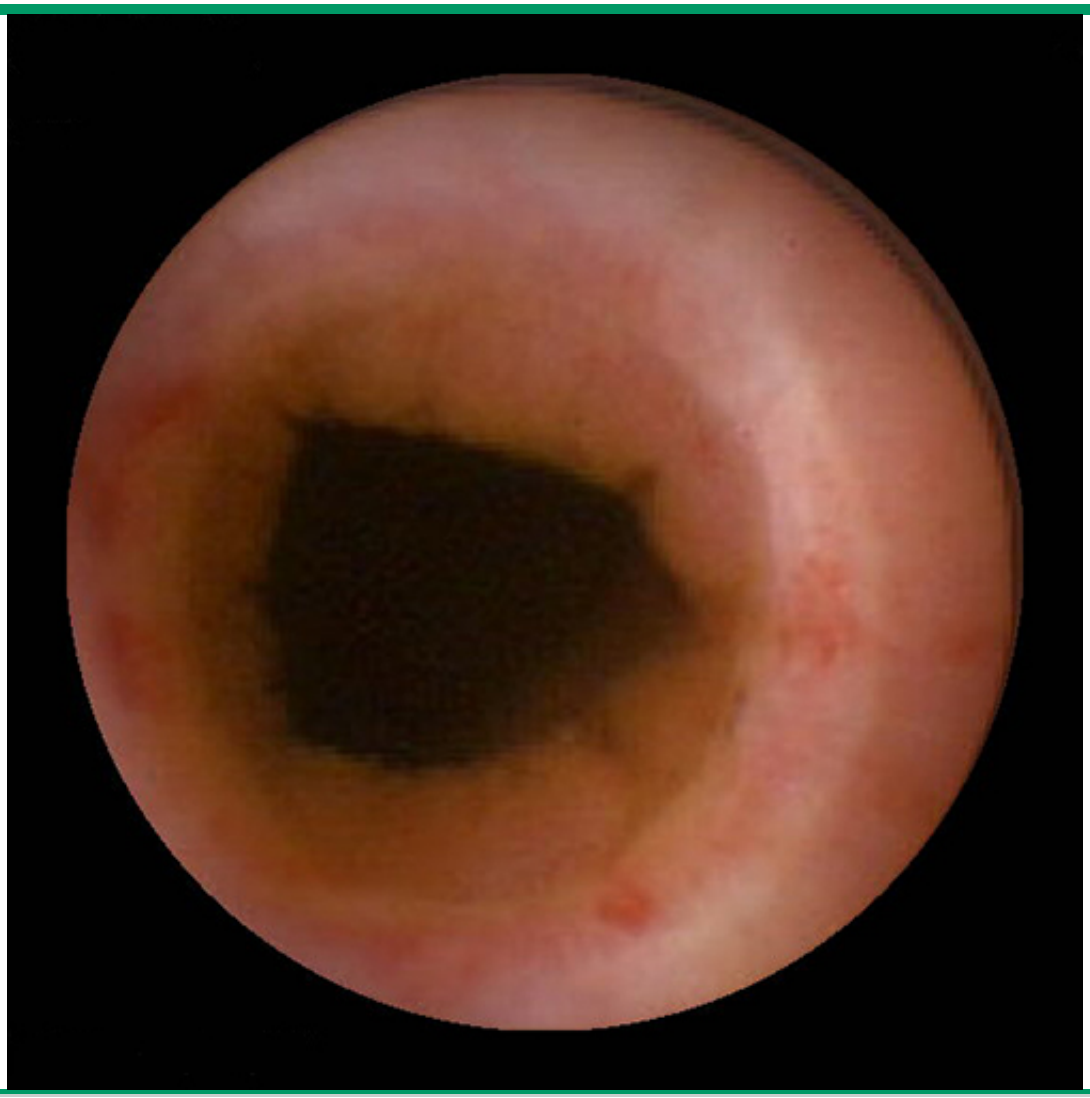
## Crohn's disease of the small bowel



Capsule endoscopy image from a patient with small bowel Crohn's disease. The image is notable for edematous villi and erythematous small bowel mucosa around a stenosis.

Graphic 83589 Version 1.0

## Small bowel stricture due to nonsteroidal anti-inflammatory drug use



Capsule endoscopy image showing a stricture due to NSAID use.

Graphic 83588 Version 1.0

## Disclosures

***Disclosures:*** **David Cave, MD, PhD** Grant/Research Support: Olympus (small intestinal disorders [video capsule]); Capsovision (small intestinal disorders [video capsule]). Consultant/Advisory Boards: Olympus (small intestinal disorders [video capsule]) **John R Saltzman, MD, FACP, FACG, FASGE, AGAF** Nothing to disclose. **Anne C Travis, MD, MSc, FACG, AGAF** Employee of UpToDate, Inc. Equity Ownership/Stock Options: Proctor & Gamble.

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