

## ASGE Technology Status Evaluation Report: wireless capsule endoscopy

To promote the appropriate use of new or emerging endoscopic technologies and those technologies that have an impact on endoscopic practice, the ASGE Technology Committee presents relevant information to practicing physicians in the form of technology reviews. Evidence-based methodology is employed wherein a MEDLINE literature search is performed to identify pertinent clinical studies on the topic, a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search is performed to identify the reported complications of a given technology, and both are supplemented by accessing the “related articles” feature of PubMed and by scrutiny of pertinent references cited in the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking; in such cases, large case series, preliminary clinical studies, and expert opinion are utilized. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Reviews are drafted by 1 or 2 committee members, reviewed in significant detail by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is appropriate, the most recent coding data and list prices at the time of publication are provided. For this review the MEDLINE database was searched through November 2005 for articles related to capsule endoscopy by using the keywords “capsule endoscopy” and “wireless endoscopy” plus “esophageal disease,” “esophageal varices,” “small intestinal disease,” “gastrointestinal bleeding,” “Crohn’s disease,” and “celiac disease.” Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and socioeconomic aspects of these technologies.

### BACKGROUND

Endoscopic examination of the small intestine is limited by its significant length and distance from accessible orifices. The desire to explore this relatively inaccessible

area led to the development of an ingestible miniature camera. Video capsule endoscopy provides visualization of the GI tract by transmitting images wirelessly from a disposable capsule to a data recorder worn by the patient. The first capsule was approved by the Food and Drug Administration (FDA) in August 2000 and to date >250,000 capsules have been ingested.<sup>1</sup> A second capsule was approved in October 2004, specifically to evaluate the esophagus.

### TECHNOLOGY REVIEW

At the time of this writing, the Given Diagnostic Imaging System (Given Imaging Ltd., Norcross, Ga) is the only wireless endoscopy system that has received FDA clearance. Given Imaging manufactures the PillCam SB, which evaluates the small intestine, and PillCam ESO (marketed by InScope, a Division of Ethicon Endo-Surgery, Inc., a Johnson & Johnson company, Cincinnati, Ohio) for the esophagus. Another wireless capsule device developed by Olympus, Inc has been released in Europe and is nearing clearance and release in the United States.

The systems consist of 3 components: (1) a capsule “endoscope,” (2) a sensing system composed of sensing pads attached to the trunk, a data recorder, and a battery pack, and (3) a personal computer workstation with proprietary software that reviews and interprets the images.

### Imaging the small intestine

The Given capsule endoscope is a disposable plastic capsule (PillCam SB) that weighs 3.7 g and measures 11 mm in diameter and 26 mm in length. The contents include a complementary metal oxide silicon (CMOS) chip camera, a short focal length lens, 6 white light emitting diode (LED) illumination sources, 2 silver oxide batteries, and a UHF band radio telemetry transmitter. Image features include a 140 degree field of view, 1:8 magnification, 1 to 30 mm depth of view, and a minimum size of detection of about 0.1 mm. The capsule is activated by removal from a magnetic holder and provides image accrual and transmission at a frequency of 2 frames per second until the battery expires after  $7 \pm 1$  hours. The capsule is passively propelled through the intestine by peristalsis while transmitting color images (256 × 256 pixels) at a transmission frequency of 431.1 MHz. The Advanced Pillcam SB,

anticipated in 2006, will acquire 4 frames per second and have an increased operational time of 8 to 9 hours.

Two data recorders are commonly used. The DR 1.5 attaches to an external power supply containing 5 rechargeable (D-cell sized) NiCad batteries, lasts for an average of 9 hours, and has a 5 gigabyte portable hard drive for archiving received images. The newer generation DR 2 uses a hard drive with an integrated Lithium-ion battery that lasts an average of 12 hours.

Capsule endoscopy can be performed in an ambulatory outpatient setting. Fasting or clear liquids for 10 to 12 hours is standard practice; some centers employ a clear liquid diet for 24 hours before the study. Data are conflicting, but several studies suggest that use of a bowel preparation the night before the study yields improved visualization of the small intestine and higher rates of capsules reaching the colon before the end of the recording period.<sup>2-5</sup> Most studies used either 2 or 4 L of polyethylene glycol based electrolyte solution; oral sodium phosphate preparation has also been evaluated. At the time of the procedure, 8 sensor pads are adhered to the abdominal wall in a designated pattern and connected to the portable hard drive, which is fitted on a belt with suspenders.

After ingestion of the capsule, patients are instructed to keep a diary of symptoms and monitor the lights on the data recorder to confirm that the signal is being received. Patients are encouraged to avoid exercise or activities that may cause the sensor to detach. A diet of clear liquids is allowed after 2 hours and a light meal after 4 hours. The reusable data-recording system can be disconnected from the patient after 8 hours. The data recorder is subsequently connected to a customized PC workstation for transfer of the acquired images. The disposable capsule is designed to be excreted.

Proprietary software (RAPID 3 Application, Given Imaging Ltd., Norcross, Ga) is used to process and display the images in single, double, or quad views at rates of 5 to 40 images per second. Representative images and video clips can be annotated and saved. The program also has a report generation feature. The "Suspected Blood Indicator" is a feature that is designed to facilitate detection of bleeding lesions in the small bowel by identifying red pixels. There is limited published data regarding its clinical relevance.<sup>6</sup> Additionally, the software localizes the capsule's position in the abdomen by means of triangulation of the signal received by the 3 closest sensors and displays its path graphically on a 2-dimensional picture. The next software upgrade (Rapid 4) will include an atlas of images for reference and improvements to aid the physician reader. The average reading time varies between 30 to 120 minutes, primarily dependant on small-bowel transit time and the experience of the reader. See standards of practice ASGE committee guidelines for credentialing and granting privileges for capsule endoscopy.<sup>7</sup>

In October 2005, Olympus Medical Systems Corporation (Tokyo) released a new small-bowel capsule (Endo Capsule) in Europe. Their system comprises a capsule with automatic brightness control, a recorder unit, antenna lead set, and a real time viewer.<sup>8</sup> As of February 2006, FDA clearance and release in the United States remain pending.

### Imaging the esophagus

The PillCam ESO capsule, for esophageal applications, has a lens and 6 LED illumination sources on each end. The capsule dimensions, transmission wavelength, field of view, and the minimum size of the object that can be detected are similar to the PillCam SB. The PillCam ESO acquires and transmits 7 frames per second from each end, for a total of 14 frames per second.<sup>9</sup> The image features are also similar to that of the PillCam SB; however, the capsule battery life is only 20 minutes. At the time of the test, the patient should be fasting for 2 hours. The patient is fitted with 3 thoracic sensors, in a designated pattern, that are connected to the DR 2 data recorder. The patient drinks 100 mL of water and simethicone while standing and then ingests the activated capsule in the supine position with a 10 mL sip of water that can be administered with the help of a syringe. The manufacturer suggests a 5 minute ingestion protocol comprising two 2-minute recording intervals with the patient supine and raised to 30 degrees, and then an additional minute at 60 degrees, followed by an upright position for 15 minutes. Image transfer and review require a recent version of the software (Rapid 3 or newer) and are similar to the PillCam SB. The average reading time varies between 5 and 15 minutes.

A handheld device that enables real-time viewing of the PillCam SB and PillCam ESO images (RAPID Access) is under development. A prototype of this device is expected to be available in the first half of 2006.

### Given patency capsule

Retention of a capsule above an intestinal stenosis may necessitate its removal either endoscopically or surgically. A radio-opaque nonvideo capsule with dimensions equivalent to the esophageal and small intestinal capsules has been developed for assessment of the patency of the GI tract. It carries a radiofrequency identification (RFID) tag that is activated and detected by a hand-held, battery-operated RFID scanner. When retained in a fluid filled environment, the core of the patency capsule dissolves after approximately 40 hours, allowing the insoluble outer membrane to collapse and pass.<sup>10,11</sup> The detection of a retransmitted signal by the handheld scanner means that the RFID tag is still retained in the GI tract. This system is approved in Europe but not in the United States as of this writing.<sup>12</sup>

## Delivery devices

A variety of accessories can be used to deliver the capsule to the stomach or small intestine for those patients with dysphagia, gastroparesis, or known or suspected anatomical abnormalities. Overtubes can be used to deliver the capsule into the stomach,<sup>13</sup> and standard polypectomy snares<sup>14</sup> and nets<sup>15</sup> can be used to deliver the capsule into the duodenum. Whether patients with altered upper GI anatomy (eg, Billroth II anastomosis) benefit from use of a delivery device<sup>16,17</sup> is uncertain.

A unique capsule delivery system, the AdvanCE (US Endoscopy, Mentor, Ohio) was designed to endoscopically deliver the video capsule. The AdvanCE catheter is preloaded through the accessory channel of an endoscope and a specialized cup is screwed onto its leading end. The activated video capsule is loaded into the capsule cup, the endoscope and the device are then advanced to the desired anatomical area, and the capsule is released.

## INDICATIONS AND CONTRAINDICATIONS

The PillCam SB is FDA approved for visualization of the small bowel mucosa in adults and children aged  $\geq 10$  years.<sup>18-21</sup> There has been clinical experience of its use in children as young as 3 years, after endoscopic placement.<sup>22</sup> The most common applications include evaluation for:

- Obscure GI bleeding-including iron deficiency anemia<sup>23</sup>
- Suspected Crohn's Disease<sup>24-26</sup>
- Suspected small intestinal tumors and surveillance in patients with polyposis syndromes<sup>27-31</sup>
- Suspected or refractory malabsorptive syndromes (eg, celiac disease).<sup>32-35</sup>

The contraindications include:

- Patients with known or suspected GI obstruction, strictures, or fistulas based on the clinical picture or preprocedure testing
- Patients with cardiac pacemakers or other implanted electro-medical devices
- Patients with swallowing disorders
- Pregnancy.

The PillCam ESO is FDA approved for visualization of the esophagus. The most common applications include evaluation for suspected Barrett's esophagus, esophagitis, or esophageal varices.<sup>9,36</sup>

## SAFETY

The capsule should be used with caution in patients with known or suspected GI obstruction, fistulas, or suspected motility disorders.<sup>37</sup> A recent consensus statement has defined capsule retention as a capsule endoscope re-

maining in the digestive tract for a minimum of 2 weeks or one that has required directed therapy to aid its passage.<sup>38</sup> Capsule nonexcretion occurred in 7 of 937 patients (0.75%) and was associated with localized pathology in all patients.<sup>39</sup> Capsule retention has not been reported in "normal" subjects or those with anatomical variants such as colon or small-bowel diverticulosis and appendiceal orifices.<sup>12</sup> The risk of non-natural excretion varies with the indication for the examination. A retention rate of 1.5%<sup>12</sup> to 5%<sup>40</sup> has been reported in patients with obscure GI bleeding and suspected Crohn's disease. Retained capsules, usually clinically asymptomatic,<sup>40,41</sup> may require surgery or endoscopic removal.<sup>42,43</sup> To date there has not been a documented case in the literature of an acute small-bowel obstruction caused by a retained capsule.<sup>38</sup> Failure to pass the capsule naturally has also manifested as asymptomatic aspiration,<sup>44</sup> retention in a Zenker's diverticulum,<sup>45,46</sup> a fractured capsule,<sup>47</sup> and intestinal perforation.<sup>48</sup>

There has been concern about potential interference between transmitted capsule wavelengths and other implanted electronic devices, most notably cardiac pacemakers and defibrillators. Nevertheless, there are no reports of failure of cardiac devices as a consequence of capsule endoscopy, and several series have described performance of capsule endoscopy in such patients without interference.<sup>49,50</sup> In one study there was a loss of acquired images while the capsule was in close proximity to a patient's abdominal pacemaker pulse generator.<sup>51</sup> In another study a test device was used to simulate the capsule frequency without clinically significant interference to implanted cardiac pacemakers.<sup>52</sup>

Patients should not undergo magnetic resonance imaging after having completed a capsule endoscopy until they have passed the capsule. The capsule can be easily identified on plain radiographs, and this should be performed if there is any question.

Patients undergoing esophageal capsule studies should also be informed of the potential risks for electromagnetic interference and esophageal or small intestinal retention. Patients with dysphagia should not undergo such a test. If the risk of capsule retention is dependent on the indication for the exam, it is expected that the intestinal retention rate will be much lower for esophageal studies in light of such patients not having small-bowel disease. For example, among  $>400$  ingestions of Pillcam SB in healthy volunteers, there were no occurrences of capsule retention.<sup>53</sup>

There is limited information about the new patency capsule. While it is intended to assess the passage of a capsule in patients at risk for intestinal stenosis, there have been reported cases that have required hospital admissions, augmentation of medical therapy, and even surgery.<sup>54</sup> As a result, improvements to the system are being implemented before it can be approved in the United States.

## EFFICACY AND COMPARATIVE STUDIES

The alternative methods for evaluation of the small intestine are either radiographic or endoscopic. Radiographic methods are relatively insensitive for flat or subtle lesions such as vascular malformations and superficial erosions or ulcers.<sup>55</sup> In contrast, the global diagnostic yield of capsule endoscopy of the small bowel is about 65%.<sup>56</sup> Hence, in 2003 the FDA modified the previous labeling of the Pillcam SB by removing its designation as an adjunctive tool and approving its use as a first-line test.<sup>57</sup>

### Obscure GI bleeding

For obscure bleeding, capsule endoscopy has shown superior results compared to radiographic studies, which are relatively insensitive.<sup>58,59</sup> Evaluation of the capsule versus push enteroscopy has the benefit of using each patient to serve as his or her own control. A recent pooled analysis of 7 prospective studies showed a capsule yield of 71% for identification of a source of bleeding compared to 29% for push enteroscopy.<sup>60</sup> The detection rate of capsule endoscopy for this indication is dependant on the character of bleeding, which in one study<sup>61</sup> was 92% in the presence of ongoing overt bleeding, 44% in patients with heme-positive stool and anemia, and only 13% in patients with a prior overt bleeding.

In a recent evaluation of obscure GI bleeding after a negative initial work-up, 47 consecutive patients underwent both capsule and intraoperative enteroscopy.<sup>62</sup> Capsule endoscopy identified the source of bleeding in 74.5% of all patients, with the highest yield in those with ongoing bleeding. The overall yield with intraoperative enteroscopy was 72.3%. One patient died of postoperative peritonitis. Compared with intraoperative enteroscopy, the sensitivity, specificity, and positive and negative predictive value of capsule endoscopy was 95%, 75%, 95%, and 86%, respectively. Studies using clinical outcome as the criterion standard have estimated similar test performance characteristics.<sup>61,63,64</sup>

Double balloon enteroscopy is a relatively new method for evaluation of the majority of the small intestine. A recent study comparing double balloon enteroscopy with capsule endoscopy identified concordant findings in 12 of 13 bleeding patients. In 1 patient an ulcer was missed on a capsule study.<sup>65</sup>

### Crohn's disease

Capsule endoscopy is useful in the evaluation of the small intestine in patients in whom the diagnosis of Crohn's disease has been elusive.<sup>41,66</sup> 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.<sup>67</sup> Further studies have shown that this is an adjunctive diagnostic modality after conventional endoscopy and ileoscopy

and that it is superior to small-bowel follow through,<sup>68-70</sup> enteroclysis,<sup>18,71</sup> push enteroscopy,<sup>71</sup> and CT enteroclysis<sup>72</sup> for identifying small intestinal disease. A recent study in 39 patients, the majority of whom had known Crohn's disease, estimated the sensitivity and specificity of capsule endoscopy to be 89.6% and 100%, respectively.<sup>73</sup>

A significant shortcoming of this technology is the lack of validated capsule criteria for the diagnosis of Crohn's disease and the inability to obtain biopsy specimens for confirmation of the diagnosis.<sup>74</sup> Some gross findings, such as scattered mucosal breaks and aphthous ulcers or erosions, may not be sufficient to confirm a diagnosis of Crohn's disease because up to 13.8% of asymptomatic healthy volunteers not taking nonsteroidal anti-inflammatory agents (NSAIDs) can have mucosal breaks and other lesions seen on capsule endoscopy.<sup>53</sup> Use of NSAIDs has also been associated with small intestinal ulcers and strictures, which can be difficult to differentiate from Crohn's disease.<sup>59</sup>

### Small intestinal tumors

Several studies have suggested the benefits of performing capsule endoscopy in patients with known or suspected polyposis syndromes,<sup>75,76</sup> even after prior intestinal surgery.<sup>77</sup> Capsule endoscopy is able to detect more polypoid lesions than barium examinations such as a small-bowel follow through.<sup>78</sup> MRI and capsule endoscopy did not differ in identifying polyps that were larger than 15 mm.<sup>79</sup> However, smaller polyps were detected more often with the use of capsule endoscopy. In one study of 9 patients, direct endoscopic visualization with double balloon enteroscopy was superior to capsule endoscopy for identification of small-bowel polyps while providing the potential for therapeutic intervention.<sup>65</sup>

### Celiac disease

Capsule endoscopy provides another modality for identification of small intestinal villous atrophy and other endoscopic findings suggestive of celiac disease.<sup>80,81</sup> Capsule endoscopy has been proposed as an alternative confirmatory test for patients with positive serologies who do not wish to undergo standard endoscopy with mucosal biopsies. However, in one series, interobserver variability was poor between investigators with limited prestudy exposure to capsule endoscopy but concordant among experienced readers.<sup>33</sup> 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.<sup>32</sup>

### Esophageal disease

To date there are limited published data on capsule endoscopy of the esophagus. 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, respectively.<sup>9</sup> In a pilot study of 32 patients, 23 had esophageal varices at both EGD and PillCam ESO evaluation. The overall concordance between PillCam ESO and EGD was 96.9% for the diagnosis of esophageal varices and 90.6% for portal hypertensive gastropathy.<sup>82</sup> The preliminary data show an excellent diagnostic yield in cases of erosive esophagitis, Barrett's esophagus, and esophageal varices.<sup>83</sup>

## FINANCIAL CONSIDERATIONS

The list price for the Given RAPID Application Software and Workstation is \$17,500. The price for the reusable Given DataRecorder (DR2) set, including aerial harness and backpack with batteries and portable hard drive, is \$4995. The disposable PillCam SB and ESO are each sold for \$450 per capsule, in packs of 10.<sup>84</sup> The cost for the AdvanCE capsule delivery system is \$125.

### Imaging the small intestine

The Center for Medicare and Medicaid Services (CMS) approved indications for capsule endoscopy of the small intestine include obscure GI bleeding, initial diagnosis of suspected Crohn's disease, and other small bowel pathology (eg, tumor). All claim forms should contain the appropriate International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis code to report the patient's clinical condition. Since approved indications may vary among payers, providers should check their individual Medicare carrier or private payers Web site for details on coverage.

The approved CPT\* (Current Procedural Terminology) code 91110 describes the small bowel capsule endoscopy procedure.

CPT 91110 - Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with physician interpretation and report.

(Visualization of the colon is not reported separately)  
(Append modifier 52 if the ileum is not visualized)

CPT 91110 is designated without a global period (ie, 'XXX' code), implying that a same day cognitive service can be billed if it involves work that is separately identifiable from the capsule service. For example, a patient is

referred for a consultation regarding obscure gastrointestinal bleeding. After visiting with the patient and performing the consultation, the decision is made to proceed with capsule endoscopy on the same day. The physician would bill for both services, including the appropriate consultation level and 91110. If the capsule exam is performed at the hospital, the 26 modifier would be appended to 91110 because only the professional component is billed for. No modifier for 91110 is necessary if the capsule exam is done in the physician's office (this payment is higher to cover both the professional interpretation fee and the additional practice expense for personnel, equipment, and the disposable capsule).

### Imaging the esophagus

To date, there is no specific CPT code for capsule endoscopy of the esophagus. It is important to remain current on this issue as it will most likely change. As with capsule imaging of the small bowel, the applicable ICD-9-CM code should be included with submissions. Until a specific procedure code is established, the use of miscellaneous code 91299 is appropriate.

## SUMMARY

Wireless capsule endoscopy is a relatively new technology for assessment of the digestive tract. Small intestinal applications are the most extensively studied, and it has quickly become a first line test for visualizing the mucosa of the small intestine. Further research and experience are still necessary to better define its role. The esophageal capsule uses similar technology but clinical data on its use are limited.

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