

## Capsule endoscopy and deep enteroscopy

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### CAPSULE ENDOSCOPY

Video capsule endoscopy (VCE) was approved by the Food and Drug Administration as an adjunctive aid for the evaluation of small-intestine diseases in 2001 and as a first-line modality for the evaluation of small-bowel disorders in 2003. At the 2013 Digestive Disease Week, held in Orlando, Florida, the major focus of presentations on the topic of capsule endoscopy included the potential ability for magnetic-guided VCE to enhance visualization of gastric pathology and introduction of new capsule technology with greater field of view in an effort to reduce miss rates for small-bowel pathology. With the potential future introduction of a capsule endoscope that has a 360-degree view into the U.S. marketplace, more studies will be required to determine the impact of this enhanced mucosal visualization on detection rates and outcomes associated with obscure GI bleeding.

In order to further diagnose and treat findings detected by VCE, technology for performance of deep enteroscopy was initially introduced into the United States in 2004, with double-balloon enteroscopy (DBE), followed by single-balloon enteroscopy (SBE), and spiral enteroscopy in 2007. The abstracts this year focused on the impact that CO<sub>2</sub> administration has on the performance of deep enteroscopy and predictive factors for patients with both abnormal and normal enteroscopy examination results.

*Abbreviations: CO<sub>2</sub>, carbon dioxide; DBE, double-balloon enteroscopy; MGCE, magnetic-guided capsule endoscopy; PC, patency capsule; PEG, polyethylene glycol; SBE, single-balloon enteroscopy; VCE, video capsule endoscopy.*

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### Preparation for capsule endoscopy

Prior meta-analyses have demonstrated that administration of purgatives before VCE examination improves small bowel visualization quality and subsequent diagnostic yield.<sup>1</sup> A prospective, randomized trial examined optimal timing of bowel lavage before capsule endoscopy in order to determine whether administration closer to VCE administration might lead to improved diagnostic outcomes.<sup>2</sup> The authors randomized patients with obscure GI bleeding to 2 L of polyethylene glycol (PEG) 14 hours before the VCE study or 2 L of PEG administered 4 hours before the study. The primary outcome was diagnostic yield; secondary outcomes included preparation quality as assessed by a validated scale,<sup>3</sup> completion rates to the cecum, and small-bowel transit times. Seventeen patients were randomized into each group; 41% of the group randomized to the preparation 14 hours before the study were inpatients, compared with 82% who received PEG 4 hours before. The authors did not find any significant differences between diagnostic yields, transit times, fluid transparency, or mucosal visibility between the two groups. The authors concluded that timing of purgative administration within 24 hours of the VCE study did not have a significant impact on overall study quality or yield. Therefore, based on this prospective study, patients undergoing VCE should receive a purgative before the examination, but the timing of the laxative does not appear to have a major impact on diagnostic yield. The sample size calculation for this study was based on a 25% difference in the scores for preparation quality; the study may have been underpowered, given the smaller differences in the scores detected. The message for gastroenterologists performing VCE is that bowel preparation should be done before VCE, but the timing of the preparation is not as crucial as the timing of the examination in relationship to an acute bleeding episode.

### Capsule endoscopy interpretation and performance

In the past, attempts to accelerate capsule endoscopy interpretation with reading times greater than 15 frames per second or usage of the “red detector” software have demonstrated that many lesions can be missed if the physician reader relies on these methods. In a prospective study primarily performed at the Mayo Clinic,<sup>4</sup> the authors tested

a novel GI Sentinel software platform (Xyken LLC, McLean, VA, USA) in order to determine whether usage of the software could improve automatic detection of small-bowel ulcers. In order to perform the study, a series of video clips was used for analysis in lieu of actual patient videos. The training samples used in the study were chips (33 × 33 pixels) selected from images demonstrating regions with ulcers and normal areas of mucosa. Pilot testing of the software demonstrated an ulcer detection rate of 70% (319 frames out of 458 test image frames). When ulcer instance was included (defined as the ability of the software to detect an ulcer on any image sequence), the detection rate increased to 82% (28/34 instances). The false positive and negative rates were 16% and 18%, respectively. The next step will be to apply this software platform to actual patient videos to determine performance for ulcer detection in live cases and assess whether efficiency for detection of ulcerations is enhanced.

A major limitation of VCE to date has been visualization of gastric pathology. Because of the tumbling of the capsule endoscope through the stomach, images of the gastric cardia and proximal fundus are typically difficult to obtain. Pilot studies that use magnetic-guided capsule endoscopy (MGCE), where the movement of the capsule can be controlled and directed to different regions of the stomach, have demonstrated improved efficiency for visualization of gastric pathology and good correlation with findings from upper endoscopy.<sup>5</sup> In a multicenter study, patients with dyspepsia underwent both upper endoscopy and MGCE independently and in a blinded fashion.<sup>6</sup> Results from the unblinded upper endoscopic examination served as the criterion standard, and the major outcome was the detection of major gastric lesions on a per-patient basis. The authors included 189 patients and found 23 major lesions in 21 patients. The sensitivity of MGCE for major lesions was 62% (95% confidence interval [CI], 35%-77%) with a specificity of 94% (95% CI, 89%-97%). The sensitivity for MGCE did not correlate with lesion localization, gastric luminal visibility, examiner case volume, or time for the examination. Of the 168 patients with minor gastric lesions, MGCE had diagnostic accuracy in 88% (95% CI, 82%-93%), with a sensitivity of 89% and specificity of 70%. When patients were interviewed about preference, they preferred MGCE to standard endoscopic examinations using visual analog scale (score 1.7 vs 1.2;  $P < .001$ ), and 100% stated that they would request MGCE for a repeat examination. The authors concluded that, given the relatively poor sensitivity of this technology for major gastric lesions, more improvement of this technology would be required before it could be introduced into clinical practice.

### Capsule endoscopy miss rates

The current capsule endoscopes have a field of view of 160 degrees, capturing 2 frames per second in the small bowel. Prior studies have demonstrated miss rates for

small-bowel pathology, including neoplasms, of approximately 20% to 30%.<sup>7</sup> In a retrospective study from Japan,<sup>8</sup> authors assessed miss rates of VCE for small-bowel tumors comparing miss rates for single versus multiple lesions. The study reviewed 579 patients undergoing VCE between 2004 and 2012, of whom 101 were diagnosed with small-bowel tumors by DBE or surgical specimens. The small-bowel tumors included 34 malignant lymphomas, 25 Peutz-Jeghers polyps, 9 GI stromal tumors, 9 cases of familial adenomatous polyposis, 3 small-bowel carcinomas, 3 leiomyomas, 3 inflammatory polyps, 3 hemangiomas, 2 carcinoid tumors, 2 cases of ectopic pancreas, 2 adenomas, 2 lipomas, and 4 others. Multiple and single tumors were found in 68 and 33 patients, respectively. The overall miss rate of VCE was 10%. The miss rate for single neoplasms (8/33, 24.2%) was significantly higher than when patients had multiple tumors (2/68, 2.9%;  $P < .001$ ). Missed small-bowel neoplasms were likely to be solitary lesions located in the upper jejunum and lower ileum, where VCE may advance faster than in other sites. Based on this study and the prior literature, patients with suspected small-bowel tumors should be examined by a combination of diagnostic procedures, including magnetic resonance or CT enterography testing when the VCE studies are negative.

Because the current capsules are limited by 160-degree field of view, a new capsule recently has been developed, with a capacity for 360-degree viewing (Capsocam; CapsoVision Inc, Saratoga, Calif). In a pilot study, the Capsocam was able to detect the duodenal papilla in 70% of patients,<sup>9</sup> compared with <10% by using traditional capsule endoscopes.<sup>10</sup> In this prospective, multicenter study conducted in France, patients with obscure GI bleeding were administered both the Given PillCam SB2 and the CapsoVision capsule in random order, with administration occurring 1 hour apart.<sup>11</sup> Among the 60 patients with data for analysis, positive concordance among VCE findings was detected in 22 (37%), negative concordant results in 27 (45%), and discordant findings in 11 cases (18%). The overall concordance between the two systems was excellent (kappa value of 0.63). There were no overall differences between capsule systems for diagnostic yield (29/73 for both Capsovision and PillCam systems). However, the number of significant (P2) lesions was significantly increased for Capsocam (108 vs 85;  $P < .001$ ) secondary to increased detection of small-bowel angiodysplastic lesions (57 vs 33). In summary, the overall diagnostic rates for both systems were similar (37% for Capsocam vs 38% for PillCam), but there was superiority for Capsocam in the detection of small-bowel angioectasias. More studies are needed to assess the impact of 360-degree viewing on miss rates and overall diagnostic yields.

### Adverse events associated with VCE

Capsule retention remains a potentially significant issue, particularly in patients with inflammatory bowel disease, in which retention rates have been reported to exceed 10%.<sup>12</sup> The patency capsule (PC) can be as efficacious as magnetic

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