Capsule endoscopy of the colon

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of emerging endoscopic technologies that have the potential to impact the practice of GI endoscopy. Evidence-based methodology is used, by performing a MEDLINE and PubMed literature search to identify pertinent clinical studies on the topic. Because many topics have limited peer-reviewed articles, abstracts from scientific meetings are used to supplement the review. The reports focus on the current status of the technologies, areas in need of further research, and barriers to incorporation into the mainstream practice of GI endoscopy. Reports on Emerging Technologies are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the governing board of the ASGE. These reports are scientific reviews provided solely for educational and informational purposes. Reports on Emerging Technologies are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

EMERGING TECHNOLOGY

Although the use of capsule endoscopy in the small bowel has become widespread, with a variety of accepted clinical indications, the dedicated application of these devices in the colon has only recently been undertaken.[1-3] The use of capsule endoscopy in the colon has been proposed as an alternative colorectal cancer screening test and as a device to investigate patients for other forms of colorectal pathology.

The PillCam Colon capsule (Given Imaging, Yoqneam, Israel) is the only capsule endoscope currently in use for colonic investigation. The U.S. Food and Drug Administration recently rejected the initial 510K application, but the device is available in Israel and parts of Europe. The device has some technical differences from the small-bowel capsule from the same manufacturer. The capsule itself is 11 × 32 mm compared with the 11-mm × 26-mm small-bowel device. There are video-capture components on both ends of the capsule, similar to that seen in the company's esophageal device. The optics provide an angle of view that is 21% wider than that found in the company's esophageal device, which permits greater imaging coverage of the larger cross-sectional diameter of the large intestine relative to the esophagus or the small bowel. The capsule captures images at a rate of 4 frames per second versus 2 frames per second for the small-bowel capsule. After initial activation, the colon capsule captures images for 5 minutes to allow esophageal and gastric visualization, and then transitions into a sleep mode for 2 hours. It is during this period that the capsule is most likely to transit the majority of the small bowel and reach, approximately, the level of terminal ileum. Once reactivated, the capsule records images for approximately 10 hours, 2 hours longer than the small-bowel device. The capsule is made of similar materials to the company's other capsule endoscopes. Data are recorded via an antenna–lead array similar to that used in other capsule endoscopy procedures. Images are then transferred from a recording device to a workstation for formal review and report generation.

POTENTIAL APPLICATIONS

The use of capsule endoscopy in the colon has several potential advantages over traditional endoscopy, most notably the lack of a requirement for sedation. In individuals at high risk for conventional colonoscopy because of age, infirmity, or cardiovascular risk of sedation, capsule endoscopy could provide an alternative to conventional colonoscopy. Individuals who required anticoagulation therapy would likely not need to withhold these medications before the examination, as is advocated for conventional colonoscopy. Given the less-invasive nature of capsule endoscopy, the procedure may increase participation in colorectal cancer screening.

CLINICAL RESULTS

To date, there are only a limited number of published reports that used capsule endoscopy in the colon. In a prospective study of 84 patients, colon-capsule endoscopy

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was followed by conventional colonoscopy on the same day.[4] All patients underwent bowel preparation before the examination, with an additional regimen of a promotility agent, and stimulant and saline solution laxatives after capsule ingestion. Indications included colorectal cancer screening, postpolypectomy surveillance, and investigation of lower-intestinal signs and symptoms. Conventional colonoscopy findings were considered the criterion standard. Each colon capsule examination was viewed by 3 experienced capsule endoscopists, each of whom was blinded to the findings of the conventional colonoscopy. The capsule was not excreted from the patient in 26% of cases, although the findings from these capsule examinations were reviewed by the investigators. Of 84 patients, 20 (24%) had significant findings, which the investigators defined as 1 polyp at least 6 mm in size or 3 or more polyps of any size. Polyps of any size were identified by either colon capsule or conventional colonoscopy in 45 patients, with capsule endoscopy identifying polyps in 34 of 45 patients (76%) versus conventional colonoscopy identifying polyps in 36 of 45 patients (80%). On a first reading of the capsule with regard to the detection of any polyp thought to be significant (ie, any polyp larger than 6 mm), the sensitivity, specificity, and positive and negative predictive values were 50%, 83%, 40%, and 88%, respectively. All of these statistics were higher if a second reading of the capsule video was performed, a practice that is not commonly performed with small-bowel capsule endoscopy. Capsule endoscopy, of note, had a 33% false-positive rate. There were no adverse events from capsule endoscopy.

A second study reported on the use of PillCam Colon in patients who were suspected to have either colon polyps or colorectal cancer, followed by conventional colonoscopy.[5] Thirty-six patients underwent both procedures, with a 17% rate of failure to excrete the capsule in 10 hours. Capsule endoscopy identified 19 of the 25 patients (76%) found to have positive findings at conventional colonoscopy and was also able to identify 10 of 13 patients (77%) with a polyp larger than 6 mm or with more than 3 polyps. These investigators concluded that PillCam Colon had a sensitivity, specificity, positive predictive value, and negative predictive value of 77%, 70%, 59%, and 85%, respectively.

A few abstracts regarding this technology have been published. The results of a multicenter European trial of 320 patients undergoing colorectal cancer screening recently revealed a negative predictive value of more than 90% for polyps larger than 1 cm, a slight improvement from the above studies.[6] However, the sensitivity for polyps larger than 6 mm was only 64%. In a small proof-of-concept study of 25 patients who were undergoing screening with capsule colonoscopy, CT colonography, and conventional colonoscopy, 44% of these patients (n = 11) had findings that were thought to be significant; however, PillCam Colon and CT colonography were both inferior to standard colonoscopy in this study.[7]

AREAS FOR FUTURE RESEARCH

The aforementioned studies were relatively small in nature, and few conclusions can be drawn beyond basic proof-of-concept notions. Before capsule endoscopy of the colon can disseminate into practice, several key aspects need to be addressed:

- Large prospective studies to assess its efficacy and limitations in colorectal cancer screening, as well as the investigation of signs and symptoms suggestive of large-bowel pathology, are required.
- Given the larger size of the capsule, retention rates, complications, and patient tolerability relative to other colorectal cancer screening strategies need to be defined.
- The value of this device in patients with less than optimal bowel preparation needs to be addressed, particularly given the inability to further cleanse an inadequately prepared colon.
- Cost analyses of this technology compared with conventional colonoscopy are warranted, because positive findings will require a conventional colonoscopy for confirmation and therapy. In addition, the time required to read a capsule endoscopy is likely longer than that required to perform a traditional endoscopic examination.
- Further investigation of optimal bowel preparation and timing of colon imaging is needed.

SUMMARY

Colon capsule endoscopy is an emerging form of colon imaging that may be useful to improve compliance with colorectal cancer screening, but published experience with this device is extremely limited. Because the technology is currently only diagnostic, any positive findings require conventional colonoscopy for tissue sampling or polypectomy. There is currently no video capsule device cleared by the Food and Drug Administration for dedicated colon imaging. Significant research on this topic is required, and many fundamental questions for this technology remain unaddressed.

Abbreviation: ASGE, American Society for Gastrointestinal Endoscopy.

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