ADVANCES IN ENDOSCOPY

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The Second-Generation Capsule Endoscope for Colonoscopy

Rami Eliakim, MD
Department of Gastroenterology
Rambam Health Care Campus
Rappoport School of Medicine
Technion—Israel Institute of Technology
Haifa, Israel

G&H Can you describe the second-generation colon capsule that has been recently developed and explain how it differs from previous capsule designs?

RE This new colon capsule, which is a second-generation device, measures 11.6 mm–31.5 mm and has 2 cameras, 1 at each end of the colon capsule, for viewing colonic mucosa. The viewing angle of each camera has been increased from 156° in the first-generation colon capsule to 172° in the second-generation colon capsule. This wider viewing angle allows for nearly 360° coverage of colonic surfaces. In order to further enhance colon coverage, conserve battery energy, and optimize the capsule's video length, the second-generation colon capsule captures images at an adaptive frame rate, alternating between 35 images per second (when in motion) and 4 images per second (when completely or nearly stationary). This adaptive frame rate enables optimization of the visual coverage of the colon when the capsule is moving quickly in certain areas (eg, the transverse colon). In comparison, the first-generation colon capsule used a fixed rate of 4 images per second for capturing images. These are two very important new features.

In addition, the new data recorder includes enhancements that are aimed at assisting and guiding the medical staff as well as patients throughout the procedure. The recorder buzzes, vibrates, and displays instruction numbers on its liquid crystal diode display to alert the patient to ingest a laxative booster when it recognizes that the capsule has entered the small bowel. It also alerts the staff when the procedure is completed.

G&H How have the enhancements of the second-generation colon capsule increased the usefulness of capsule endoscopy in the colon?

RE As mentioned, the two most significant enhancements are the colon capsule's adaptive frame rate and the expanded viewing angle of the cameras at each end of the capsule. These enhancements appear to have produced a substantial improvement and increase in the polyp detection yield of the colon capsule, as compared to the first-generation colon capsule. Indeed, our study noted a sensitivity rate of 89% for the detection of polyps (≥6 mm in size) compared to colonoscopy. The specificity for polyps larger than or equal to 6 mm was 76%; sensitivity and specificity for polyps larger than or equal to 10 mm was 88% and 89%, respectively. These results are very encouraging. In the past, due to the unimpressive sensitivity rates of capsules in the colon, many investigators did not consider capsule endoscopy to be useful in the colon.

G&H Can you discuss the main findings of your study evaluating the new colon capsule?

RE The results of our study, which was published in a recent issue of *Endoscopy*, showed that the second-generation colon capsule endoscope is a safe and effective device for visualizing the colon and detecting colonic lesions. The colon capsule's sensitivity (versus colonoscopy) for the detection of polyps of at least 6 mm was 89% (95% confidence interval [CI], 70–97%) and 88% (95% CI, 56–98%) for polyps of at least 10 mm. The associated specificities were 76% (95% CI, 72–78%) and 89% (95% CI, 86–90%), respectively. Colonoscopy was considered the golden standard.

Although the specificity of the colon capsule was calculated based upon strict statistical rules, the clinical relevance of these data is unclear, as polyps missed by colonoscopy or minimal mismatch in polyp size were recorded as false-positive findings. Some of these patients agreed to undergo a second colonoscopy in which these

polyps were found, but we strictly adhered to the initial conditions and, thus, did not adjust the statistics.

Of the 104 patients enrolled, 98 patients were eligible for evaluation. Their mean age was 50 years, 34% were women and 66% were men. Standard colonoscopy was done on the same day, upon capsule excretion or by 5 PM, whichever came first.

G&H What are the advantages and disadvantages of the second-generation colon capsule compared to standard methods such as colonoscopy and computed tomography colonography?

RE In terms of advantages, the new colon capsule is a safe, minimally invasive device for visualization of the colonic mucosa, without the need for sedation, intubation, or air insufflation. In addition, the colon capsule has potential for home use, which would allow patients to undergo the procedure during the weekend and, thus, avoid the need to miss work.

In comparison to computed tomography (CT) colonography, the advantages of capsule colonoscopy are its lack of irradiation and its ability to be administered by gastroenterologists, rather than radiologists. In the future, it may be possible for the patient to undergo the capsule procedure, receive test interpretation, and, if a polyp is detected, undergo standard colonoscopy and polypectomy using the same preparation on the same day.

The main disadvantage of the colon capsule is that it can be used only for imaging; as with computed tomography colonography, the capsule does not have the ability to obtain biopsies or excise polyps. When the colon capsule detects lesions, patients are then referred to colonoscopy for treatment. Another disadvantage, though a minor one, is that on the day of the procedure, patients have to take 1 or 2 Na phostate boosts to enhance capsule passage in the small bowel. These boosts are not needed in CT colonography. The colon capsule procedure is relatively easy with only a minority (<1%) having a problem to swallow it.

G&H How is capsule colonoscopy expected to compare in cost with standard colonoscopy?

RE This aspect is not yet clear. However, I would expect that capsule colonoscopy should compete with the costs of standard colonoscopy.

G&H Are third-party payers such as government health systems and insurers in the United States showing interest in capsule colonoscopy?

RE The second-generation colon capsule endoscope has been approved for use in the European community and in some other countries such as Israel, when the results of our study were reported. However, the colon capsule has not yet been approved by the US Food and Drug Administration (FDA). If our study is replicated by the ongoing multicenter studies in Europe and the United States, I think that the colon capsule will be FDA-approved within a year or two, and that health providers will find interest in it.

G&H What are the contraindications to capsule colonoscopy?

RE Contraindications to colon capsule endoscopy include the standard contraindications for small-bowel capsule endoscopy such as dysphagia, history of bowel obstruction, life-threatening conditions, an implanted pacemaker, pregnancy, or chronic use of nonsteroidal anti-inflammatory drugs (at least in our study). Other contraindications include those specific to bowel preparations (such as contraindications for using small boosts of sodium phosphate or for the prokinetic agent used in the procedure). No capsule retention was observed in our study or in healthy volunteers.

G&H What are the next steps for future research for capsule endoscopy in the colon?

RE The next steps involve the improvement and simplification of the associated cleansing process, as the increased sensitivity and specificity of the colon capsule in our study was attributed to the enhancements made in the capsule itself and not in the cleansing process. The methods of polyp detection should also be improved, perhaps via the use of specific markers. In addition, one of the long-term research goals is the modification of the second-generation colon capsule for use in panendoscopy (ie, endoscopy from the mouth to anus).

Suggested Reading

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