New Advances Reported in Capsule Endoscopy

BY DAVID MONAGAN

LONDON — Capsule endoscopy received positive reviews in several presentations at the 13th World Congress of Gastroenterology, with speakers championing new applications and technological improvements.

In one of several "state of the art" presentations, Dr. Martin Keuchel of the Asklepios Clinic in Hamburg, Germany, asserted that the minimally invasive technology should already be viewed as a successful first-line screening approach for detection of suspected Crohn's disease associated with obscure gastrointestinal bleeding.

"We have been able to identify nearly 80% of small bowel tumors by capsule endoscopy alone, including those undetectable by other methods. It can be useful for screening for early-stage Crohn's disease, both by stratifying larger tumors needing surgical removal and identifying clusters of smaller polyps and adenomas needing ongoing surveillance," Dr. Keuchel commented.

Multicenter German trials have shown that the technology detected an overall 2.4% incidence of primary tumors of the small bowel, Dr. Keuchel said. But he acknowledged that one of the main concerns in this setting was the risk of retention, potentially requiring surgical retrieval.

Interestingly, the gastroenterologist observed that this risk was low in early-stage patients who were only suspected of having Crohn's disease. In this situation, when screening was prompted by obscure GI bleeding, the retention rate in the German analysis was only 1.5%, or 10 out of 664 patients.

However, the rate of capsule retention rose to 13% among patients who already had established Crohn's disease.

In an attempt to stave off capsule retention problems, Dr. Keuchel and colleagues tried first using dummy patency capsules in 106 patients with a known stenosis.

These patency capsules have a permeable membrane that allows them to dissolve within 48 hours.

About 50% of the patients were able to quickly excrete the patency capsule, providing evidence that the actual diagnostic capsule was likely to pass as well. But 11 patients reported significant pain from initial retention of the patency capsule; this pain was generally resolved by the capsule's dissolution within 48 hours. One surgical extraction was required, however.

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"Small bowel capsule endoscopy has become an accepted first-line diagnostic tool for obscure GI bleeding," Dr. Keuchel said in summarizing the findings. "It may be the best test for suspected small bowel Crohn's disease, whereas in established Crohn's disease there is a significant risk of retention to be considered, although prior testing with patency capsules appears to reduce this risk significantly."

"The capsule has clearly revolutionized small bowel imaging, but imaging the colon can be a lot more difficult," Dr. André Van Gossum of Erasmus Hospital in Brussels said while discussing the next-generation twist for the technology—a so-called "wake-up" capsule that shuts off 3 minutes after ingestion to preserve its battery power for reactivation during its eventual slow pass through the colon.

The capsule is timed to reactivate image broadcasting after 1 hour 45 minutes, when it is predicted to enter the terminal ileum. It can then transmit images during its entire pass through the colon.

Dr. Van Gossum reported on twin pilot studies and a new multicenter trial that appear to show increasing efficacy for the new technology.

He acknowledged that an initial Israeli pilot study of capsule endoscopy in 91 patients, which was first reported in the journal Endoscopy in 2006, had achieved mixed results, with an overall sensitivity of 50%. He ascribed those disappointing results to inadequate preprocedure bowel cleansing.

A second pilot study of 48 patients conducted in Belgium raised sensitivity to 75% by employing a laxative boost to achieve enhanced bowel cleansing and better resultant imaging, the utility of which was further improved by the use of expert readers to interpret the results.

Dr. Van Gossum also noted that his eight-center European trial of 320 patients, first reported in October, had further supported the broad utility of the "wake-up" colon capsule (N. Engl. J. Med. 2009;361:264-70).

The double-headed wake-up camera became activated just as it reached the ileum in 97% of these patients.

And in 93% of the procedures, the capsule was rapidly excreted without retention problems.

The investigator did note that 8% of the patients experienced a variety of adverse events, including nausea, vomiting, and headaches during their preparation.

"In our study, the technology was shown to have a negative predictive value of over 80%, and detected several lesions not seen on colonoscopy. The endoscopy capsule may be considered a complementary tool to colonoscopy or an alternative for patients who resist further probes with colonoscopy—which may occur in 70%. The capsule may soon offer a view of the entire esophageal tract," Dr. Van Gossum said. ■

Disclosures: *Dr. Keuchel disclosed that he has received research support from Given Imaging and will receive research support from IntroMedic. He has received speakers fees for other presentations and educational capsule endoscopy courses from Given and Olympus, as well as travel support for other conferences.*

Wireless Capsule Colonoscopy Not Ready for Prime Time

BY DAVID MONAGAN

LONDON — In a French study of 545 patients, wireless capsule colonoscopy achieved an overall sensitivity of only 39% and a positive predictive value of just 46%, Dr. Jean Paul Galmiche reported at the 13th World Congress of Gastroenterology.

The 16-center study was designed to discover the reliability of the colon capsule (Pillcam, Given Imaging Ltd.)—which travels through the GI tract equipped with a tiny camera—for finding colon polyps of at least 6 mm. Two cohorts were studied: asymptomatic patients aged 50-74 years needing routine screening (30% of subjects), and patients at increased risk for colorectal cancer because of a personal or family history of colon polyps or cancer (70% of subjects). The patients' mean age was 60 years.

The colon capsule results were compared with results from conventional colonoscopy performed the following day by colonoscopists who were blinded to the capsule findings. Images obtained during the two procedures underwent subsequent examination by an outside panel of experts.

The interim analysis by Dr. Galmiche's group at the University Hospital Nantes, France, showed that the wireless capsule colonoscopy (WCC) results achieved an overall sensitivity of 39% and a positive predictive value of 46% in terms of the total number of polyps correctly identified.

This was no match for conventional colonoscopy, which had a positive predictive value of 57% and a sensitivity of about 85% for all polyps regardless of size.

'At this stage of the development of the technology, WCC cannot replace colonoscopy for screening and surveillance of patients at risk for colon cancer.'

"At this stage of the development of the technology, WCC cannot replace colonoscopy for screening and surveillance of patients at risk for colon cancer," Dr. Galmiche said in an interview.

"Future research should focus on better preparation and improved technology, that is to say, a new capsule generation," he added.

The primary problem is that, despite rigorous attempts at preprocedure cleansing, colonic debris frequently obscured the wireless capsule's capacity to transmit reliable images. Only 52% of the 377 WCC patients were judged to have sufficiently "good to excellent" colon cleansing to allow full visualization from the technology.

In contrast, more than 85% of the 183 colonoscopy patients in the study achieved the same "good to excellent" bowel prep results.

The study began with patients on a 3-day low-residue diet, with 3 L of polyethylene glycol solution taken the night before the procedure, and another liter taken the following morning. Domperidone and a laxative booster were used to ensure prompt expulsion of the video capsule—which occurred within 10 hours in 93% of the patients.

About one-quarter of the way through the study, the 3-day low-residue diet was replaced with an all-liquid diet for the remaining patients, to improve visualization.

"Somewhat better results have been achieved with this newer approach to preparation," Dr. Galmiche said.

In addition to the drawback of the high cost of WCC, the noninvasive procedure was associated with 20 adverse events, chiefly excessive abdominal pain and vomiting. However, these effects were all considered related to the bowel prep used before swallowing the video capsule, rather than mishaps with the capsule itself.

Dr. Galmiche noted that the WCC procedure had a negative predictive value of 88% for identifying polyps larger than 10 mm.

But he concluded by saying its sensitivity was "not optimal" and that a new iteration of the technology would need to have dramatic improvements before it could contend with colonoscopy as a gold standard screening tool for colorectal cancer.

The Nantes group's presentation was formally cited as one of the two Best Abstracts at the meeting. ■

Disclosures: *Dr. Galmiche disclosed that he is on the advisory board of Given Imaging but has no financial links. The study was sponsored by a National Research Grant.*