New Video Capsule Screens for Esophageal Lesions

Pillcam ESO is designed to detect premalignant changes, but does not replace traditional endoscopy.

BY JEFF EVANS
Senior Writer

ORLANDO, FLA. — A novel video capsule device for imaging the esophagus appears to detect esophagitis and Barrett's esophagus just as well as traditional endoscopy in patients with chronic symptoms of gastroesophageal reflux disease, according to the results of a prospective, multicenter study.

The U.S. Food and Drug Administration approved Pillcam ESO for the detection of esophageal pathologies in late October.

The new device is similar to the M2A capsule (now called Pillcam SB) but has cameras on each end of the pill to capture a total of four frames per second. Both of the devices are manufactured by Given Imaging Ltd.

Pillcam ESO, which is meant to be an easy screening procedure for potential premalignant lesions, "is not meant to replace a traditional endoscope," Rami Eliakim, M.D., said at the annual meeting of the American College of Gastroenterology.

Use of the device for widespread screening may lead to an increase in the number of patients undergoing traditional endoscopy, he added, noting that many gastroenterologists regularly perform endoscopic screening of patients with Barrett's esophagus who have chronic GERD symptoms.

Up to 10% of white male patients with chronic GERD may have Barrett's esophagus. Studies suggest that patients with Barrett's esophagus develop esophageal adenocarcinoma at a rate of 0.5% per year.

Recent studies have shown that screening 50-year-old men with chronic GERD symptoms for esophageal adenocarcinoma "is probably cost-effective," said Dr. Eliakim of Rambam Medical Center, Haifa, Israel.

Following a 6-hour fast, 109 patients with a mean age of 51 years ingested Pillcam ESO in the supine position, then underwent traditional endoscopy 30 minutes later with 2.5-5 mg of IV midazolam (Versed). One patient could not swallow Pillcam, and images could not be viewed in two other patients. Individuals with dysphagia, Zenker's diverticulum, suspected intestinal obstruction, major abdominal surgery within the last 6 months, or cardiac pacemakers did not participate—nor did pregnant or breast-feeding women.

Of the 106 remaining patients, 61 had positive and 38 had negative findings on both traditional and capsule endoscopy. In five patients, traditional endoscopy made a positive finding when capsule endoscopy did not. Two patients had positive findings with capsule endoscopy when traditional endoscopy found nothing.

Barrett's esophagus was not confirmed histologically in all of the patients who showed signs of the condition during capsule endoscopy.

Based on those results, Pillcam ESO had 92% sensitivity, 95% specificity, 97% positive predictive value, and 88% negative predictive value for detecting either Barrett's esophagus or esophagitis.

Capsule endoscopy with Pillcam ESO detected Barrett's esophagus with 97% sensitivity and 99% specificity. Pillcam ESO reached 89% sensitivity and 99% specificity in patients with esophagitis.

Patients may prefer using capsule endoscopy instead of the traditional procedure, which involves recovering from sedation, Dr. Eliakim said.


GIVEN IMAGING LTD.

This image captured by Pillcam ESO shows Barrett's esophagus.

Patients in the study gave Pillcam ESO a significantly better rating than traditional endoscopy in response to questions regarding ease of swallowing, comfort with the procedure, and overall convenience.

Dr. Eliakim said the cost of capsule endoscopy of the esophagus with Pillcam ESO is not yet known. ■

Capsule Endoscopy Used to Diagnose Ca, Crohn's

BY JEFF EVANS
Senior Writer

ORLANDO, FLA. — Indications for capsule endoscopy may expand in the future as researchers investigate new ways to use the technique in the small bowel to detect disease, evaluate its extent, or locate its cause, David R. Cave, M.D., said at the annual meeting of the American College of Gastroenterology.

Capsule endoscopy with the Pillcam SB (formerly called the M2A video capsule) is indicated for obscure GI bleeding, suspected small bowel tumors, and suspected Crohn's disease, although many insurers do not cover the last two indications, said Dr. Cave, professor of medicine at Tufts University, Boston.

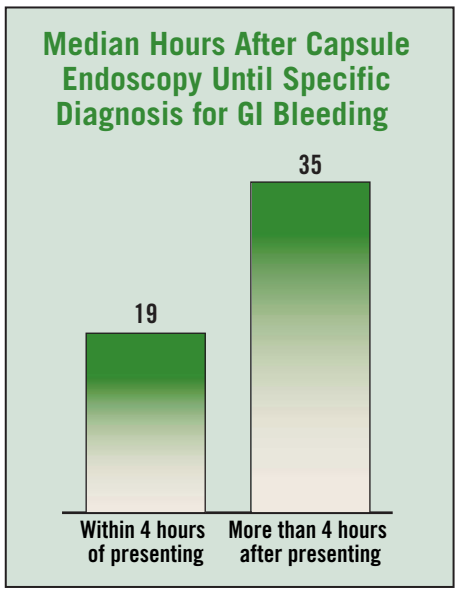
He discussed some of the current areas of research on capsule endoscopy:

► **GI bleeding without hematemesis.** This condition can be difficult to evaluate if the hospital does not have a 24-hour bleeding team in the emergency department that can provide support in the detection of GI bleeding. Dr. Cave and his colleagues thought they might be able to save time with capsule endoscopy and still diagnose GI bleeding without hematemesis accurately. At St. Elizabeth's Medical Center in Brighton, Mass., they used capsule endoscopy to investigate the source of bleeding in 24 patients.

In the randomized feasibility study, 16 patients underwent capsule endoscopy within 4 hours of arriving at the emergency department, with further endoscopic procedures if needed. After capsule endoscopy finished, the investigators immediately interpreted the data and provided the information to the attending physician on the GI team without making any recommendations. Another eight patients first received a conventional workup with esophagogastroduodenoscopy (EGD) and colonoscopy before they underwent capsule endoscopy more than 4 hours after presenting to the emergency department.

The patients who received capsule endoscopy early had a specific diagnosis in a median of 19 hours, compared with 35 hours in the patients who had capsule endoscopy later. Capsule endoscopy located active bleeding in 13 of 24 patients, while EGD detected active bleeding in 2 of 17 patients and colonoscopy found it in 0 of 13 patients.

► **Suspected Crohn's disease.** Capsule endoscopy can be used to verify the presence of Crohn's disease and other inflammatory bowel diseases in the small bowel, and it may turn out to be even more valuable: A Crohn's disease activity index based on capsule endoscopy is being developed.



The technique also may be used to assess the extent of disease, especially in preparing for surgery or assessing the degree of healing before and after treatment with some of the new biologic medications, Dr. Cave said.

► **Celiac disease.** Clinicians can take duodenal biopsies and perform serologic tests to diagnose celiac disease, but they haven't really been able to measure the extent of disease. Capsule endoscopy should help to visualize neoplasias, such as lymphomas or adenomas, and ulceration that can occur in patients with celiac disease. The technique also should be able to detect coexistent inflammatory bowel disease.

► **Abdominal pain.** Capsule endoscopy may be useful in patients who present to the emergency department with abdominal pain for which it is difficult to distinguish between an organic disease and a pain syndrome. Only about 15% of people with abdominal pain turn out to have structural abnormalities. The goal is to avoid repeat endoscopies and CT scans in patients without lesions; instead, these patients can be treated for a pain syndrome. But there is currently very little research on this issue, Dr. Cave said, "maybe because insurance carriers are not paying for this indication."

► **Chronic diarrhea.** Gastroenterologists may sometimes give "short shrift" to patients with substantial diarrhea by diagnosing them with diarrhea-predominant irritable bowel syndrome, Dr. Cave suggested. Full-thickness biopsies taken during laparoscopy in these patients have shown lymphocytic infiltration of the myenteric plexus. Capsule endoscopy could help to determine if there is a counterpart to this infiltration in the small bowel mucosa. No systematic study has examined mucosal changes in these patients, he noted.

Capsule endoscopy also may be able to help researchers understand the nature of the Brainerd diarrhea syndrome, which is "often labeled as [irritable bowel syndrome], but it might not be," he said. Brainerd diarrhea syndrome is an acute condition that can occur sporadically or in outbreaks and may last for months to years. It "probably has an infectious etiology," Dr. Cave said.

► **Small bowel obstruction.** Gastroenterologists initially had great concern that a retained capsule in patients with small bowel obstruction would cause trouble, "but some of us have started to look at capsule retention now in a more positive light and are actually using it as a means of detecting patients who have small bowel obstruction with no definable source," he said. It's important to get consent from patients and explain to them that in this procedure, you are actually expecting the capsule to be retained, Dr. Cave advised. The gastroenterologist must work with a surgeon to arrange laparoscopic surgery and, possibly, intraoperative enteroscopy.

► **Surveillance of polyposis syndromes.** Work is just starting in this area, for the detection of conditions such as familial adenomatous polyposis and Peutz-Jeghers syndrome. Little is known about how often these patients should undergo surveillance with capsule endoscopy and what should be done about the results. ■