New Capsule Detects Esophagitis, Barrett's

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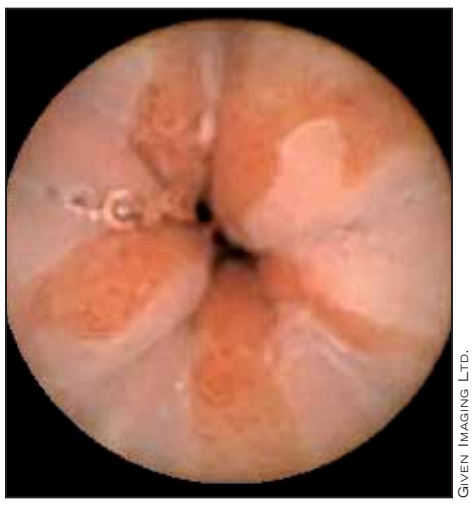
ORLANDO, FLA. — A new video capsule for imaging the esophagus appears to detect esophagitis and Barrett's esophagus just as well as traditional endoscopy in patients with chronic symptoms of gastroesophageal reflux disease, according to the results of a prospective, multicenter study.

The Food and Drug Administration approved Pillcam ESO for the detection of esophageal pathologies last 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 devices are manufactured by Given Imaging.



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Pillcam ESO had 92% sensitivity and 95% specificity for Barrett's esophagus.

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., explained 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 said, adding that many gastroenterologists regularly do 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. 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 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 detected Barrett's esophagus with 97% sensitivity and 99% specificity. The sensitivity of Pillcam ESO reached 89% sensitivity and 99% specificity in patients with esophagitis, Dr Eliakim said. ■

Patency Capsule Screens for Strictures in Small Bowel

ORLANDO, FLA. — A new diagnostic capsule can verify the presence of small bowel strictures seen on radiology and determine when it is safe to use video capsule endoscopy, Cristiano Spada, M.D., reported at the annual meeting of the American College of Gastroenterology.

Small bowel radiology is not always reliable in determining the presence of a stricture and the functional patency of the small bowel, so it is necessary to identify the presence of any stricture before using the Pillcam SB (formerly called the M2A video capsule) to perform capsule endoscopy. Both devices are manufactured by Given Imaging.

The Patency Capsule could be used to confirm the functional patency of the small bowel and show that it is safe to use the Pillcam.

The investigational Patency Capsule contains a radiofrequency tag surrounded by a dissolvable lactose and parylene polymer coating.

A small window exposes the inside of the capsule to GI fluids to help digest the coating. A timing plug built into the capsule keeps the capsule intact for about 40-100 hours, after which it can pass through the small bowel if it encounters a stricture. At 8 and 24 hours after patients ingested the Patency Capsule, Dr. Spada and his colleagues identified the location of the capsule by using fluoroscopy and a device called the Patency scanner to locate the radiofrequency signal emitted by the capsule.

Overall, 46 of the 91 patients with radiologically confirmed or suspected small bowel stricture who ingested the Patency Capsule excreted the capsule intact. The other 45 patients excreted a partially intact or nonintact (dissolved) capsule. Most of the patients in the study had Crohn's disease, said Dr. Spada of Catholic University, Rome.

Overall, 22 patients reported abdominal pain after ingesting the Patency Capsule. The pain resolved within 24 hours in 17 patients, and 3 went to the hospital with severe pain that passed once the capsule was excreted.

Two patients underwent surgery for pain: One patient's stricture was so large that the intestinal lumen became completely occluded with the capsule while another underwent surgery for an unrelated problem. The Patency scanner failed to detect the capsule in two patients.

The transit time of the Patency Capsule was correlated with dissolving of the capsule. But the researchers could not find a correlation between the anatomical features of the stricture and the capsule's transit time. "In fact, in some patients with a tight stricture, the capsule was excreted intact after 2 hours," Dr. Spada said.

These data suggested that the Patency Capsule could be used to confirm the functional patency of the small bowel and show that it is safe to use the Pillcam, he said.

In 67 patients with a small bowel stricture who excreted the capsule in 72 hours, 29 had a functionally patent small bowel and received the Pillcam video capsule.

The other 38 were not eligible to use the Pillcam. All 29 patients with small bowel strictures who used the Pillcam passed the capsule uneventfully in the same mean transit time that they had passed the Patency Capsule.

Capsule Endoscopy May Be Safe With Pacemaker, Defibrillator

ORLANDO, FLA. — New data suggest that product labeling stating that capsule endoscopy is contraindicated in patients with implantable pacemakers or defibrillators may be unnecessary, Manish S. Patel, M.D., reported at the annual meeting of the American College of Gastroenterology.

The scant data that are available do not support the contraindication. In several case series, no complications or loss of images have been reported in 18 patients with either implantable pacemakers or implantable cardioverter defibrillators (ICDs) who underwent capsule endoscopy, noted Dr. Patel, of Eastern Virginia Medical School, Norfolk.

The basis for the contraindication stems from concern that the 100- to 472-kHz radiofrequency band used by the PillCam SB capsule (formerly called the M2A capsule) might interfere with the operation of pacemakers and ICDs, which use the 100- to 175-kHz band.

Electromagnetic interference from the environment has the potential to inhibit pacing, trigger inappropriate pacing, cause a spurious ICD discharge, cause physical damage to the device's circuitry, and reset the device to a different mode, possibly causing asynchrony and hemodynamic instability.

'This study shows that there is no interaction between capsule endoscopy and pacemakers and defibrillators.'

The number of people in the United States who have implantable pacemakers is expected to rise from about 2.4 million in 2004 to 3.2 million in 2008. Similarly, the number of individuals with implantable cardioverter defibrillators (ICDs) may rise from 460,000 in 2004 to 1 million in 2008.

Dr. Patel and his colleagues tested two pacemakers (AT501 and KDR901) and one ICD (7274 Marquis DR) manufactured by Medtronic Inc. and one pacemaker (1296 Insignia) and one ICD (A155 Vitality AVT) made by Guidant Corp. Together, the five devices represent 80% of the U.S. and world market for implantable pacemakers and ICDs, Dr. Patel said.

The investigators placed each device in an electrode gel bath at distances of 2, 6, 12, and 18 cm away from a PillCam SB capsule in a random sequence in three 30-second trials at each distance. In a separate set of similar trials, the pacemakers and defibrillators were attached to standard unipolar and bipolar pacing and defibrillation leads. During each set of trials, Dr. Patel and his associates varied the output of each device from a "nominal" to its most sensitive setting at each distance.

An electrophysiologist who was blinded to all of the test parameters did not detect any abnormalities in atrial or ventricular electrograms recorded from a Virtual Interactive Patient (model 9595, Medtronic) during any trial.

"This study shows that there is no interaction between capsule endoscopy and pacemakers and defibrillators, which is consistent with clinical observational reports," Dr. Patel said. ■