Pacemaker, Defibrillator Warning Unnecessary?

BY JEFF EVANS
Senior Writer

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, a resident in gastroenterology at the 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.

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 programmable 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. "We suggest that exclusionary criteria on pacemakers and defibrillators as listed on the formal product label of the M2A capsule endoscopy should be reevaluated and revised to reflect this new information." ■

Patency Capsule Ascertains Safety of Deploying Video Capsule

BY JEFF EVANS
Senior Writer

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.

A timing plug built into the capsule keeps the capsule intact for 40-100 hours, after which it can pass through the small bowel if it encounters a stricture.

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 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. ■

Intrastricture Steroids Improve Esophageal Stricture Outcomes

BY SHARON WORCESTER
Tallahassee Bureau

ORLANDO, FLA. — Intrastricture steroid injections should be used routinely as part of the treatment for complex esophageal strictures caused by acid-peptic disease that are smaller than 13 mm, Tarun Mullick, M.D., said at the annual meeting of the American College of Gastroenterology.

In a randomized, placebo-controlled study of 120 patients, intrastricture Kenalog injections significantly reduced the number of dilations needed to achieve a successful outcome by an average of about three, when compared with sham injections (4 vs. 7 dilations). This reduced the number of days lost from work by patients in the steroid group, and also improved quality of life as measured in terms of dysphagia, the ability to take pills, and effects on diet, said Dr. Mullick of Delnor-Community Hospital, Geneva, Ill.

The findings represent a major advancement in the treatment of complex esophageal strictures caused by acid-peptic disease, but steroid injections should be reserved only for those strictures smaller than 13 mm in size, he said.

In this study, 40 of 60 patients in the steroid group and 45 of 60 in the sham injection group had strictures smaller than 13 mm, and the therapeutic benefit of the steroid injections was entirely limited to these strictures.

Significantly fewer patients in the steroid group than in the sham injection group failed to achieve a successful outcome (0/60 vs. 9/60), which was defined as dilation of at least 18 mm. Failure to progress to the next size dilator occurred 2 times in the steroid group, compared with 132 times in the sham injection group; this difference was also statistically significant.

The steroid and sham injection groups were similar in terms of demographics, and all patients in both groups were treated with a proton pump inhibitor and underwent gradual dilation of the stricture using fluoroscopically-assisted balloon dilation over a guidewire every 4-6 weeks. ■

Small-Bowel Injury Is Common In Chronic NSAID Users

A study of 41 people aged 22-66 years found evidence of small-bowel injury on capsule endoscopy in 71% of those taking a nonsteroidal anti-inflammatory drug for at least 3 months.

By comparison, 10% of control patients not taking NSAIDs had such injuries—a highly significant difference. While it's known that NSAIDs are associated with small-intestine injuries and may be the cause of unexplained hypoalbuminemia or anemia, the extent of the small-intestine damage had previously not been well characterized, according to the lead investigator, David Y. Graham, M.D., chief of gastroenterology and professor of medicine at Baylor College of Medicine in Houston.

The study does not have clinical implications for managing patients currently, but will serve as a basis of future studies, he said in an interview. The next step is to investigate how these findings correlate with anemia or protein loss and whether NSAIDs vary in their ability to induce these effects, he added.

Patients in the study had various arthritides, but were generally healthy and did not have anemia or hypoalbuminemia. Of the 21 patients on NSAIDs, 5 had major damage defined as having more than four erosions or large ulcers. None of the 20 control patients had major damage (Clin. Gastroenterol. Hepatol. 2005;3:55-9).

The ulcers were more common than anticipated, said Dr. Graham, noting that previous estimates of small-intestine damage associated with NSAIDs have come from autopsy studies, which found a rate of 5%-8%.

—Elizabeth Mechcatie