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 video capsule) could 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 pacemaker triggers or inappropriate pacing, cause a spurious ICD discharge, cause physical damage to the device’s circuity, 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 or ICDs 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 (AT701 and KDR001) and one ICD (7274 Marquis DR) with an electrophysiologist who was blinded to all of the test parameters did not detect any abnormalities in atrial or ventricular electrogams recorded from a Virtual Interactive Patient (model 9396, Medtronic) during any trial.

“This study shows that there is no interaction between capsule endoscopy and pacemakers and defibrillators, which is consistent with clinical observations,” 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.”

Intrastructure Steroids Improve Esophageal Stricture Outcomes

BY SHARON WORCESTER
Talkhaussen Bureau

ORLANDO, Fla. — Intrastructure 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, intrastructure 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 De Norh 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 152 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.

Patency Capsule Ascerns 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.

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.

Overall, 84% of the 41 patients with radiologically confirmed or suspected small bowel strictures who ingested the Patency Capsule had strictures smaller than 13 mm in size, he said.

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 presence of any stricture is determined by the capsule scanner as it locates the radiofrequency signal emitted by the capsule.

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 intact the correct transit time that they had passed the Patency Capsule.

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

Elizabeth Mechcatie