Cardiac Device Wearers: Beware of Technology

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SNOWMASS, COLO. — The everyday 21st century electronic communications environment poses unprecedented electromagnetic interference hazards for patients with pacemakers or implantable cardioverter-defibrillators, Dr. William H. Spencer III cautioned at a conference sponsored by the Society for Cardiovascular Angiography and Interventions.

"What are you going to tell your patients in 2006 regarding smart phones and other wireless communication devices such as PDAs, wireless computers, and iPods? Can they use them, and how should they use them?" asked Dr. Spencer, professor of medicine at the Medical University of South Carolina, Charleston.

Pacemakers can respond to electromagnetic interference (EMI) in a plethora of unwelcome ways: complete inhibition of pacing, asynchronous pacing, rapid pacing, mode reset to a very safe pacing mode, or physical damage to the generator and/or pacing leads. Implantable cardioverter-defibrillators (ICDs) may deliver an inappropriate shock or antitachycardia therapy or, worse, be inhibited from delivering therapy when needed. Device memory corruption can occur, making it impossible for physicians to reconstruct what happened when EMI was encountered.

The important thing to know about EMI due to wireless communication devices is the 10-cm rule. All implanted cardiac devices now incorporate internal filters that are highly effective in rejecting all but the strongest electromagnetic signals—those originating within about 10 cm of the device or leads. For this reason patients shouldn't carry their cell phone in a shirt or breast pocket. Patients are also supposed to hold the phone to the ear farthest from the device, which is typically the right ear.

Walk-through metal detectors used in airport screening are safe provided the patient moves briskly through. Heart devices contain very little ferromagnetic material and shouldn't trip the alarm. But if the alarm does go off, under no circumstances should the patient submit to a search using a hand-held wand over the chest; far better to be thoroughly searched by hand.

Electronic article surveillance systems used in stores to prevent shoplifting can also cause problems. "The patient should be instructed to walk rapidly through the gate and do not tarry," said Dr. Spencer, who holds stock in Medtronic and Boston Scientific. ■

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At security gates, under no circumstances should a patient submit to a search using a hand-held wand over the chest.

Medical Environments Pose a Minefield for Implant Recipients

SNOWMASS, COLO. — Magnetic resonance imaging is by far the most problematic medical source of electromagnetic interference with implanted cardiac device function, according to Dr. William H. Spencer III.

Other potential sources of electromagnetic interference include radiotherapy, neurostimulators, electrosurgery, and radiofrequency catheter ablation of arrhythmias, as well as lithotripsy.

Manufacturers have made development of MRI-safe pacemakers and ICDs a priority, but none exist yet.

DR. SPENCER

Device wearers don't need to worry about diagnostic x-rays, CT scanning, mammograms, ultrasound, and most forms of laser surgery, he said at a conference sponsored by the Society for Cardiovascular Angiography and Interventions.

Dr. Spencer shed light on the sources of interference that may affect implanted cardiac devices:

► **MRI.** The Food and Drug Administration and cardiac device manufacturers list MRI as absolutely contraindicated. Deaths have occurred. It has been estimated that if not for the contraindication, an MRI would be recommended for various indications in up to 75% of U.S. pacemaker and implantable cardioverter-defibrillators users during the course of the device's service life.

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► **Radiotherapy.** The damage to pacemakers and implantable cardioverter-defibrillators by radiotherapy is dose dependent, cumulative, and permanent, said Dr. Spencer, professor of medicine at the Medical University of South Carolina, Charleston.

Protocols should be in place for avoiding direct irradiation of the device, creating the greatest possible distance between device and radiation beam, and maximum shielding.

► **Neurostimulators.** Transcutaneous electric nerve stimulation, and the peripheral and spinal nerve stimulators used to treat neuropathic and orthopedic pain, can be used safely in patients with modern bipolar pacemakers. But the patient should first undergo testing at the stimulator's maximum output to ensure it doesn't trigger or deactivate the pacemaker.

► **Electrosurgery.** This creates one of the most powerful and dangerous electromagnetic fields found in the medical environment. The best option is to find an alternative form of surgery.

► **Radiofrequency ablation.** This procedure interacts unpredictably with cardiac devices. Turn off rate-responsive and antitachycardia features and program the device to asynchronous mode for the procedure duration. If the goal is to create complete heart block, a temporary pacemaker must be inserted to ensure ventricular capture.

► **Shock wave lithotripsy.** This method of breaking up kidney and other stones is not nearly the problem it once was. Indeed, only patients with an abdominally implanted device generator are at high risk, and those are now uncommon.

Atrial Pressure Monitors May Revolutionize HF Management

SNOWMASS, COLO. — Implantable left atrial pressure sensors may provide a breakthrough in the outpatient management of heart failure by identifying impending acute decompensations hours to days before symptom onset, said Dr. James S. Forrester at a conference sponsored by the Society for Cardiovascular Angiography and Interventions.

"I believe that by using implanted hemodynamic sensors, the mechanisms responsible for acute decompensation of heart failure can be defined in the vast majority of patients, and that the physician can prevent these episodes using preplanned strategies. Implanted sensors will be able to decrease hospitalization, reduce progression of heart failure, and increase quality of life in these patients," said Dr. Forrester, professor of cardiovascular research at Cedars-Sinai Medical Center and professor of medicine at the University of California, both in Los Angeles.

Dr. Gregg C. Fonarow of the University of California, Los Angeles, showed in previous research that heart failure (HF) patients with a well-controlled left atrial pressure (LAP) of 16 mm Hg or less at hospital discharge had a 46% lower mortality and 85% reduction in rehospitalizations, compared with those with a higher LAP.

In contrast, cardiac output, right atrial or pulmonary artery pressures, and systemic vascular resistance each failed to predict outcomes.

"Increased left atrial pressure is associated with increased acute and long-term mortality and is the real driver of heart failure rehospitalization," explained Dr. Forrester.

There are two investigational implanted devices being developed for LAP assessment. The first is the Medtronic Chronicle, which is under review by the Food and Drug Administration for possible marketing approval. Dr. Forrester is involved in studies of a second device, the Savacor HeartPOD System, which was invented by colleagues at Cedars-Sinai.

To date, the HeartPOD has been implanted in 18 HF patients, with a collective 76 months of follow-up. Although that is insufficient clinical experience from which to draw conclusions, the pilot study results are encouraging. The number of total hospitalizations was significantly lower, compared with an equal period in the previous year, and there have been no unplanned HF hospitalizations or clinic visits since the monitors were activated, Dr. Forrester said.

The early experience with the HeartPOD has already yielded fascinating new insights into HF physiology that may offer opportunities to intervene early with pharmacotherapy, according to Dr. Forrester.

The Medtronic device was assessed in the previously reported 274-patient Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) randomized trial.

In that study, physicians used data from patients' implantable monitors to guide HF therapy. The patients had a 22% reduction in the primary study end point—the 6-month combined incidence of HF-related hospitalizations and emergency department and urgent-care visits—compared with controls. However, this finding was not statistically significant, probably because the trial was underpowered, Dr. Forrester said. But he noted that the Chronicle's sensor, which is placed near the right ventricular outflow tract and infers LAP indirectly from a measurement of pulmonary artery end diastolic pressure, could sometimes give inaccurate LAP results.

Dr. Forrester is chair of the scientific advisory committee for Savacor, a Research!America company in which he holds a significant financial interest. ■