New Cardiac Pacemaker Avoids MRI Interference

BY MITCHEL L. ZOLER
Philadelphia Bureau

MUNICH — A new type of cardiac pacemaker was safe in patients undergoing an MRI examination, with no need for a special imaging protocol in a randomized study with 151 evaluable patients.

"The functionality of the new pacemaker is the same as a conventional pacemaker, but one is MRI safe and the other is not," Dr. Torsten Sommer said at the annual congress of the European Society of Cardiology. There is no apparent downside to the new pacemaker, except that it may cost more than current units do, he said.

Patients with a standard pacemaker face "a huge limitation" by not being able to easily undergo MRI imaging, which has become a practice staple, said Dr. Sommer, chief of the cardiovascular imaging section at the University of Bonn (Germany). He estimated that an average pacemaker patient today has a 50%-75% lifetime chance of needing at least one MRI exam.

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The major danger that MRI poses to a patient with a conventional pacemaker (or other implanted cardiac device) is heating of the lead tips by radiofrequency radiation. Other concerns are interference with pacemaker function and risk of an electrical reset of the device.

A special MRI protocol has been reported that avoids these problems, but the method is complicated and available only at a limited number of experienced imaging centers, commented Dr. Christopher Cannon, a cardiologist at Brigham and Women's Hospital and Harvard Medical School, Boston. Having a new pacemaker without the MRI limitation would be "very helpful," he said in an interview.

The new pacemaker, called EnRhythm, was developed by Medtronic Inc., which funded the current study. Dr. Sommer is a consultant to Medtronic, but he and his associates in Bonn do not hold any patents on the new device or technology. The data he reported came from the first phase of a study designed to eventually place the new pacemaker in 470 patients. When the final results are available, Medtronic will apply for marketing approval from the Food and Drug Administration, a step that the company hopes to take in 2010, said Tracy McNulty, a Medtronic spokeswoman.

The new, dual-chamber pacemaker features a reduced number of ferromagnetic parts, better protection of internal circuits, and altered software. But the implantation technique is the same as for a standard pacemaker, Dr. Sommer said.

The study is being done at 53 centers in the United States, Canada, and Europe. So far, 245 patients with a class I or II indication for a pacemaker have been implanted with the EnRhythm device. Ninety patients were randomized to undergo MRI imaging and 101 were randomized as controls who received no imaging.

The MRI exam was done on a 1.5-T unit and involved 15 clinically relevant head- and lumbar spine–imaging sequences. To maximize safety during the first phase of testing, no magnetic coils were placed directly above a spinal region that extended from the C1 to the T12 level. But even with this limitation, full imaging of the chest region was obtained, Dr. Sommer said.

Follow-up data collected 1 month after the MRI exam were available for 70 patients and for 81 of the matched controls. The results showed no adverse events or complications triggered by the MRI exam, and no electrical resets of the pacemakers. During follow-up, no patients had sustained arrhythmias and the pacemakers did not show any changes in their rhythm-capture thresholds or any other performance changes. ■

Duplex Ultrasound Looks Safe For Post-EVAR Surveillance

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — Postendovascular aneurysm repair surveillance, with color flow duplex ultrasound only, is a safe alternative to the current standard practice of follow-up CT with contrast, results from a single-center study showed.

After endovascular aneurysm repair (EVAR), "CT follow-up is associated with significant risk, including increased cost, contrast nephropathy, contrast allergy, and radiation exposure," Dr. Rabih A. Chaer said at the Vascular Annual Meeting. "Alternative follow-up methods have been proposed, including color flow duplex ultrasound, MRI, and contrast-enhanced ultrasound. Of all these modalities, it's clear that simple color flow duplex ultrasound is the most readily available, the cheapest, and the least invasive."

He and his associates in the division of vascular surgery at the University of Pittsburgh Medical Center studied 184 patients who were switched to color flow duplex ultrasound (CDU) surveillance in 2003 as an alternative to CT. Selective CT scanning was used only for new endoleaks or for patients who presented with an enlarging abdominal aortic aneurysm (AAA) sac. Only patients with at least 1 year of follow-up were included.

Criteria for switch to CDU included patients with a residual AAA sac of 4 cm or less anytime after the first year of follow-up, patients with a stable AAA sac size for 2 years, or patients with a stable type II endoleak for 2 years. The average CDU study duration was 20 minutes. The researchers used a GE Logiq 9 machine with a 3.5-MHz curve probe.

Of the 184 patients, 13 had an active stable type II endoleak, 23 had a prior endoleak that was treated or that resolved spontaneously. The mean follow-up on CDU was 24 months. Of the 184 grafts, 76 were Ancure, 58 were Zenith, 39 were Excluder, 7 were AneuRx, and 4 were Lifepath.

Dr. Chaer reported that there were three new endoleaks detected on CDU follow-up, all in patients who received an Ancure graft. Only one patient presented with sac enlargement. "One type II endoleak was detected, but this spontaneously resolved at 3 months," he said. "There were two distal type I endoleaks that were treated with limb extension."

CDU identified two patients (one with an Ancure and one with an AneruRx graft) who had an increase in their AAA sac size, yet no endoleak was detected. No endoleak was seen on CT scan, but when both patients underwent angiograms, a distal type I endoleak was detected in one patient.

There were no ruptures or graft occlusions observed during the follow-up period. Eight patients died. One was an aneurysm-related death following an Ancure explantation for infection that occurred 4 years post EVAR; two were related to malignancy, and five were related to acute myocardial infarctions.

The cumulative freedom from secondary intervention after the switch to CDU was 98% at 4 years.

In order to determine the applicability of the switch criteria for a full cohort of EVAR patients, the researchers examined 196 consecutive EVAR patients in 2004. Of these, 86 (44%) had been switched to CDU surveillance, whereas the remaining 110 were still followed with CT scan. At the 6-month follow-up, only 1.5% of patients followed with CT scan met the current criteria for the switch to CDU-only surveillance. But the proportion at 1, 2, and 3 years was 55%, 86%, and 97%, respectively.

"CDU-only surveillance is safe and can be initiated early after treatment on patients with a shrinking or a stable AAA sac," he concluded. "Most patients treated with EVAR are eligible for this modality. After the 1 year follow-up, we do recommend that CT scanning should only be selectively utilized in patients treated with EVAR. This policy should result in cost-saving advantages and avoid the complications associated with CT."

Dr. Chaer disclosed he had no relevant conflicts. ■

Infection May Increase Risks From MRI Contrast Agents

BY KERRI WACHTER
Senior Writer

The presence of infection at the time of magnetic resonance imaging using gadolinium contrast may predispose patients with renal failure to nephrogenic systemic fibrosis, according to a hospital analysis.

The estimated NSF development rate for infected patients with renal failure was 6.7%, compared with 0.3% for uninfected patients with renal failure—a 33-fold difference that was highly significant.

"If the presence of infection indeed proves to be a risk factor for the development of NSF, then some renal failure patients presently judged to be acceptable risks for MR contrast administration on the basis of the degree of renal failure might be reconsidered as high-risk patients," wrote Dr. Lauren Goldberg of Moses H. Cone Memorial Hospital, Greensboro, N.C., and Dr. James Provenzale, a radiologist at Duke University, Durham, N.C. (Am. J. Roentgenol. 2008;190:1069-75).

Eight patients with symptoms consistent with NSF between 2002 and 2006 were prospectively identified by the nephrology group. Seven biopsy-proven cases were identified, along with another case involving strong clinical signs and symptoms of NSF without biopsy confirmation.

Seven patients had MRI contrast with gadodiamide (Omniscan, GE Healthcare), at a dose from 0.1 mmol/kg to 0.3 mmol/kg. NSF symptoms began 2 days to 5 months after contrast administration. The sole patient not exposed to gadolinium contrast had end-stage renal disease, breast carcinoma, and calciphylaxis.

All eight patients with NSF noted stiffening and thickening of the hands and lower extremities—often described as woody changes of the skin. Five patients had severe chronic pain, the authors reported.

No single medication was common to all patients with NSF. None had vascular thrombosis. Only one patient had undergone major surgery. Five of the patients had documented infection, including catheter infection, urinary tract infection, bacteremia, pneumonia, cellulitis, and osteomyelitis. Two patients who received gadolinium contrast did not have proinflammatory conditions. The one patient who did not receive gadolinium contrast was also considered not to have a proinflammatory condition.

The researchers estimated that 750 renal-failure patients without documented infection and 75 renal-failure patients with documented infection underwent contrast-enhanced MRI between 2002 and 2006.

"All six patients who were hemodialysis dependent at the time of contrast-enhanced MRI were dialyzed 1 day after gadodiamide administration, suggesting that prompt hemodialysis may not be protective against the development of NSF," the authors wrote.

The investigators disclosed no conflicts of interest. ■