MRI of implantable devices: Do we need safer devices, safer scanning procedures, or both?

MARCH 18, 2010 | Reed Miller

©Norebbo/Dreamstime.com

La Jolla, CA - Just as some of the first so-called "MRI-safe" implantable cardiac devices are starting to seek **FDA** approval, leaders of the first large registry to address MRI safety are cautioning clinicians against overenthusiasm for the new devices until the "true risk" of allowing patients with pacemakers and defibrillators to undergo MRI has been adequately studied.

The MagnaSafe registry is an ongoing investigator-initiated registry launched last spring to study the safety of nonthoracic MRI scans of patients with implanted pacemakers or implantable cardioverter defibrillators (ICDs). The study has so far enrolled about 125 of a planned 1500 patients (1000 pacemakers, 500 ICDs); the primary outcomes are rate of device failure and rate of device parameter changes.

Dr Robert Russo [Source: Scripps Institute]

MagnaSafe co-principal investigator **Dr Robert Russo** (Scripps Clinic, La Jolla, CA) told **heart*wire*** that the purpose of the study is to accurately assess the real risk of MRI of patients with devices, so that patients can make an informed risk/benefit decision about getting a scan.

Dr Christian Machado (Providence Heart Institute, Southfield, MI), whose team is working on safe procedures for MRI scans of patients with implantable devices, is optimistic that MagnaSafe will "give clinicians important valuable information with regard to safety and device interrogation," he told **heart*wire***. He points out that most of the previous studies on MRI-device interactions have been small. They have identified potential or "theoretical" hazards, but they do not accurately quantify the real risk of those problems. "The MaganSafe registry would be the final push to get over the hurdle of theoretical paranoia to pragmatic reality without harming the most important variable: the patient."

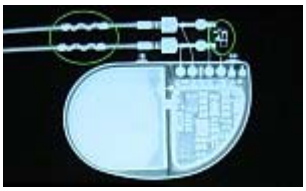
Although the FDA and a variety of private sponsors have been very supportive of the study, according to Russo, he claims the study has run into "quite a pushback [from some clinicians], because one vendor is trying to move forward in marketing the need for an MRI-safe device." MagnaSafe coinvestigator **Dr Jennifer Cohen** (Scripps Institute) said that she agrees that a device specifically designed to be MRI-safe would be useful, but that shouldn't interfere with research on how to perform MRI on the millions of patients who already have a device.

Currently, the FDA regards patients with implantable cardiac rhythm management devices to be contraindicated for MRI scans, but Medtronic is set to meet with the FDA Circulatory System Device's advisory panel on March 19 to discuss its premarket approval application (PMA) for the REVO MRI pacemaker system. The REVO MRI, formerly called EnRhythm MRI, is specifically designed to be safe for the MRI environment under certain MR scanning conditions. As reported by heartwire at the **Heart Rhythm Society** meeting in May, investigators announced results of a randomized, multicenter clinical study of the device in 445 patients, including 211 undergoing head and lumbar scans with 1.5-T MRI machines. In the study, there were no complications reported among subjects who underwent scans and there were no MRI-attributed sustained ventricular arrhythmias, asystole, or pacemaker malfunctions.

REVO MRI SureScan implantable pulse generator [Source: FDA executive summary prepared for the March 19, 2010 meeting of the Circulatory System Devices Panel]

Meanwhile, rival St Jude Medical is developing the Accent MRI pacemaker, which it hopes to begin studying in the US this year.

Despite the promising results, Russo argues that the FDA does not have any established in vitro tests for evaluating the safety of these devices in an MRI environment, nor does the agency have set protocols for looking for the types of potential malfunctions that have been reported with MRIs and implantable devices over the years, such as interference with lead transmission and local heating around the lead tip. "Certainly the FDA doesn't have a way to certify a device," he said.



X-ray image of MRI labeled device with radiopaque symbols on the lead and IPG, indicating a complete MR-conditional system [Source: FDA executive summary prepared for the March 19, 2010 meeting of the Circulatory System Devices Panel]

"Unfortunately, the juggernaut that we're fighting is the fact that industry doesn't really want to know this stuff. They just want to sell more new devices," Russo said. "We're really depending a lot on people in the press to keep the device manufacturers at bay, because they have an endless stream of propaganda that everybody can fall into—'there's an MRI-safe device coming,' or 'it's super unsafe to start scanning people with devices'—all of which are crafted to change press and public opinion about the safety of MRI and devices."

Other experts believe that there are just too many variables involved in MRI and complex devices such as pacemakers or ICDs, and therefore a device designed and studied "from the ground up" to be MRI-safe is necessary.

Dr Claas Philip Nähle (University of Bonn, Germany) told **heart*wire***, "The devices that are available without any kind of approval for MRI have been tested quite well to the extent possible, but there simply are too many possible combinations of device and leads, making it impossible to test them all. . . . This is an important reason that the development of an MRI-conditional or MRI-safe device is necessary."

Dr J Rod Gimbel

Dr J Rod Gimbel (Cardiology Associates of East Tennessee, Knoxville) argued that "the [reason we need] MRI-compatible devices is quite simple: We've gone just about as far as we can with the monitoring, supervision, reprogramming, and [specific absorption-rate] reductions previously suggested by experts to make MRI of *currently* marketed devices safe.

"Each of the suggestions [for monitoring and programming] mitigates, to some degree, the risks of scanning device patients but does not solve the problems entirely or sufficiently," Gimbel said. "Comprehensive industry investigations—including bench and phantom testing, computer modeling, and animal and human testing—working to reduce the remaining risk are required.

"What will drive the marketplace will be not only the significant incremental safety advantage of using an MRI-compatible device for both pacer- and non-pacer-dependent patients, but also the important time saving that will accrue to clinicians from using a device that does not require their direct supervision during MRI," Gimbel said.

With 1000 MRIs planned for a hodgepodge of pacemaker patients and 500 MRIs planned for mishmash of ICD patients in the MagnaSafe registry, what will we really have at the end of it all?

Gimbel believes MagnaSafe will help clinicians better understand hour-to-hour variations in pacing, sensing, impedances, and battery voltages of a variety of devices. But, "despite its relatively large overall size, MagnaSafe will not likely be sufficiently powered for any *particular* device-lead combination to yield any meaningful insights as to the real risk of scanning a device," he said. "With 1000 MRIs planned for a hodgepodge of pacemaker patients and 500 MRIs planned for mishmash of ICD patients in the MagnaSafe registry, what will we really have at the end of it all?"

What are the risks?

Other researchers who have studied MRI-device interactions told **heart*wire*** that Russo may be understating the potential dangers of MRI with implantable devices and therefore underestimating the real value of a device specifically designed to be safe in an MRI environment.

"If all the efforts [to create an MRI-safe device] are somewhat unnecessary, why are these listed as exclusion criteria in MagnaSafe—ICD or pacemaker generator placement prior to 2002, ICD and pacing dependent, presence of implanted cardiac device in the abdominal position?" Nähle asked rhetorically. "It seems that the authors don't quite trust their own beliefs too far."

As reported by **heart*wire***, researchers at **Providence Heart Institute** recently introduced a new MRI protocol for patients with implantable devices that allows for the early detection and response to potential complications and might make routine testing of post-MRI defibrillation thresholds and defibrillator safety margins of ICD patients unnecessary. The protocol calls for continuous monitoring during imaging and device interrogation before and after the scan for lead impedance, battery life, pacing, and sensing thresholds. All tachyarrhythmia therapies are disabled during the scans. Pacemakers are set to an asynchronous mode in pacemaker-dependent patients and to a nontracking/sensing mode in non-pacemaker-dependent patients.

However, the success of the Providence protocol for MRI scans of patients with implantable devices does not mean that specific MRI-safe devices are unnecessary, according to Machado, one of the authors of the Providence study. The Providence protocol also requires careful planning, monitoring, reprogramming, and supervision from a team of professionals, which may be unfeasible at some centers. "To proceed with indiscriminately scanning patients with devices on a large scale, there will have to be an FDA-approved MRI-safe device," Machado told **heart*wire***.

Gimbel suggests that the labor- and time-intensiveness of the Providence protocol shows that MRI in these patients is risky. "If 'modern' devices are so safe, why must we be in attendance during MRI, monitor them during MRI, and reprogram them to undergo MRI?" he asked in an email exchange with **heart*wire***.

Urban legends or real danger?

Russo and Cohen argue that the fears of major adverse events with MRI-device interactions are based on older studies that do not represent the best current clinical practice for preparing and monitoring these patients.

For example, a 2005 study of pacemakers explanted from deceased patients who underwent MRI by **Dr Werner Irnich** (University Hospital, Giessen, Germany) and colleagues suggested that six patient deaths in Germany may have been due to MRI interactions with their implantable devices [1].

However, Cohen points out that in that study, the devices were not reprogrammed prior to entering the scanner and the examination of the devices shows that they reached high pacing rates that could have been caused by the magnet. The six patients who died in the group Irnich et al looked at were examined in private radiology practices for orthopedic or neurological reasons and were not monitored like the patients in MagnaSafe or the Providence study, she points out.

In MagnaSafe, during the MRI scan, the pacing function in non-pacemaker-dependent patients' devices is turned off and programmed to asynchronous pacing in pacing-dependent patients, while both therapy and monitoring are turned off in ICDs. Patients are monitored continuously during the scan with ECG and pulse oximetry, and an electrophysiologist is present throughout the exam, Cohen said.

> **"All of the concerns, for the most part, are almost hysterical concerns, and none of them are based on facts.**

Inhibition of pacemaker output or induction of arrhythmias were the suspected culprits in the deaths reported by Irnich's group, but Cohen points to an earlier study by **Dr Torsten Sommer** (University of Bonn, Germany) of MRI at 0.5 T of patients with pacemakers, which did not show induction of arrhythmias or reduction of output [2]. Sommer et al concluded that MRI can be safely performed in patients with implanted pacemakers if the

devices are programmed to an asynchronous mode and the patients are appropriately monitored.

Sommer et al did found increases in the pacing capture threshold that were statistically significantly greater than the mean values. But Cohen and Russo argue that they were not clinically relevant changes. The MagnaSafe researchers have measured the absolute change in pacing capture threshold post-MRI compared with the pre-MRI value and found that the average change is 0.01±0.15 V in the atrium and 0.04±0.17 V in the right ventricle.

"These are negligible changes. The important thing to report is how many patients had an increase of 0.5 V or greater," Cohen said. Her group's retrospective analysis of 125 pacemaker patients undergoing MRI compared with pacemaker patients not undergoing MRI showed a battery voltage decrease of greater than 0.04 V in only 4.4% of patients compared with 0% in controls, lead-impedance changes of >50 Ω in 6.2% of patients compared with 4.3% in controls, and a threshold increase of >0.5 V in 2.6% of patients vs 1.1% in controls. The risk of any of these events in the MRI group was 18% vs 22% in the controls, but none of these differences were statistically significant, and only one patient required temporary reprogramming of the device, Cohen said.

Cohen noted that it is possible for MRI to cause the devices to temporarily lose the ability to "capture" the heart rhythm, but "we still believe that the frequency of these events is so low that, given appropriate monitoring and programming during the scan, poor outcomes can still be prevented."

"All of the concerns, for the most part, are almost hysterical concerns, and none of them are based on facts," Russo said. "Every kind of potential disaster that we've tried to research has all just ended up being an urban legend across the community or the literature."

"We don't deny that these problems have been documented. However, despite some of the reports of loss of capture, electrical reset to 'on,' and deaths, we have scanned more than 200 patients and not had any of these events," Cohen said. "We cannot be sure why we are not seeing the same events, except to think that we may be programming the devices differently and we are using newer devices [than were used in previous trials]."

Understanding normal variations

Several researchers who spoke to **heart*wire*** said they hope that MagnaSafe can reveal more about normal hour-to-hour variations of parameters such as battery voltage and pacing and sensing thresholds—information that has to date been relatively scant. By understanding the normal range of variation, researchers and clinicians using MRI will be able to tell when a device has deviated from the norms and therefore be better able to assess the risk of MRI in their patients.

For example, Cohen said that the often-accepted limit for changes in pacing capture threshold of 1.0 V was established in the 1960s in very different devices.

She also pointed out that not all previous studies fixed the pulse width when evaluating a threshold change, so that is one of the variables that has been prospectively defined in MagnaSafe, so that pre- and post-MRI measurements can be compared. She also predicted that that the evaluation of data from control patients in MagnaSafe will help the researchers define cutoffs, "so that we might be able to better distinguish the inherent variability in measurements vs a true effect of the MRI."

MRI-safe replacements? Probably not

The MagnaScan investigators suggest that the marketing of a device FDA approved as MRI safe could lead some patients or physicians to believe that they should replace their current device with an MRI-safe device if they have an indication for an MRI scan such as cancer or an orthopedic injury.

Cohen pointed out that the major complication rates for replacement of pacemakers and ICDs is 2.5% and 6.0%, respectively, according to results of the REPLACE registry. "These are very high numbers and cannot be ignored."

"This low frequency of events [with MRI] does not, in and of itself, justify explanting existing devices and implanting new MRI-conditional/safe devices solely for the need of an MRI," she said.

Although the experts **heart*wire*** contacted believe an MRI-safe device will be a useful option for some patients, there does not appear any support for replacing already-implanted devices with an MRI-safe device. Machado believes that "there is a much greater inherent risk to the patient by removing existing devices and leads. This would also create an excessive burden on healthcare dollars just to mitigate a hypothetical, potential issue."

"No one—or company—is suggesting that you replace all of your device patients with an MRI-compatible device," Gimbel said.

Gimbel has received honoraria from Gilead Sciences, Sorin, Medtronic, and Boston Scientific; participated in a clinical trial sponsored by Medtronic; and served as a consultant to Medtronic, St Jude, and Biotronik.

Sources

1. Irnich W, Irnich B, Bartsch C, et al. Do we need pacemakers resistant to magnetic resonance imaging? *Europace* 2005; 7:353-365. PUBMED
2. Sommer T, Vahlhaus C, Lauck G, et al. MR imaging and cardiac pacemakers: In-vitro evaluation and in-vivo studies in 51 patients at 0.5 T. *Radiology* 2000; 215:869-879. PUBMED

Related links

- New MRI protocol for patients with implantable devices may eliminate defibrillation-threshold testing [*Imaging* > *Imaging*; Feb 19, 2010]
- No complications, no overheating with MRI-compatible pacemaker and leads [*Arrhythmia/EP* > *Arrhythmia/EP*; May 14, 2009]
- New statement on safety of MRI with CV devices [*Arrhythmia/EP* > *Arrhythmia/EP*; Nov 30, 2007]
- MRI may be safe for patients with some types of pacemakers, ICDs [*heartwire* > *News*; Aug 04, 2004]