DEVICE THERAPY

RESEARCH ARTICLE

MRI Conditional Pacemakers: The Future Begins Here

DAWN F. SABIN, RN, BS, FHR$ and WALTER K. CLAIR, MD, MPH, FACC, FHRS

Division of Cardiovascular Medicine, Vanderbilt University Medical Center, Nashville, TN

ABSTRACT. Cardiac rhythm management is evolving at a rapid pace. Advances in pacemaker technology continue to improve the quality of life for our patients, allowing us to diagnose and treat them more efficiently than ever before. With the release of the first US Food and Drug Administration labeled magnetic resonance imaging (MRI) conditional pacemaker, more patients will have access to the diagnostic capabilities of MRI. We will review current studies that demonstrate the safe use of MRI in pacemaker patients. We will also report on our own experience with these patients.

KEYWORDS. cardiac rhythm management device, impedance, magnetic resonance imaging, pacemaker, generator.

Introduction

Over the last half century, the practice of medicine has been enhanced by technological developments in both the diagnosis and the treatment of patients with cardiovascular diseases. The evolution of implantable pacemakers in the middle of the twentieth century1 and the placement of the first implantable cardioverter-defibrillator (ICD) in 19802 have significantly improved the quality and length of life for millions of patients worldwide. These cardiac rhythm management devices (CRMDs) now have diagnostic capabilities that not only direct patient treatment modalities but also monitor patient activity levels and heart failure status.3 Together with implantable loop recorders,4 these devices allow clinicians to detect pathology at stages that often precede the patient’s development of significant symptoms.

Concurrent with the evolution of CRMDs, the diagnostic modality of magnetic resonance imaging (MRI) grew out of the field of nuclear magnetic imaging.5-7 Now MRI with its lack of radiation exposure is becoming a preferred imaging modality in neurology, orthopedic, and cardiac patients. Cardiac MRI is even enhancing the efficiency of caring for patients undergoing ablation procedures for arrhythmias in the electrophysiology laboratory.8 However, only a relatively small number of patients with CRMDs have been able to benefit from MRI technology because of the real and theoretical concerns about interactions between the strong magnetic fields generated by MRI and CRMDs.9,10 The electromagnetic fields generated by MRI scanners have been documented to result in inhibition and triggering of pacing as well as reprogramming of pacemaker function or sometimes resulting in power on reset. These changes may result in inappropriate pacing, failure to pace or capture, induction of ventricular fibrillation, early battery depletion, or total system failure requiring replacement. Pacing and defibrillation leads, even when not attached to a generator, may heat or stimulate cardiac tissue because of induced currents.11 Therefore, until recently, all pacemakers and ICDs available in the United States have been considered MRI unsafe by the US Food and Drug Administration (FDA).12 Also, many relevant societies consider MRIs for patients with CRMDs to be absolutely or relatively contraindicated.9,13 Nonetheless, CRMD patients with compelling indications have had MRI examinations under controlled conditions in specialized centers.
Clinical Studies of MRI and CRMDs

Since 1996 several studies have been published describing the experiences of patients who have undergone MRI examinations with a CRMD implanted. With appropriate planning, temporary device reprogramming, and patient monitoring, these studies and reports have been encouraging.

To assess the safety of MRI in patients with standard CRMDs, Naehle et al. performed cardiac MRI on a series of 32 patients who had clinical indications for the examinations. These patients had devices from a variety of manufacturers and the devices had been implanted for no less than 3 months. Additionally, no patients had other MRI unsafe devices or abandoned leads. Also excluded were patients who had undergone recent cardiothoracic surgery or an evaluation for unstable angina or myocardial infarction. The devices were programmed to minimize interference with magnetic fields and were evaluated before and after imaging with a 1.5-T scanner using a cardiac phased-array coil. The investigators found no safety issues in the patients imaged. And although there were lead-related artifacts, these did not compromise the delineation of the cardiac tissue and anatomy. In spite of the image quality being rated average or better by the experienced readers, artifacts from CRMDs implanted on the left side affected a significant number of myocardial segments limiting the diagnostic value of the cardiac magnetic resonance image.

In a recent and larger study of patients with conventional CRMDs, Nazarian et al. reported on 438 patients who underwent 553 MRI examinations with both acute and long-term evaluation of their CRMD function. The majority (237) of these patients had pacemakers that had been implanted after 1998, and the remainder had ICDs that had been implanted after 2000. Using a monitoring and safety protocol that required the leads to be implanted for 6 weeks or more and that the patients and their CRMDs be evaluated for clinical stability, they performed MRI scans only on patients who had no abandoned epicardial or transvenous leads. Pacemaker patients were studied with their pacing therapies in an asynchronous mode if they were pacemaker dependent and in an inhibited mode (VVI/DDI) if not. If the patients had an ICD, tachyarrhythmia therapies were turned off. Because of the inability to program most ICDs to an asynchronous mode, pacing-dependent ICD patients were not included in the study.

These authors found that MRI scanning could be performed safely in patients with CRMDs from a variety of manufacturers and for a range of indications using a 1.5-T scanner. Forty percent of the MRI examinations were of the brain, 22% were of the spine, and 16% were of the heart, with the remainder being for the pelvis or an extremity. Though there was some degree of image distortion when the CRMD was located in the MRI field of view, no patients were harmed. There were three instances of power on reset during their MRIs. One of these patients had an ICD and two had pacemakers. During long-term follow-up, all three devices functioned normally. Immediate and long-term follow-up of device and lead function of these patients demonstrated no lead sensing, impedance, or capture threshold changes significant enough to warrant system revision or reprogramming from chronic parameters.

Although various other trials have shown that with proper planning and patient selection MRI examinations can safely be performed, there have been ongoing concerns about the potential adverse interactions between conventional CRMDs and MRI. Because of this, pacemaker systems have been specially designed for safe use in patients who undergo MRI evaluation. The first such system to receive the CE (Conformité Européenne) mark of approval for conditional use was the Medtronic (St. Paul, MN) EnRhythm MRI SureScan system in November 2008. This system consists of both a redesigned pacemaker generator and a specifically designed complementary Medtronic CapSureFix MRI 5086 lead. The generator was produced with less ferromagnetic material and improved internal circuitry protection. Instead of the traditional reed switch which responds to magnetic fields, the Revo MRI has a Hall sensor providing predictable behavior in a magnetic field. To decrease heating at the lead tip, the active fixation leads (which are based on the CapSureFix 5076 lead) were designed with an inner coil that uses two filars rather than four (Figure 1). Both the pacemaker generator and the leads have a “wavy line” radiopaque marker (Figure 2) so that they may be radiographically confirmed to be MRI conditional. Another component of this system is a programming algorithm with integrity checks that allows one to quickly program the device to specific parameters prior to MRI scanning and back to baseline parameters when the scan is completed. The final feature of this system is a set of very specific recommendations on the scanner power and examination positioning specifications to be used when scanning a patient in whom the device has been implanted. The static magnetic field must be no more than 1.5 T, and the isocenter of the MRI bore must be either superior to vertebra C1 or inferior to vertebra T12. More detailed specifications may be found in the Revo MRI Surescan Pacing System technical manual (http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@crdm/documents/documents/wcm_prod053354.pdf).

Wilkoff et al. implanted the Medtronic Enrhythm MRI SureScan pacing system in 464 patients. After device implantation, patients were prospectively randomized such that 258 patients were assigned to MRI examinations with 1.5-T scanners at 9–12 weeks post implantation, and 206 were assigned to the control group. The pacing systems were evaluated before, immediately after, 1 week after, and 1 month after the scans. There were no MRI-related complications in the scanned patients, and when compared with the control patients, pacing lead capture thresholds and sensing were similar and required no reprogramming related to scanning. There was a total of 17 patients who had lead dislodgements during the study period, but these were unrelated to the MRI examinations.
The Vanderbilt Heart and Vascular Institute experience

In February 2011, the FDA, using terminology adopted from the American Society for Testing and Materials, approved the Medtronic Enrhythm MRI SureScan pacing system for use as an MRI conditional pacemaker. This approval was meant to convey that under specific conditions of use, there were no known hazards or risks to patients. For use in the United States, the system was renamed the Medtronic Revo MRI SureScan Pacing System (Revo MRI) to avoid confusion with other devices.

Even before FDA approval, some of our more informed patients were making inquiries about MRI “safe” pacemakers. In fact, one patient with a history of MRI examinations for headaches and musculoskeletal complaints declined an elective pacemaker for chronotropic incompetence until he could get an MRI conditional pacemaker. Occasionally, patients with previously implanted conventional pacemakers inquire as to whether or not they will be given an “MRI pacemaker” at the time of generator replacement. Anticipating the need to gain comfort with this new technology and recognizing the growing demand for MRI examinations in patients with conventional devices, our institution began the process of reviewing our policy on the performance of MRI in CRMD patients. This resulted in a procedure that involves having the pacemaker patient’s system assessed by the arrhythmia service prior to an MRI. Then, before the MRI scan is done, a cardiology order (Figure 3) form must be completed and placed in the patient’s electronic medical record.

On February 16 2011, we implanted our first Revo MRI system. The patient was a woman who expressed a desire to have a pacemaker that would not interfere with the assessment and management of her chronic low back pain for which she had previously undergone several MRI examinations. To date we have implanted a total of 16 complete Revo MRI systems (Table 1). Of these patients, only two have since had an MRI examination at our institution. We have also performed MRI examinations on four patients whose systems were placed elsewhere. Four of these scans were cranial and two were cardiac (Figure 4). Thus far, the only complications observed have been three atrial lead dislodgements. These dislodgements occurred when the implanting attendings were placing their first CapSureFix MRI 5086 leads in the atria. Nonetheless, the Medtronic 5086 MRI lead is thicker than the lead after which it is modeled. It is a relatively stiffer lead with torque transfer that is jerky when deploying the helix. We recommend a careful review of the CapSurefix MRI SureScan 5086 MRI technical manual (http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@crdm/documents/documents/wcm_prod061948.pdf) prior to implanting these leads.

Our small number of Revo MRI implantations is not a reflection of dissatisfaction with the system. We have purposely been slow to replace conventional devices which have a greater range of diagnostic features. For instance, the platform on which the Revo MRI is based does not allow for rate drop response, and it can only be implanted as a dual-chamber system. We have also been cautious in light of the historical problems manufacturers have had with new leads. Additionally, we have felt that with the higher cost of this system, it is prudent, for the present time, to limit its implantation to patients who are most likely to be candidates for MRI scanning.
the near term. This approach has been somewhat justified in light of published reports\textsuperscript{14–16} which demonstrate that it is reasonable to make MRI examinations more available to patients with conventional pacemakers when the risk–benefit ratio is favorable.

**The future**

The adoption of MRI conditional pacemakers has lagged in the United States relative to Europe. Two years before the Revo MRI system received FDA labeling as MRI conditional in the United States, it was granted CE mark approval allowing its implantation in Europe. CE mark approval has since been given to its second-generation relative, the Medtronic Advisa DR MRI SureScan pacing system. Additionally, CE mark approval has been achieved by St Jude Medical (St Paul, MN) for its Accent pacemaker and Tendril lead as well as Biotronik (Berlin, Germany) for its ProMRI series of pacemakers. Most recently, Biotronik has also received CE Mark approval for an MRI conditional ICD. There are specific conditions under which patients with CE mark-approved CRMDs can be scanned. There is no doubt that the FDA will be asked to approve use of these devices in the United States. When this occurs, under carefully designed protocols, many more patients will find that their CRMDs will not compromise their ability to have MRI examinations.

---

**Figure 3:** Magnetic resonance imaging order form for patients with the Revo MRI system.
The effort to make CRMDs less likely to cause harm in patients who undergo MRI examinations has resulted in the development of a new generation of devices. The resulting enhancements in CRMD technology and the improved understanding of the interactions between device components and the electromagnetic fields generated by MRI scanners will allow more patients to receive the benefits of both these technologies. Nonetheless, caution is still warranted. Patients may have other implanted devices that preclude MRI examination. Also, the clinical experience with current CE mark and FDA-approved devices is based primarily on their exposure to MRI scanners with a maximum magnetic field strength of 1.5 T. In the editorial he wrote regarding the clinical trial of the Medtronic Enrhythm MRI SureScan pacing system, Sorrentino\(^1\) referred to it as an “MRI-safe” device. However, the Revo MRI system is at best an MRI conditional device. “MRI-safe” is a term that neither the CE nor the FDA has granted any pacemaker or defibrillator. It is important that we adhere to the current and future conditions of use for these new devices if we are to safely offer our patients the advantages of both CRMD technology and MRI technology.

### Table 1: Characteristics of patients implanted with Revo MRI system at Vanderbilt University Medical Center

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yr)</th>
<th>Gender</th>
<th>Implant date</th>
<th>Implanter</th>
<th>Atrial lead dislodgement</th>
<th>Indication for pacing</th>
<th>Perceived need for MRI</th>
<th>Pre-implant MRI</th>
<th>Post implant MRI at Vanderbilt</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60</td>
<td>F</td>
<td>2/16/2011</td>
<td>A</td>
<td>No</td>
<td>Symptomatic bradycardia</td>
<td>Chronic back pain</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>51</td>
<td>M</td>
<td>3/4/2011</td>
<td>B</td>
<td>No</td>
<td>Sick sinus syndrome</td>
<td>Seizures</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>47</td>
<td>M</td>
<td>3/23/2011</td>
<td>A</td>
<td>No</td>
<td>Symptomatic bradycardia</td>
<td>Multiple sclerosis</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>23</td>
<td>M</td>
<td>4/18/2011</td>
<td>C</td>
<td>No</td>
<td>High grade AV block</td>
<td>Future MRI</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>51</td>
<td>M</td>
<td>5/17/2011</td>
<td>D</td>
<td>No</td>
<td>Syncope and sinus pauses</td>
<td>Cerebrovascular disease</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>76</td>
<td>F</td>
<td>5/25/2011</td>
<td>E</td>
<td>Yes</td>
<td>Symptomatic bradycardia</td>
<td>Uterine cancer</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>78</td>
<td>M</td>
<td>5/31/2011</td>
<td>A</td>
<td>No</td>
<td>AV Block</td>
<td>Degenerative joint disease</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>80</td>
<td>M</td>
<td>5/31/2011</td>
<td>F</td>
<td>Yes</td>
<td>Sick sinus syndrome</td>
<td>Hip disease</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>64</td>
<td>M</td>
<td>6/1/2011</td>
<td>A</td>
<td>No</td>
<td>Sick sinus syndrome</td>
<td>Patient request</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>10</td>
<td>69</td>
<td>F</td>
<td>7/11/2011</td>
<td>A</td>
<td>No</td>
<td>Sick sinus syndrome</td>
<td>Spinal stenosis</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>11</td>
<td>57</td>
<td>M</td>
<td>7/28/2011</td>
<td>G</td>
<td>Yes</td>
<td>AV Block</td>
<td>Cervical disc disease</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>12</td>
<td>75</td>
<td>M</td>
<td>8/22/2011</td>
<td>B</td>
<td>No</td>
<td>Sick sinus syndrome</td>
<td>Neurological symptoms</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>13</td>
<td>80</td>
<td>F</td>
<td>8/29/2011</td>
<td>B</td>
<td>No</td>
<td>Sinus node disease</td>
<td>Subdural hematoma</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>14</td>
<td>75</td>
<td>F</td>
<td>9/28/2011</td>
<td>E</td>
<td>No</td>
<td>Sick sinus syndrome</td>
<td>Cerebral aneurysm</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>15</td>
<td>50</td>
<td>F</td>
<td>11/4/2011</td>
<td>A</td>
<td>No</td>
<td>Symptomatic bradycardia</td>
<td>Chronic back pain</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>16</td>
<td>62</td>
<td>M</td>
<td>12/13/2011</td>
<td>D</td>
<td>No</td>
<td>Symptomatic bradycardia</td>
<td>Arthritis</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Conclusion

The effort to make CRMDs less likely to cause harm in patients who undergo MRI examinations has resulted in the development of a new generation of devices. The resulting enhancements in CRMD technology and the improved understanding of the interactions between device components and the electromagnetic fields generated by MRI scanners will allow more patients to receive the benefits of both these technologies. Nonetheless, caution is still warranted. Patients may have other implanted devices that preclude MRI examination. Also, the clinical experience with current CE mark and FDA-approved devices is based primarily on their exposure to MRI scanners with a maximum magnetic field strength of 1.5 T. In the editorial he wrote regarding the clinical trial of the Medtronic Enrhythm MRI SureScan pacing system, Sorrentino\(^1\) referred to it as an “MRI-safe” device. However, the Revo MRI system is at best an MRI conditional device. “MRI-safe” is a term that neither the CE nor the FDA has granted any pacemaker or defibrillator. It is important that we adhere to the current and future conditions of use for these new devices if we are to safely offer our patients the advantages of both CRMD technology and MRI technology.

*Figure 4: A transverse (left) and a coronal (right) MR image of a patient with a Revo MRI system. Note the artifact from the pacemaker generator in the upper right corner of the coronal image.*
References


