Magnetic Resonance Imaging and Implantable Devices

Saman Nazarian, MD, PhD; Roy Beinart, MD; Henry R. Halperin, MD, MA

Magnetic resonance imaging uses high-strength magnetic and electric fields to obtain multiplanar images with unrivaled soft tissue resolution. The image resolution and availability of various pulse sequences, each optimized for the evaluation of particular tissue attributes, make MRI the imaging modality of choice for numerous neurological, musculoskeletal, thoracic, and abdominal conditions. In addition, because of the absence of x-ray radiation, MRI is optimal for follow-up of chronic diseases that require repeat imaging and for diagnostic imaging in young patients and women of child-bearing age. Because of the advancing severity of disease and age of the population, and advances in device technology, the number of patients with permanent pacemakers and implantable cardioverter defibrillators (ICD) continues to increase. It has been estimated that patients with a pacemaker or ICD have up to 75% likelihood of having a clinical indication for MRI over the lifetime of their device. When performed with appropriate supervision and following a protocol for safety, many studies over the past 10 years have reported the safety of MRI with selected devices. However, in older devices, catastrophic complications have also been reported. Familiarity with each device class and its potential for electromagnetic interaction is essential for cardiologists and electrophysiologists whose patients may require MRI.

Physics of MRI Related to Devices

MRI uses high-strength magnetic and electric fields to evaluate tissue structure, heterogeneity, and motion. Within the MRI scanner, hydrogen nuclei (predominantly in water and fat) become aligned with or against the axis of the static magnetic field. A net magnetization vector is created because more protons are aligned with the static magnetic field than against it. The protons also rotate around their own axis and precess around the magnetic field lines at a rate dependent on the local magnetic field strength. Weaker gradient magnetic fields are then applied to introduce regional variability in the precession frequency of hydrogen nuclei, allowing for spatial localization. Radiofrequency pulses tuned to the precession frequency of hydrogen nuclei in the desired spatial location are then used to tip the net magnetization vectors of select nuclei from the equilibrium state. As the nuclei that received energy from the radiofrequency pulse relax to their equilibrium state, a weak current is induced in the radiofrequency receiver coil. The receiver coil current is converted to interpretable images via a Fourier transformation. The static and gradient magnetic fields and radiofrequency pulses described above are associated with several potential risks involving implanted devices.

The most intuitive potential interaction of implanted devices with an external magnetic field is the possibility for movement and dislocation of the device because of magnetic force. Ferromagnetic device components in or near the scanner bore are exposed to static and gradient magnetic field–induced force and torque. Current lead designs contain little or no ferromagnetic components and are not likely to experience force and torque. Although the amount of ferromagnetic materials in cardiac device generators continually decreases, some ferromagnetic components, such as transformers (needed for charging defibrillator capacitors), remain necessary. The potential for movement of a pacemaker or ICD generator in the MRI environment depends on the magnetic field strength, ferromagnetic properties of the device components, the implant distance from the magnet bore, and the stability of the implant.

Current induction is the most feared potential interaction when conducting wires are placed in an MRI scanner. The radiofrequency and pulsed gradient magnetic fields of the MRI scanner may induce electric currents in leads within the field, if the lead is part of a current loop that is completed through the body. The ratio of lead length versus radiofrequency wavelength and lead conformations, such as loops, are strongly associated with the extent of current induction. Another important potential interaction of devices with MRI is the possibility of heating and tissue damage where the lead tip contacts tissues. The extent of MRI radiofrequency energy deposition in tissues is described by the specific absorption rate (SAR; watts per kilogram). Metallic devices and leads can act as an antenna thus amplifying local radiofrequency energy deposition. Fractured leads or lead loop configurations may increase the potential for heating. Epicardial leads that are not cooled by blood flow and abandoned leads may also be prone to increased heating.

Finally, implanted cardiac devices may provide unnecessary therapies or fail to provide necessary therapies when placed in the MRI scanner. Pacemakers and ICDs have the potential for receiving electromagnetic interference (EMI) in the MRI environment, resulting in radiofrequency noise tracking, asynchronous pacing, inhibition of demand pacing, delivery of ICD therapies, programming changes, or loss of function.

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The static magnetic field of the MRI scanner can also alter device function by inducing unexpected reed switch opening or closure. In addition, temporary programming changes made to avoid device interaction with the MRI scanner (such as disabling of tachycardia therapies) may lead to catastrophic results if a spontaneous arrhythmia occurs and is not recognized.

Nonclinical Testing: In Vitro and In Vivo Studies

Before performing clinical studies of MRI in the setting of implanted cardiac devices, we and others performed extensive in vitro and in vivo animal studies to understand the extent of interactions between MRI and implantable devices and the potential for lead heating, device malfunction, generator movement, and image distortion at 1.5 Tesla.

We started by analyzing the extent of force exerted on pacemaker and ICD generators within the MRI environment. We found that the maximal force acting on modern permanent pacemakers (manufactured after 1996) and ICDs (manufactured after 2000) was <0.98 N (equivalent to 100 g) in a 1.5-Tesla MRI scanner. The maximum torque was 90 gcmd. This amount of force and torque is unlikely to dislodge a chronic device that is anchored to the surrounding tissue. These results are consistent with the findings of Luechinger et al14 on modern pacemakers. However, they found that some modern ICDs may still pose problems because of strong magnetic force and torque.

We measured temperature using an EMI-immune probe connected to the electrode tip (and in ICD leads to the distal and proximal coils). When performing clinical MRI protocols (SAR<2.0 W/kg), temperature changes were limited to 1.0ºC in the vitro model and to 0.2ºC in the vivo model.15 It is important to note, however, that because of poor correlation of heating at different SAR of sequences across different scanners even within the same manufacturer, the SAR limits from each study should not be directly applied to other MRI systems. The extent of heating also varies as a function of lead length and configuration, proximity to the edge of the scanner, proximity to the transmit coil,16 lead insulation thickness, and lead design.16

To complete in vivo testing, we implanted modern ICD systems (manufactured after 2000) from the 3 major US manufacturers in 18 dogs, and after 4 weeks, we performed 3 to 4 hours of MRI examinations with imaging over the region containing the generator, and SAR up to 3.5 W/kg. No device dysfunction occurred. After 8 weeks of follow-up, pacing threshold and intracardiac electrogram amplitude were unchanged, with exception of 1 animal with transient (<12 hours) capture failure. Owing to this observation, we currently do not perform MRI on pacemaker-dependent ICD patients. ICD leads are generally longer than pacemaker leads and may be prone to heating at the lead tip. Pathological data of the scanned animals revealed very limited necrosis or fibrosis at the tip of the lead area, which was not different from controls not subjected to MRI.13 Similarly, Luechinger et al17 found no clear evidence of heat-induced damage on histology, despite observing lead parameter changes in their in vitro model.

A later study from our laboratory assessed the magnitude of MRI-induced current using a current recorder connected in series to single chamber permanent pacemakers programmed to subthreshold asynchronous output during unipolar and bipolar pacing. Under conventional implant conditions (without additional lead loops), the magnitude of induced current was ≤0.5 mA. Current induction at >30 mA resulting in myocardial capture was possible with the addition of >4 lead loops that substantially increased the total circuit area. However, the presence of so many lead loops is never observed in the clinical setting.18 Bassen et al19 have also investigated the possibility of current induction in MRI and reported that unintended stimulation may occur in the setting abandoned leads and leads connected to a pulse generator with loss of hermetic seal at the connector. In addition, Bassen et al19 noted that pacemaker-dependent patients can receive altered pacing pulses during MRI.

Prior Clinical Studies

Implantable Monitors

Gimbel et al20 demonstrated the safety of MRI in the setting of implantable loop recorders in 10 patients that underwent 11 examinations. Abnormalities, including decreased signal amplitude, altered programming, decreased battery status, or inability to communicate with or program the devices, were not observed. Sensations of tugging or warmth at the implant site were not reported. We have also performed thoracic and nonthoracic MRI on numerous implantable loop recorder recipients with similar findings of safety. Patients with an implantable loop recorder can be safely scanned. However, the device may record MRI EMI artifacts as arrhythmia. Care should be taken to clear episodes recorded during MRI to prevent future misinterpretation of artifact as clinically significant arrhythmia. The Reveal (Medtronic, Minneapolis, MN) and Confirm (St Jude Medical, St. Paul, MN) implantable monitors have received MRI conditional labeling.21,22

Temporary Pacemakers

Temporary pacemakers (implanted outside of the electrophysiology laboratory) have leads that are prone to movement. Furthermore, the leads are longer and potentially more susceptible to induction of lead currents and heating. An in vitro study of temporary transvenous pacing leads showed that lead heating exceeding 15ºC is common, and temperature rises up to 63.1ºC are possible.23 In addition, the electronic platform of external temporary pacemakers is less sophisticated and has less filtering compared with modern permanent pacemakers. Therefore, such devices are likely more susceptible to EMI in the MRI environment, and imaging of patients with temporary pacemakers cannot be recommended. We have, however, safely performed MRI in the setting of temporary pacing using an active fixation lead and externalized permanent pacemaker with nonconductive covering adhered to the body with a pressure dressing.

Permanent Pacemakers and ICD

Previous studies of clinical MRI in the setting of permanent pacemakers have been reviewed in Table 1. At our institution, we began the process of imaging patients with permanent pacemakers on the basis of our in vitro and in vivo studies, which
led to the development of a protocol, including (1) device selection based on previous testing, (2) device programming to minimize inappropriate activation or inhibition of brady/tachyarrhythmia therapies, and (3) limitation of the SAR of MRI sequences (<2.0 W/kg). The protocol is discussed in detail below. Using this protocol, we have now safely performed >1500 MRI examinations in patients with implantable devices. Our latest report of safety included 237 patients with permanent pacemakers, 53 of whom were pacemaker-dependent. PAC mode was changed to an asynchronous mode for pacemaker-dependent patients, and to demand mode for others. Blood pressure, ECG, oximetry, and symptoms were monitored. In our series, the primary clinically significant event attributable to MRI was the occurrence of power-on-reset.

Table 1. Clinical Studies of MRI in the Setting of Standard Permanent Pacemakers

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Patients</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gimbel et al</td>
<td>5</td>
<td>No device abnormalities were noted after MRI (0.5 Tesla). A 2-s pause was noted on pulse oximetry in the pacemaker-dependent patient whose device (with unipolar leads) was programmed to dual-chamber asynchronous pacing. Patients did not report generator movement or warmth.</td>
</tr>
<tr>
<td>Sommer et al</td>
<td>18</td>
<td>Reed switch activation and continuous pacing at a fixed rate noted in the static field. Programming changes, damage of components, dislocation/torque of the generator, and rapid pacing were not observed. Atrial and ventricular stimulation thresholds remained unchanged.</td>
</tr>
<tr>
<td>Sommer et al</td>
<td>44</td>
<td>MRI at 0.5 Tesla did not inhibit pacing output or cause pacemaker malfunction.</td>
</tr>
<tr>
<td>Vahlhaus et al</td>
<td>32</td>
<td>Lead impedance and sensing and stimulation thresholds did not change immediately or 3 mo after MRI at 0.5 Tesla. However, diminished battery voltage was noted immediately after MRI with recovery 3 mo later. Reed switch temporary deactivation was seen in 12 of 32 patients when positioned in the center of the bore.</td>
</tr>
<tr>
<td>Martin et al</td>
<td>52</td>
<td>Cardiac, vascular, and general 1.5 Tesla MRI studies were performed. Significant changes were reported in 9.4% of leads; however, only 1.9% required a change in programmed output.</td>
</tr>
<tr>
<td>Del Ojo et al</td>
<td>13</td>
<td>MRI at 2.0 Tesla was unassociated with pacemaker inhibition, inappropriate rapid pacing, or significant changes in device parameters.</td>
</tr>
<tr>
<td>Gimbel et al</td>
<td>10</td>
<td>Seven patients showed a rise or fall of 0.5 V in pacing threshold values between baseline and 3-month follow-up. More patients had a decrease than a rise in pacing capture threshold.</td>
</tr>
<tr>
<td>Sommer et al</td>
<td>82</td>
<td>MRI at 1.5 Tesla was unassociated with inhibition of pacemaker output or induction of arrhythmias. However, increased capture threshold was noted post MRI. In 4 of 114 examinations, troponin increased from a normal baseline value to above normal after MRI (one was associated with a significant increase in capture threshold).</td>
</tr>
<tr>
<td>Nazarian et al</td>
<td>31 (with pacemakers, of 55 total patients)</td>
<td>MRI at 1.5 Tesla was not associated with any inappropriate inhibition or activation of pacing. There were no significant differences between baseline and immediate or long-term (median 99 days after MRI) sensing amplitudes, lead impedances, or pacing thresholds.</td>
</tr>
<tr>
<td>Nazarian et al</td>
<td>44</td>
<td>MRI at 3 Tesla was unassociated with changes in lead impedance, pacing capture threshold, or serum troponin-I.</td>
</tr>
<tr>
<td>Mollerus et al</td>
<td>32 (with pacemakers, of 37 total patients)</td>
<td>MRI at 1.5 Tesla was unassociated with changes in troponin-I levels or pacing capture thresholds.</td>
</tr>
<tr>
<td>Naehle et al</td>
<td>47</td>
<td>Repetitive MRI at 1.5 Tesla (171 examinations on 47 patients) was associated with decreased pacing capture threshold and battery voltage.</td>
</tr>
<tr>
<td>Mollerus et al</td>
<td>46 (with pacemakers, of 52 total)</td>
<td>Ectopy was observed but was unrelated to peak SAR, scan time duration, or landmark. Significant changes in pacing thresholds were not observed.</td>
</tr>
<tr>
<td>Mollerus et al, et al</td>
<td>105 (with pacemakers, of 127 total)</td>
<td>MRI at 1.5 Tesla was associated with decreased sensing amplitudes and pace impedances. Other parameters were unchanged.</td>
</tr>
<tr>
<td>Halshtok et al</td>
<td>9 (with pacemakers, of 18 total)</td>
<td>MRI at 1.5 Tesla was associated with 5 power-on-reset events in 2 patients. No other effects were reported and device replacement was unnecessary.</td>
</tr>
<tr>
<td>Strach et al</td>
<td>114</td>
<td>MRI at 0.2 Tesla was unassociated with changes in lead impedance, capture threshold, or battery voltage.</td>
</tr>
<tr>
<td>Burke et al</td>
<td>24 (with pacemakers, of 38 total)</td>
<td>MRI at 1.5 Tesla was unassociated with device circuitry damage, programming alterations, inappropriate shocks, failure to pace, or changes in sensing, pacing, or defibrillator thresholds.</td>
</tr>
<tr>
<td>Buendia et al</td>
<td>28 (with pacemakers of 33 total patients)</td>
<td>Temporary communication failure in 2 cases, sensing errors during imaging in 1 case, and a safety signal in 1 pacemaker were noted.</td>
</tr>
<tr>
<td>Nazarian et al</td>
<td>237 (with pacemakers, of 438 total patients)</td>
<td>MRI at 1.5 Tesla was associated with 2 power-on-reset events. Statistically significant but clinically small (not requiring device revision or reprogramming) changes in lead parameters were observed.</td>
</tr>
<tr>
<td>Cohen et al</td>
<td>69 (with pacemakers, of 109 total patients)</td>
<td>Decreases in battery voltage of ≥0.04 V in 4%, pacing threshold increases of ≥0.5 V in 3%, and pacing lead impedance changes of ≥50 Ω in 6% were observed. Clinically important differences were not observed between the MRI group and a historic control group.</td>
</tr>
<tr>
<td>Boilson et al</td>
<td>32</td>
<td>Power-on-reset was noted in 5 patients. Magnet-mode asynchronous pacing was seen in 3 patients. Significant changes were not observed in battery voltage, P/R wave amplitudes, pacing thresholds, lead impedances, or cardiac enzymes.</td>
</tr>
</tbody>
</table>

SAR indicates specific absorption rate.
events in up to 1.5% of device recipients. Other investigators have found higher rates of power-on-reset. Aside from transient episodes of asynchronous pacing induced by reed switch activation in certain pacemakers, no episodes of inappropriate inhibition or activation of pacing were observed. The great majority of lead parameters were stable after MRI with <20% change compared with baseline. Statistically, right ventricular sensing and atrial and right and left ventricular lead impedances were reduced immediately after MRI. At long-term follow-up, decreased right ventricular sensing, decreased right ventricular lead impedance, increased right ventricular capture threshold, and decreased battery voltage were noted. The range of immediate and long-term post-MRI lead parameter changes were within 40% of baseline for sensing amplitude, 30% of baseline for impedance, and 50% of baseline for capture threshold. The most prominent changes were seen in immediate post-MRI right ventricular R wave amplitude (median, 0 mV; interquartile range, −0.7 to 0), left ventricular R wave amplitude (median, −0.8 mV; interquartile range, −1.8 to 0.3) and long-term right ventricular R wave amplitude (median, 0 mV; interquartile range, −1.1 to 0.3), and left ventricular R wave amplitude (median, −0 mV; interquartile range, −1.1 to 0.1) measures. The observed changes did not require device revision or reprogramming, and there were no significant differences between baseline and immediate or long-term sensing amplitudes, lead impedances, or pacing thresholds.

Previous studies of clinical MRI in the setting of implanted defibrillators have been reviewed in Table 2. During our in vitro testing of ICDs, we found several generators (manufactured before 2000) that were damaged by MRI. Therefore, in clinical studies, we restricted enrollment to patients with ICD systems manufactured after 2000. On the basis of our prior in vitro and in vivo testing, the safety protocol has now been used to safely perform >400 examinations in patients with ICDs. Our latest report of safety included 201 patients with ICD systems. All examinations were completed safely and no inappropriate tachycardia therapies were delivered.

We continue to track the safety of MRI with larger patient numbers and new pacemaker and ICD systems. Other groups of investigators are also studying MRI safety in the setting of implanted devices (Tables 1 and 2). A noteworthy study is the ongoing MagnaSafe Registry, a multicenter, prospective study designed to determine the frequency of major adverse clinical events and device parameter changes for 1500 patients with standard implantable cardiac electronic devices who undergo clinically indicated, nonthoracic MRI at 1.5 Tesla.

### Retained Leads

Retained leads are prone to previously described risks of heating and current induction. Depending on the lead length and configuration, retained segments may be prone to significantly higher temperature rises than those attached to pulse generators. It has been our practice to exclude patients with retained lead fragments and unused capped leads from MRI. However, we have performed 2 MRI examinations in the setting of absolute clinical necessity and a retained lead segment. Both studies were completed without safety issues. More studies are warranted to accurately delineate the risks and benefits of MRI in this patient group.

### Safety Protocol for MRI of Patients With Implanted Devices

The safety protocol followed at our institution has been summarized as a checklist in Figure 1. The protocol is based on selection of device generators previously tested with prolonged imaging over the region containing the generator, and SAR up to 3.5 W/kg. To perform MRI on patients with implanted devices, we recommend that device generators prone to EMI (generally devices manufactured before 2000) be excluded. A report of safe MRI immediately post implant exists in the literature, and the risk for lead and generator movement is extremely low. However, we recommend conservative measures to exclude patients with leads that are prone to spontaneous (regardless of MRI) dislodgement or do not have chronic stable lead parameters. Therefore, we recommend avoiding MRI in patients with <6 weeks’ time since device implant and those with acute parameter changes suggestive of lead malfunction. However, in our experience, patients with mature active and passive fixation endocardial (and coronary sinus) leads of any diameter can safely undergo MRI. We do recommend avoidance of MRI when device leads that are prone to heating, such as nontransvenous epicardial and abandoned (capped) leads, are present. To reduce the risk of inappropriate inhibition of pacing due to detection of radiofrequency pulses, we prefer device programming to an asynchronous, dedicated pacing mode in pacemaker-dependent patients. Also, given the lack of asynchronous pacing programming capability and transient loss of pacing capture after worst-case scenario (SAR 3.5 W/kg for 3 hours) in vivo testing of 1 of 15 animals implanted with an ICD, we recommend excluding pacemaker-dependent patients with ICDs. To avoid inappropriate activation of pacing due to tracking of radiofrequency pulses, we suggest device programming in patients without pacemaker dependence to a nontracking ventricular or dual-chamber–inhibited pacing mode. We also recommend deactivation of rate response, premature ventricular contraction response, ventricular sense response, and conducted atrial fibrillation response to ensure that sensing of vibrations or radiofrequency pulses does not lead to unwarranted pacing. Although asynchronous pacing for short time periods is typically well tolerated, we prefer to reduce the already minimal chance of inducing arrhythmia or causing atrio-ventricular dyssynchrony by minimizing asynchronous pacing in patients without pacemaker dependence through deactivation of the magnet mode when possible. We typically deactivate tachycardia monitoring to avoid battery drainage that results from recording of multiple radiofrequency pulse sequences as arrhythmic episodes. Reed switch activation in ICD systems disables tachycardia therapies. However, reed switch function in the periphery versus the bore of the magnet is unpredictable; therefore, therapies should be disabled to avoid unwarranted antitachycardia pacing or shocks. Finally, blood pressure, ECG, pulse oximetry, and symptoms should be monitored for the duration of the examination. We also favor the presence of a radiologist and cardiac electrophysiologist, or advanced cardiac life support trained individual familiar with device programming and trouble shooting during all scans. At the end of the examination all device parameters should be checked, and programming should be restored to pre-MRI settings.
Table 2. Clinical Studies of MRI in the Setting of ICDs

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Patients</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coman et al⁴⁵</td>
<td>11</td>
<td>One patient felt mild heating near the generator during spin echo sequences. One patient had a brief, but asymptomatic, pause in pacing during scanning. One patient with a device past the elective replacement interval had power-on-reset, and the device could not be interrogated after the scan. Normal device function and circuit integrity were noted at destructive testing.</td>
</tr>
<tr>
<td>Gimbel et al⁴⁶</td>
<td>7</td>
<td>No changes in pacing, sensing, impedances, charge times, or battery status were observed with MRI at 1.5 Tesla. However, 1 implantable cardioverter defibrillator (Medtronic 7227Cx, lumbar spine MRI) experienced a power-on-reset.</td>
</tr>
<tr>
<td>Nazarian et al⁴²</td>
<td>24 (with ICDs, of 55 total patients)</td>
<td>MRI at 1.5 Tesla was not associated with any inappropriate inhibition or activation of pacing. There were no significant differences between baseline and immediate or long-term (median 99 days after MRI) sensing amplitudes, lead impedances, or pacing thresholds.</td>
</tr>
<tr>
<td>Mollerus et al⁴⁴</td>
<td>5 (with ICDs, of 37 total patients)</td>
<td>MRI at 1.5 Tesla was unassociated with changes in troponin-I levels or pacing capture thresholds.</td>
</tr>
<tr>
<td>Naehle et al⁴⁷</td>
<td>18</td>
<td>MRI at 1.5 Tesla was unassociated with device circuitry damage, changes in lead parameters, or troponin-I levels. However, battery voltage decreased post MRI, and oversensing of EMI as ventricular fibrillation occurred in 2 devices, but therapies were not delivered.</td>
</tr>
<tr>
<td>Mollerus⁴⁶</td>
<td>6 (with ICDs, of 52 total)</td>
<td>Electropy was observed but was unrelated to peak SAR, scan time duration, or landmark. Significant changes in pacing thresholds were not observed.</td>
</tr>
<tr>
<td>Pulver⁴⁶</td>
<td>8</td>
<td>Inappropriate pacing or significant changes in generator or lead parameters were not observed.</td>
</tr>
<tr>
<td>Mollerus et al³⁷</td>
<td>22 (with ICDs, of 127 total patients)</td>
<td>MRI at 1.5 Tesla was associated with decreased sensing amplitudes and pace impedances. Other parameters were unchanged.</td>
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<tr>
<td>Halshtok et al³⁸</td>
<td>9 (with ICDs, of 18 total patients)</td>
<td>MRI at 1.5 Tesla was unassociated with any untoward effects, and device replacement was unnecessary.</td>
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<tr>
<td>Burke et al⁴⁰</td>
<td>14 (with ICDs, of 38 total patients)</td>
<td>MRI at 1.5 Tesla was unassociated with device circuitry damage, programming alterations, inappropriate shocks, failure to pace, or changes in sensing, pacing, or defibrillator thresholds.</td>
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<td>5 (with ICDs of 33 total patients)</td>
<td>Sensing errors during imaging in 1 case was noted.</td>
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<td>Nazarian et al⁴²</td>
<td>201 (with ICDs, of 438 total patients)</td>
<td>MRI at 1.5 Tesla was associated with 1 power-on-reset event. Statistically significant but clinically small (not requiring device revision or reprogramming) changes in lead parameters were observed.</td>
</tr>
<tr>
<td>Cohen et al⁴³</td>
<td>40 (with ICDs, of 109 total patients)</td>
<td>Decreases in battery voltage of ≥0.04 V in 4%, pacing threshold increases of ≥0.5 V in 3%, and pacing lead impedance changes of ≥50 Ω in 6% were observed. Clinically important differences were not observed between the MRI group and a historic control group.</td>
</tr>
</tbody>
</table>

EMI indicates electromagnetic interference; ICD, implantable cardioverter defibrillators; and SAR, specific absorption rate.

MRI Quality in the Setting of Implantable Cardiac Devices

Image quality is not affected when the pacemaker or ICD is located outside the field of view. In our experience, diagnostic questions were answered in 98.8% of nonthoracic sequences, and MRI often illuminated diagnoses missed by alternative imaging (Figures 2 and 3). However, when performing thoracic imaging, the presence of a pacemaker or ICD system can cause variations in the surrounding magnetic field resulting in image distortion, signal voids or bright areas, and poor fat suppression. Such artifacts are most pronounced on inversion recovery and steady state sequences. The artifact area is significantly larger with ICD versus pacemaker generators. Greater than 50% of cardiac sectors (primarily anteroapical segments) can be affected by generator susceptibility artifacts in patients with left-sided ICD systems.⁵⁶ Artifacts on inversion recovery images show high signal intensity and can mimic areas of delayed enhancement, which would otherwise indicate myocardial fibrosis. Correlation of artifactually bright areas on different pulse sequences can help avoid misidentification of artifact. Selecting imaging planes perpendicular to the plane of the device generator, shortening the echo time, and using spin echo and fast spin echo sequences reduces the qualitative extent of artifact. Using such techniques, images of sufficient quality to answer diagnostic questions can be obtained in most of the cases (Figure 4).

MRI Conditional Devices

Given the public health importance of the capability to perform MRI in the expanding population of implantable cardiac device recipients, all device manufacturers have made significant efforts to develop devices specifically designed for safety in the MRI environment. Such new technologies will enable MRI examinations of pacemaker and ICD recipients with reduced concern regarding the short- and long-term safety issues, and may eventually reduce the need for monitoring by dedicated personnel.

The term MRI conditional refers to devices that pose no known hazards when MRI is performed with specific device programming and monitoring conditions, and using specified imaging protocols and MRI magnetic strength and scanner types.⁵⁷ The modifications in MRI conditional devices are often proprietary. However, depending on the manufacturer, the modifications may include minimization of ferromagnetic materials, as well as lead modifications in conductor design and filtering to mitigate heating and current induction. In
addition, the EnRhythm MRI conditional system uses a Hall sensor instead of a reed switch to achieve predictable behavior within magnetic fields. Other modifications typically include a specific device module to simplify the steps for MRI safe programming. For example, in the EnRhythm MRI conditional system, the program features include a binary choice between asynchronous (VOO/DOO) with increased pacing output to 5.0 V at 1.0 ms and nonstimulation (VVI/DDI) modes. In addition, the MRI safe mode can be enabled only following a successful system integrity check.

Forleo et al59 studied the safety of EnRhythm system implantation in a study that included 107 patients who underwent implantation of either an MRI conditional device or a conventional dual-chamber device. No complications were observed during the follow-up period. Given the increased diameter of the MRI conditional leads, there was a trend toward failure of cephalic vein access in patients who received MRI conditional leads (60.0%; CapSure Fix 5086 lead, Medtronic, Minneapolis, MN; diameter, 2.3 mm) compared with patients who received conventional leads (68.4%; CapSure Fix Novus 5076 lead, Medtronic, Minneapolis, MN; diameter, 2.0 mm). In parallel, there was a trend to higher use of subclavian venous access for at least 1 lead in patients with MRI conditional leads (40.0% versus 31.6%, respectively). There was no difference in procedure times (71.7±27.6 minutes versus 76.9±30.3 minutes), fluoroscopy time (6.0±3.6 minutes versus 6.6±3.8 minutes), or duration of hospitalization. This preliminary study was followed by a randomized prospective multicenter study that enrolled 484 patients, 464 of whom were implanted with the EnRhythm MRI conditional system. The study recruited both pacemaker-dependent and nonpacemaker-dependent patients. Of 258 patients randomized to undergo MRI, 211 patients underwent the examination at 1.5 Tesla. Avoidance of MRI before 6 weeks after implantation was to
ensure stability of the pacing capture threshold so that any detected changes would be clearly attributable to MRI rather than normal lead maturation. The maximum SAR was set to 2 W/kg, and the maximum gradient slew rate was limited to 200 Tesla/m per second. During these examinations, the imaging iso-center was limited to the level above the superior surface of C1 vertebra and below the inferior surface of the body of T12. No events were observed during the scan and no system-related complications, such as lead dislodgement, elevated capture thresholds, pericardial effusion, or failure to capture, were attributable to MRI. In addition, no differences between the MRI group and the 206 patients randomized to a control group were detected with regard to the proportion of patients that experienced an increase in capture threshold, the proportion that did not maintain sensed electrogram amplitudes >1.5 mV (atrial lead) or >5 mV (ventricular lead), or the proportion with impedance changes. As a result of this study, and the supporting bench and animal testing and computer modeling, the US Food and Drug Administration approved the Revo MRI Pacemaker System with 5086 MRI CapSureFix MRI Pacing Leads (Medtronic) and the SureScan Software (Medtronic) as MRI conditional.58

In Europe, additional MRI conditional pacing systems (Accent MRI, St Jude Medical, St. Paul, MN60; Evia and Estella, Biotronik, Berlin, Germany61; Ingenio and Advantio, Boston Scientific, St. Paul, MN)59 and MRI conditional ICD/Cardiac resynchronization therapy systems (Lumax 740, Biotronik, Berlin, Germany)60 are commercially available. Importantly, in addition to specified MRI and programming protocols, these systems are approved for MRI with specific leads (eg, CapSureFix, Medtronic, Inc, Minneapolis, MN; Tendril MRI, St Jude Medical, St. Paul, MN; and Linosxsmart, Biotronik, Berlin, Germany). In addition, the currently approved MRI field strength is 1.5 Tesla, and higher or lower field strengths are not approved.

**Future Directions**

MRI systems with a magnetic strength of 3 Tesla offer improved signal/noise ratio, spatial resolution, and speed, which result in improved image quality and diagnostic strength. Therefore, the use of these systems for neurological, musculoskeletal, abdominal, and cardiovascular applications is increasing. Safety issues, however, are also magnified at 3 Tesla. Importantly, higher power radiofrequency pulses

Figure 2. Cervical spine computed tomography (CT) vs MRI in a patient with neck pain and fever. The CT image in the left panel shows degenerative changes and possible C3-4 spinal stenosis, but no evidence of epidural or soft tissue abscess. The T1-weighted MRI of the same patient in the right panel shows signal hypo-intensity in the C3-4 vertebral bodies in addition to abnormal signal in the para-vertebral soft tissues consistent with osteomyelitis and epidural phlegmon with mass effect upon the cervical spinal cord. C3 indicates cervical vertebral body 3; C4, cervical vertebral body 4; and T1 hypo-intensity, hypo-intensity on T1-weighted image.

Figure 3. Brain computed tomography (CT) vs MRI in a patient with weakness. The CT image in the left panel shows no evidence of acute infarction. The MRI of the same patient (obtained the same day) in the right panel shows acute left parietal infarction (arrow).

Figure 4. Cardiac computed tomography (CT) vs MRI in a patient with facial swelling. The CT image in the left panel reveals a poorly defined filling defect of the right atrium. The MRI in the right panel reveals a sarcoma which extends from the anterior mediastinum to the interatrial septum, completely obliterates the right atrial cavity (note difference in signal intensity of right atrial mass vs left atrial cavity), compresses the left upper lobe pulmonary vein, and abuts the aortic root. The extent of lead “star” artifact in the CT panel is significantly larger than the lead susceptibility artifact with MRI. The bottom panel shows a right lateral 3D MRI reconstruction with minimal device or lead artifact. The sarcoma nearly completely obstructs the superior and inferior vena cava. IVC indicates inferior vena cava; LA, left atrium; and SVC, superior vena cava.
increase the potential for tissue heating, and stimulation effects from stronger and higher frequency switching gradients exist.

Although there is limited experience in scanning patients with cardiac devices in 3-Tesla MRI scanners, the general notion is that there is no significant increase in adverse events. Gimbel et al reported results from 16 MRI examinations at 3 Tesla, in patients with cardiac devices (9 pacemakers, 6 ICDs, and 1 implantable loop recorder). The authors observed no arrhythmia or changes in programmed parameters, pacing capture thresholds, sensing, impedance, or battery parameters. One patient, however, reported a sensation of burning in his chest during the scan. Later on, Gimbel reported 2 cases of inhibition of pacing during MRI in a 3-Tesla scanner. The first patient was a pacemaker-dependent patient, who was programmed to an asynchronous mode. She underwent MRI using a 3-Tesla scanner. During the beginning of the scan, power-on-reset to the inhibited back up mode (VVI) was observed which was followed by asystole. This important event is an example of EMI-induced output inhibition, which can occur at any magnetic strength and underscores the importance of close monitoring during MRI. The second patient had a previously implanted ICD and had underlying sinus bradycardia. The ICD therapies were turned off, and the device was set to an atrial inhibited (AAI) pacing mode at 70 ppm. On moving the patient into the MRI bore and before application of radiofrequency or gradient magnetic fields, pacing was inhibited. The phenomenon was attributed to the magnetohydrodynamic effect; inhibition of pacing because of current induction from the to-and-fro motion of MRI induced charged ions contained in blood within the aortic root. The patient had a stable escape rhythm, and the examination was completed without safety issues.

Importantly, all current MRI conditional devices were studied using scanner systems with static magnetic fields of 1.5 Tesla, and none are currently approved for use in 3-Tesla scanner systems. However, because of increasing use of 3-Tesla scanners, the experience with MRI at this magnetic strength in the setting of standard and MRI conditional systems will likely grow in the near future.

As a result of the data collection methodology in the United States which limited the imaging iso-center, the US Food and Drug Administration (and not the Conformité Européenne) approval of the Revo MRI Pacemaker System is limited to above the superior surface of C1 and below the inferior surface of the T12 vertebra. The thoracic iso-center restriction may reduce the image signal/noise ratio and resolution. Optimal thoracic MRI with high signal/noise ratio is often necessary for assessment of myocardial viability; investigation of infiltrative processes of the heart, lung, and chest wall; assessment of mass lesions in the thorax; visualization of lymph nodes; blood vessels; vascular and lymphatic malformations of the chest; assessment of musculoskeletal disorders, including pathologies contained to the thoracic spine; and characterization of mediastinal or pleural lesions. Thus, it is highly important to study the safety of MRI conditional devices with MRI iso-center between C1 and T12 and to characterize the extent of artifacts compared with nonconditional devices.

Summary

MRI is the preferred imaging modality in many clinical scenarios. The decision to perform MRI in patients with implantable cardiac devices is frequently made by considering the potential benefit of MRI relative to the attendant risks. Given the potential risks, it is important to conduct a systematic review of the patient’s condition and implanted devices before proceeding with MRI. The arrival of MRI conditional devices will likely improve the safety and routine availability of MRI. However, as the number of device recipients undergoing MRI examination and the number of centers performing MRI in this setting increase, it is ever more important that all centers use updated checklists for patient safety, such as that in Figure 1. The reader is encouraged to consult other resources, such as the American Heart Association Scientific Statement, and web sites that provide specific information on individual devices (eg, http://www.mrisafety.com).

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