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Magnetic resonance imaging for patients with cardiac implantable electrical devices

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Abstract

Magnetic resonance imaging (MRI) has become an invaluable tool in the evaluation of both soft tissue and bony abnormalities, with an increasing number of studies ordered per year. The presence of a cardiac implantable electrical device (CIED) may complicate matters, however, as these devices are currently considered a relative contraindication to MRI scanning. When performed in patients with a CIED, risks of MRI include reed switch activation in older devices, lead heating, system malfunction, and significant radiofrequency noise resulting in inappropriate inhibition of demand pacing, tachycardia therapies, or programming changes. This report reviews the common indications and risk-benefit evaluation of MRI in patients with CIED, and provides a clinical algorithm which has been successfully implemented at our institution for performing MRI in patients with implanted devices.

Keywords

Magnetic resonance imaging; pacemaker; defibrillator; cardiac implantable electrical device

INTRODUCTION

The use of magnetic resonance imaging (MRI) for the diagnosis of soft tissue and bony abnormalities is increasing, as scanners have become more available throughout the United States. Magnetic resonance scans yield higher spatial resolution than computed tomographic images, without the need for ionizing radiation or iodinated contrast injection.[Marcu 2006] At present, almost two million Americans have CIEDs [Nazarian 2011], and an estimated

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50-75% of these individuals will have an indication for MRI during the lifetime of their device.[Kalin 2005, Levine 2007] The body of evidence reporting the successful use of MRI in patients with CIEDs is growing [Martin 2004, Gimbel 1996, Sommer 2000, Valhaus 2001]. Here, we review the risks and recent literature on the use of MRI in patients with CIEDs, and report our institution's safety protocol.

KNOWN RISKS ASSOCIATED WITH MRI

Current guidelines from the American Heart Association discourage MRI scanning in non-pacemaker-dependent patients, except in cases with a strong clinical indication ("highly compelling") where benefits clearly outweigh the risks and an alternative diagnostic modality is unavailable.[Levine 2007] There are three major sources of risk associated with MRI with regard to implantable devices. First, CIED components are subject to potential magnetic field-induced force and torque, that might result in lead tip or internal reed switch activation (in older devices) – the latter of which could permanently disable tachycardia therapies or result in asynchronous pacing.[Roguin 2004, Nazarian 2006] Electrical current may also be induced by the magnetic field and result in myocardial capture and rarely, ventricular or atrial arrhythmia induction. Device leads can also act as an antenna and amplify local energy deposition, resulting in lead heating, tissue damage, and resultant sensing or capture threshold changes.[Sommer 2006, Vahlhaus 2005] Radiofrequency noise may also result in inappropriate inhibition of demand pacing, tachycardia therapies, or programming changes. Early use of MRI in patients with CIEDs resulted in suboptimal outcomes or even death in a small number of patients;[Roguin 2008] therefore, several institutions initiated MRI protocols to evaluate the safety of this imaging modality for strong clinical indications.

THE HOPKINS PROTOCOL

Our institution initiated a protocol for both non-cardiac and cardiac MRI over 10 years ago in patients with either permanent pacemakers or ICDs.[Nazarian 2006] Since its inception, our program has successfully performed greater than 1,500 MRI examinations under an institutional review board-approved research protocol (Figure 1)[Nazarian 2011]. Imaging at our institution was performed using 1.5 Tesla scanners. Patients with newly implanted (<6 weeks), abandoned, or epicardial leads were excluded, as well as those who are pacemaker-dependent with ICD devices. All patients signed an informed consent form that delineated potential risks as discussed above.

In its first stage, our protocol assists the provider by screening out devices which have no significant data supporting their safe use with MRI technology. Subsequent stages include device reprogramming to minimize both inappropriate device activation of tachycardia therapies and inhibition of bradycardia therapies, pre-scan and post-scan lead parameter checks, and restoration of original programming settings. For most patients, an inhibited pacing mode is programmed for the duration of the MRI scan, and if the device is an ICD, tachycardia therapies are disabled. In pacemaker-dependent patients, an asynchronous mode is chosen to minimize risks of inappropriate pacing inhibition. Following the scan, our

institution strongly encourages long-term follow-up 6 months after MRI to ensure no significant chronic changes in device parameters.

In the first 555 MRI studies performed at our institution in patients with CIEDs [Nazarian 2011], the median age of patients undergoing the scan was 68 years. Roughly half of patients had pacemakers (54%), while the other half (46%) had ICDs. Most scans were performed for brain (40%) or spine (22%) imaging, with indications including abscess or infection, mental status changes, stroke, seizure, and radiculopathy. A smaller number of scans (16%) were used to evaluate cardiac viability and/or cardiomyopathy. When comparing immediate changes following MRI to pre-scan values, we observed small changes in right ventricular sensing and various lead impedances. Although statistically significant, no changes were clinically significant enough to require system revision or device reprogramming.

Three patients in our cohort experienced power-on-reset episodes. In one patient (who had a single-chamber ICD), a “pulling sensation” was noted and the MRI scan was stopped. In the other two patients (who both had pacemakers, and were not pacemaker-dependent), the scan was continued. Occasional pacing inhibition was noted with reversion to an inhibited pacing mode, but no immediate or long-term adverse events were seen in follow-up in any of these three individuals.

In addition to our expanding experience, the MagnaSafe Registry is an on-going, multi-center, prospective cohort study of up to 1,500 MRI examinations in patients with either pacemakers or ICDs undergoing non-thoracic MRI.[Russo 2013] As of August 2012, 701 MRI scans had been performed. The registry utilizes a safety protocol similar to our own, in that patients with an ICD who are pacemaker-dependent are referred for a different imaging modality, while those who are not dependent undergo reprogramming to a monitoring-only mode (OVO/ODO). Patients with pacemakers are also divided into two groups: those who are device-dependent (with reprogramming to an asynchronous mode, VOO/DOO) and those who are not (set to monitoring-only). All patients then undergo MRI examination, followed by restoration of initial programming and evaluation of parameter changes. Follow-up interrogation is planned at 7 days, 3 months, and 6 months if post-scan parameters have significantly changed, or at 3 and 6 months if no significant changes are detected. Results of the MagnaSafe Registry are expected to add to the body of literature regarding the safety profile of MRI scanning in patients with devices implanted after 2001.

MRI WITHIN SIX WEEKS OF DEVICE IMPLANTATION

The protocol previously reported from our institution excludes patients who have newly-implanted leads. A recent publication by Friedman and colleagues,[Friedman 2013] however, reported outcomes from 171 patients who underwent MRI scanning with CIEDs, including 8 patients who received an MRI scan within 42 days of new lead implantation. All studies were performed in a 1.5 Tesla MRI scanner, and patients were excluded if they were pacemaker-dependent or had more than one implanted generator. An asynchronous pacing mode (AOO, VOO, or DOO), programmed to 20 beats above the intrinsic rate, was used if

the intrinsic rate was 90 beats per minute. If the intrinsic rate was 90 beats per minute, a monitor-only mode (OAO, OVO, ODO) was programmed.

Of the 8 patients in the early cohort, one had a “permanent-temporary” system in place, using an active fixation right ventricular lead (Medtronic 5076) attached to an externalized pacemaker generator (Medtronic Sensia) secured to the patient’s skin. In a different individual, right ventricular lead impedance increased from 550 to 950 ohms following MRI scanning, but there were no significant changes in sensing or capture thresholds. Overall, there were no clinically-significant complications for any patient in the early cohort, suggesting that recent lead implantation (within 6 weeks) is not an absolute contraindication to MRI scanning. We have also performed MRI in 2 patients with acutely implanted systems and another 2 patients with temporary systems with active fixation right ventricular leads and an externalized permanent pacemaker in the setting of absolute urgency for imaging. All examinations were completed uneventfully without significant changes in system parameters.

STATE-OF-THE-ART: MRI-CONDITIONAL DEVICES

At present, medical devices are categorized into one of three groups by the American Society for Testing and Materials (ASTM): i) “MR-safe”: an item that poses no known hazards in an MR environment; ii) “MR-conditional”: an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use; and iii) “MR-unsafe”: an item that is known to pose hazards in all MR environments. [ASTM ref] Although a recent review[Zikria 2011] of 1,400 pacemaker recipients with non-MR-conditional devices revealed no fatalities associated with MRI in the modern era, the use of this technology cannot be considered safe in all settings. Device manufacturers are now addressing the need for MRI-compatible devices with several different “MR-conditional” systems in varying stages of Food and Drug Administration (FDA) approval, with several prominent studies described below.

Initial safety and efficacy studies regarding MR-conditional devices were performed largely in European centers, with the first clinical report by Forleo et al. in 2010.[Forleo 2010] During an 11-month study period, 107 patients (34% female, mean age 73) were implanted with either an MR-conditional Revo system (n=50) consisting of an EnRhythm MRI pulse generator and CapSureFix 5086 MRI leads (Medtronic Inc., Mounds View, MN), or a standard dual-chamber pacemaker (n=57). In the novel system, the leads were modified to reduce radiofrequency lead tip heating, internal circuits were changed to reduce the potential for cardiac stimulation, ferromagnetic materials used for construction were limited, and internal circuits were protected to prevent disruption of the internal power supply. Further, the reed switch was replaced by a Hall sensor to allow improved predictability in a static magnetic field. Study results found that upon serial follow-up, lead and pacing parameters were stable in both study groups. Neither group experienced clinically-significant complications or lead dislodgement.

In 2011, Wilkoff and colleagues published the results of a prospective, randomized, controlled trial utilizing the same MR-conditional dual chamber pacemaker system (Revo/

EnRhythm) with the addition of randomization to MRI scanning versus no scan.[Wilkoff 2011] A total of 484 patients were enrolled, and 258 were randomized to an MRI scan 9-12 weeks post-implant in a 1.5T scanner. All patients were seen and evaluated at 3 and 4 months post-implant. Overall, the study found no MRI-related complications at the time of the scan, with minimal changes in capture threshold or sensed electrogram amplitude between study groups. Further, MRI scanning with the Revo system was not associated with any major or minor complications through the end of the study period.

The Advisa MRI study, a prospective, randomized controlled trial, enrolled 269 subjects (with 263 implants) from 35 centers internationally.[Gimbel 2013] The protocol utilized the second-generation Advisa SureScan MRI pacemaker system, consisting of an Advisa MRI implantable pulse generator and two CapSureFix 5086 MRI leads (Medtronic Inc.; Mounds View, MN). Patients were randomized in a 2:1 fashion to 16 chest and head MRI evaluations in a 1.5T scanner 9-12 weeks post-implant, versus no scan. The system passed both primary endpoints, demonstrating no significant increase in MRI-related complications or capture threshold from pre-versus one month post-MRI scan in the intervention group. The Advisa pacemaker system was FDA-approved for scanning from above C1 and below T12 in February 2013. We have safely performed thoracic MRI in patients with Medtronic MR-conditional systems using our safety protocol for standard pacemakers. The Revo and Advisa systems and their leads include a distinctive radiographic device label and lead appearance to allow identification by chest x-ray. Similar studies are underway to evaluate pacing systems from other major device manufacturers, including:

- The Accent MRI pacemaker with Tendril MRI lead (St. Jude Medical; St. Paul, MN),[Clinical Trial NCT01576016]. The Accent MRI system also has distinct radiopaque markers for quick radiographic identification of the system.
- The ImageReady pacemaker system comprised of an Ingenio MRI pulse generator with the Ingevity lead platform (Boston Scientific; Natick, MA), [Clinical Trial NCT01781078].
- The Evia/Entovis ProMRI pacemaker with Safio S pacing leads (Biotronik SE & Co. KG; Berlin, Germany).[Clinical Trial NCT01460992].

Thus far, however, none of these three latter systems have been FDA-approved for use in the United States.

EARLY CLINICAL EXPERIENCES WITH LEAD-RELATED COMPLICATIONS

As of the writing of this report, there have been two recent publications [Rickard 2013, Elmouchi 2013], which did find an increased incidence of clinically-significant adverse events in patients receiving MR-conditional pacemaker leads. In a retrospective case-control study of 65 consecutive patients implanted with two 5086 MRI leads compared with 92 consecutive control patients implanted with two 5076 leads over a 14-month period, Elmouchi and colleagues identified a significantly higher complication rate (including lead dislodgement, cardiac perforation, tamponade, or death) within 30 days in 8 out of 65 cases (12.3%) versus 2 out of 92 controls (2.2%), yielding an odds ratio of 6.3 (95% CI 1.3 – 30.8,

$p=0.02$) for an adverse event. Four patients receiving 5086 MRI leads experienced lead dislodgement, while none were seen in the 5076 group ($p<0.03$).

When evaluating a larger cohort of 466 patients enrolled prospectively in the EnRhythm MRI study (each receiving two 5086 MRI leads) versus 316 patients receiving two 5076 leads in previous clinical studies, Rickard et al. also identified a higher lead dislodgement rate (3.8%) with the 5086 MR-conditional lead when followed over a mean 30.8 month period, compared to the 5076 lead (0.6%; $p=0.05$) when followed for a mean 9.6 months. In this study, the overall rate of cardiac perforation was not significantly different between groups (0.6% for the 5086 MRI group vs. 0.9% for control), and there were otherwise no clinically-significant differences in lead performance.

SUMMARY

In many situations, the clinical utility of MRI scans may outweigh the risk of performing the study in patients with a CIED. MRI evaluations can be performed safely in patients with certain pacemaker and ICD systems, using a protocol based on device selection, appropriate device reprogramming, and close monitoring during the scan. MRI should only be performed in cases where the potential benefit clearly outweighs the risks, and with adequate subspecialty supervision and monitoring equipment. At present, the vast majority of available data has been obtained in closed-bore scanners with a magnetic strength of 1.5 Tesla; thus, results of these studies should not be generalized to all MRI scanners. An FDA-approved, MR-conditional pacemaker system is now available for use in the United States, with all major device companies in the process of refining their technology. Continued monitoring of MR-conditional leads will be needed to ensure that complication rates remain reasonable in comparison to the benefit attained.

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KEY POINTS

- The clinical utility of MRI scans may outweigh the risk of performing the study in patients with a CIED.
- MRI evaluations can be performed safely in patients with certain pacemaker and ICD systems, using a protocol based on device selection, appropriate device reprogramming, and close monitoring during the scan.
- MRI should only be performed in cases where the potential benefit clearly outweighs the risks, and with adequate subspecialty supervision and monitoring equipment.
- An FDA-approved, MR-conditional pacemaker system is now available for use in the United States, with all major device companies in the process of refining their technology.
- Continued monitoring of MR-conditional leads will be needed to ensure that complication rates remain reasonable in comparison to the benefit attained.

Figure 1. Hopkins safety protocol for MRI use with a cardiac implantable electrical device

DDI = dual-chamber inhibited pacing without atrial tracking; DOO = dual-chamber asynchronous pacing; ECG = electrocardiography; ICD = implantable cardioverter-defibrillator; MRI = magnetic resonance imaging; PVC = premature ventricular contraction; VOO = ventricular asynchronous pacing; VVI = ventricular inhibited pacing. Adapted from Nazarian S, Hansford R, Roguin A, et al. A prospective evaluation of a protocol for magnetic resonance imaging of patients with implanted cardiac devices. *Ann Intern Med* 2011;155:415-24; with permission.