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SAFETY OF MRIS IN PATIENTS WITH PACEMAKERS AND DEFIBRILLATORS

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Abstract

With a burgeoning population, increases in life expectancy, and expanding indications, the number of patients with cardiac devices such as pacemakers and implantable cardioverter defibrillators continues to increase each year. A majority of these patients will develop an indication for magnetic resonance imaging (MRI) in their lifetime. MRIs have established themselves as one of the most powerful imaging tools for a variety of conditions. However, given the historic safety concerns, many physicians are reluctant to use MRIs in this patient population. In this paper, we discuss the potential adverse effects of MRIs in patients with cardiac devices, review key studies that have addressed strategies to limit adverse effects, and provide our cardiovascular MRI laboratory's protocol for imaging patients with implanted cardiac devices.

Introduction

Magnetic resonance imaging (MRI) is considered the imaging modality of choice for diagnosing many musculoskeletal, central nervous system, and cardiovascular disorders.[1-6] It offers great resolution and delineation of soft tissue without the use of nonionizing radiation and iodine contrast administration. Cardiovascular MRIs are particularly advantageous for evaluating cardiac masses, infiltrative cardiac diseases, valvular structures, complex congenital cardiac lesions, and myocardial viability.[1] It is estimated that up to 75% of patients with pacemakers (PMs) and implantable cardioverter defibrillators (ICDs) will develop at least one indication for an MRI study following their device implantation.[7] These studies are routinely denied due to historical concerns surrounding the safety of MRIs in patients with cardiac devices. This is of great significance as there are certain clinical situations in which an MRI would clearly be the best modality for the patient.

In 2011, the U.S. Food and Drug Administration (FDA) approved the first magnetic resonance (MR) conditional pacemaker, the Medtronic EnRhythm MRI™ SureScan™ pacing system (Medtronic, Inc., Minneapolis, Minnesota), which included both device and leads. While this allowed MRI scanning in patients implanted with the device after its approval, it did not address the needs of patients with devices implanted before 2011, with devices by other manufacturers, or for patients with implanted defibrillators (there are currently no FDA-approved defibrillators).

The safety of performing MRI scans in patients with pacemakers and defibrillators has always been a concern, especially given the fatalities that occurred before 1996. During the last decade, at least 17 fatalities in patients with pacemakers have been reported worldwide. It is important to note that all of these instances involved an MRI being performed without appropriate physician supervision.[8, 9] The major safety concerns include mechanical forces and induced currents generated by the electromagnetic (EM) field, alterations in device programming, and induction of thermal energy in the leads, which may cause tissue injury.

There have been significant improvements in cardiac device construction to mitigate the effects of the EM field—for example, restricting ferromagnetic content and incorporating titanium and its alloys, smaller device size, and the use of bipolar leads. EM interference is minimized with improved band pass filters and shielding. The new generation of MR conditional devices contains further modifications that allow for safe use of MRI under pre-specified conditions.

In this paper, we discuss some of the significant safety concerns in performing MRIs in patients with implanted cardiac devices, review the most important clinical studies on MRI safety with these patients, and present data for the newest MR conditional devices.

Safety Concerns

The adverse effects of MRI on PMs and ICDs are either mechanical or induced via electromagnetic interference (EMI). A rapidly changing EM field will induce a force in ferromagnetic materials such as cobalt, nickel, and iron. The use of these materials in cardiac devices can cause net torque within the MRI machine. The generated torque can theoretically result in device movement and lead dislodgement, especially in leads that are less than 6 weeks post-implant or not fixated. To resolve this issue, newer devices incorporate titanium or its alloys and limit the use of ferromagnetic materials. Torque generation is also reduced by smaller device size. The estimated force experienced by PMs and ICDs under such conditions is no more than 0.05 to 3.6 N and 1.0 to 5.9 N, respectively,[10] with forces less than 2 N not felt by the patient. Therefore, this is mainly a concern with older devices.

Another issue is EMI within the device that may cause multiple untoward effects. Older devices employed unipolar leads, where the impulse generator functions as the anode and the electrode lead tip as the cathode. This is in contrast to later-generation bipolar lead systems in which the lead tip functions as the cathode and the ring electrode above it as the anode. With a unipolar system, there is a longer separation between the anode and cathode, resulting in

a larger antennae effect that allows for greater EMI. In the presence of a pulsed radiofrequency (RF) field or gradient magnetic fields (which occur in the MRI scanner), low frequency lead currents may be induced. Within PMs, this could result in unwanted inhibition, reversion to asynchronous pacing mode, or overdrive pacing in response to perceived cardiac electrical activity. In ICDs, the ramifications include undersensing, which leads to undesired inhibition, or induction of antitachycardia pacing or inappropriate shock delivery when noise from the rapidly changing gradient EM fields is interpreted as native cardiac activity.[10] The newer cardiac devices contain improved band pass filters, programming, and shielding to reduce background noise, thereby lowering the rate of the aforementioned complications.

Another potential adverse side effect is heating of the leads, which can hinge on several factors including the patient's position within the bore of the MRI scanner, length of the straight segments of device leads, implant area, lead geometry, distribution of blood vessels surrounding the device, and thickness of the silicone or polyurethane insulation encasing the leads.[11] If the RF field is not uniformly distributed over the patient, local thermal hotspots may theoretically result. This will affect device functioning and promote scar tissue formation around the leads. For implants that are less than 6 weeks old, scar tissue resulting in a fibrous cap may not be fully formed yet. In these patients, formation of hotspots may not be as significant since there would be more viable cardiac tissue present around the lead tip. After 6 weeks, however, when scar tissue is fully formed, the conductance at the device-tissue interface and thus the dissipation of heat would be expected to be less. Thus, the capture and sensing thresholds could be increased accordingly. Conversely, it is possible for the scar tissue to cause a failure to sense and capture or serve as a nidus for development of arrhythmias, especially based on animal models. For these reasons, it is generally advisable to limit specific absorption rate (SAR) to no more than 2 W/kg.[10]

Lead impedance, and thus potential thermal damage, is another potential risk with MRI scans.[12] In designing leads, impedance needs to remain high enough that current flow through the device is limited and enables it to perform longer. To address this challenge, current leads are being constructed with a higher surface area to mitigate the effects of polarization and with a small diameter to attain the desired impedances. Following an MRI, alteration in lead impedance of more than 200 Ω is clinically significant and may necessitate earlier replacement.

Finally, battery voltage should be carefully monitored as it may be reduced after an MRI due to constant sensing by the device, thus potentially draining its supply and reducing device longevity. Abandoned PM or ICD leads can also experience induction of currents due to rapidly changing EM fields. Therefore, if not capped, they also serve as possible sources of cardiac excitation or thermal damage.[13]

MRI Safety Studies

Major studies assessing the safety of MRI scans in patients with cardiac devices are summarized in Table 1. The study by Sommer et al. was the first to assess potential long-term effects of MRIs on implantable cardiac devices. In this trial, 115 exams were performed on 82 non-PM-dependent patients.[14] Exclusion criteria included PM dependence, having a device not manufactured by Medtronic, a history of ventricular tachycardia or fibrillation, and having abdominal PM lead length >70 cm. The MRI exams excluded thoracic imaging. Several safety measures were implemented, including limitation of SAR to <1.5 W/kg, MRI field strength of 1.5 Tesla, and scan time of 30 minutes or less. The regions imaged involved the abdomen/pelvis (n = 20), extremities (n = 10), lumbar spine (n = 17), neck (n = 4), and the brain (n = 64), with planned follow-up of 3 months.

An increase in capture threshold of ≥1.0 V was noted in only 3.1% of leads but did not require any change in device output.

Study	Number of Patients	Cardiac Devices	Magnetic Field Strenght (Tesla)	SAR (Watts/kg)	Regions Imaged	Adverse Events
Sommer et al.	82	PPM	1.5	1.5	Extrathoracic	Increased capture threshold, 7 electrical resets, 4 increased troponin values
Mollerus et al.	103	PPM/ICD	1.5	No specific limit	Extrathoracic, Thoracic	1 PPM electrical reset, 1 ICD arrhythmia log erased, decrease in sensing amplitudes and pacing lead impedances
Gimbel et al.	14	PPM/ICD	3.0	2.0	Extrathoracic	1 artifactually recorded prolonged asystole event
Nazarian et al.	438	PPM/ICD	1.5	2.0	Extrathoracic, Thoracic	Decreased atrial and ventricular lead impedances and RV sensing, decreased battery voltage, increased RV capture threshold, 3 power-on reset events

Table 1. Selected studies assessing safety of MRI in patients with implantable cardiac devices. ICD: implantable cardioverter defibrillator; MRI: magnetic resonance imaging; PPM: permanent pacemaker; SAR: systemic absorption rate.

Only one patient had an increased serum troponin value associated with an increase in capture threshold, indicating a low risk but nevertheless the need to reduce risks for thermal damage. Seven patients also experienced electrical resets of their devices. However, all of the exams were safely completed with reprogramming afterward as needed. There were no other lasting clinically significant changes in device parameters. This study therefore showed that nondependent PM patients could undergo extrathoracic MRI with an acceptable risk-versus-benefit profile and with appropriate safety precautions.

In a larger trial, Mollerus et al. evaluated the performance of ICDs and PMs when exposed to MRI.[15] Exclusion criteria included PM dependence with native pulse <40 bpm, those with devices that were known to pose more difficulty with MRI exposure, and epicardial or fractured leads. Altogether, 127 MRI exams were performed on a study population of 103 patients, with 22 exams being on ICDs. Peak SAR was limited to the upper end for the particular sequences used, MRI field strength to 1.5 Tesla, and median scan time to <30 minutes. Sixty five of the scans were nontruncal (focusing on head or extremities only), and the average peak SAR was higher for the remaining scans that evaluated the cervical spine, thoracic spine, lumbar spine, chest, abdomen, or pelvis.

One patient experienced electrical reset of his pacemaker that necessitated reprogramming, and another patient's ICD arrhythmia log was erased. Also, post-MRI, there was a significant decrease in sensing amplitudes and pacing lead impedances. Pacing thresholds did not appear to be affected by the scans, nor by whether a low or high SAR was employed, and no lasting adverse effects were experienced by any patient at the 3-month follow-up. This study was the first to assess performance of cardiac devices in an MRI environment without restriction of the SAR, and it appears to demonstrate that the level of SAR used during a scan does not correlate well with potential alterations of device parameters.

Gimbel et al. performed the first study to evaluate the safety of cardiac devices at a magnetic field strength of 3.0 Tesla.[16] This was in contrast to prior studies that employed no more than 1.5 Tesla and 1 small study that used up to 2.0 Tesla. A total of 14 patients, 5 with ICDs, underwent 16 scans with SAR limited to 2.0 W/kg. Patients were not excluded based on PM dependency, body region imaged, and type of cardiac device implanted. Most of the MRI scans were of the brain and none were done on the thoracic region; however, this was by chance rather than from a limitation posed by the study design. Devices were interrogated 3 to 6 weeks post-MRI, and no clinically significant changes in device parameters, arrhythmias, electrical reset events, or reprogramming occurred. Although this study was limited by small sample size, it illustrates that patients with cardiac devices should not necessarily be excluded from undergoing MRI.

The largest trial to date evaluating the safety of MRI in patients with cardiac devices was performed by Nazarian et al.[8] A total of 555 MRI scans were done in 438 patients, with approximately 46% constituting ICDs. Exclusion criteria consisted of device leads that were <6 weeks post-implantation, PM-dependent patients with an ICD, patients with nontransvenous, epicardial, abandoned, or unfixed leads, and impulse generators that were implanted before 1998 in the case of PMs and before 2000 for ICDs. The MRI scans were carried out at 1.5 Tesla and SAR was kept under 2.0 W/kg in the first 55 patients. However, given the lack of a strong correlation between SAR and alteration of device parameters, the remainder of the study did not limit the SAR other than to stay within the boundaries set by the manufacturer. The areas examined included cardiac (n = 89), brain (n = 222), abdomen and pelvis (n = 72), and extremities (n = 50). Established goals for long-term follow-up for device interrogation were 3 to 6 months post-MRI.

There were no clinically significant short- or long-term changes in the device parameters that necessitated device reprogramming or revision of the impulse generator or leads. However, 3 of the 438 patients experienced power-on reset events by their devices, with one occurring during a cardiac MRI and the remaining during neurological imaging. Only the former required premature termination because the patient experienced a pulling sensation; however, tachyarrhythmia therapy was not activated by the single-chamber ICD in that instance. Overall, this study demonstrates that MRIs are a feasible option in patients with cardiac devices who have no acceptable alternative, but that they should be carried out in centers that have specific expertise and equipment for close monitoring.

As a result of these studies evaluating MRI safety in patients with implantable cardiac devices, our suggested protocol for performing MRI exams in such cases is proposed in Figure 1.

MR Conditional Devices

The most recent generation of MR conditional devices is unique because the devices are deemed to be safe under prespecified MRI conditions. This includes magnetic field strength limited to 1.5 Tesla, whole body SAR limited to 2.0 W/kg, and a maximum gradient magnetic field slew rate of 200 Tesla/m/s. Their design encompasses various improvements over previous devices, including: (1) incorporation of more advanced filters; (2) enhanced internal circuit protection to decrease the likelihood of power supply disruption; (3) replacement of the Reed switch with a Hall sensor to allow for more predictable performance under EMI; (4) utilization of an even lower content of ferromagnetic materials and improved heat dissipation within the generator; (5) integrity checks of the pacing system before allowing the MRI compatible mode; (6) increased energy delivered to capture during an MRI exam; and (7) return of the device to pre-MRI programming following completion of the scan. Regarding the leads, the number of coiled filars has been reduced and more turns added to increase inductance. The diameter of the filars is increased as well to maintain lead integrity.[17] Nevertheless, more design changes will need to be made before cardiac devices are deemed "MR safe," in which case even prespecified MRI conditions would not be necessary for safe use.

The Medtronic EnRhythm MRI™ SureScan™ pacing system and associated CapSureFix MRI™ SureScan® leads is the first FDA-approved MR conditional pacing system in the United States. However, a restriction is placed on positioning of the RF coil isocenter to outside the C1 to T12 vertebral region during thoracic MRI scans, possibly affecting image resolution. This system was recently evaluated in a prospective randomized clinical trial by Wilkoff et al.[18] Altogether, 464 patients underwent the pacemaker system implantation, with 258 patients randomized to the MRI group and 206 patients to the control group. Inclusion criteria included class I or II indications for a dual-chamber pacemaker and the understanding that the MRI scan was not clinically indicated. Exclusion criteria included patients with MRI-incompatible devices and those with abandoned leads. MRI exams were performed at 9 to 12 weeks post-implantation in the MRI group. The devices were evaluated immediately before and after MRI and in both groups at 1 week and 1 month post-implant.

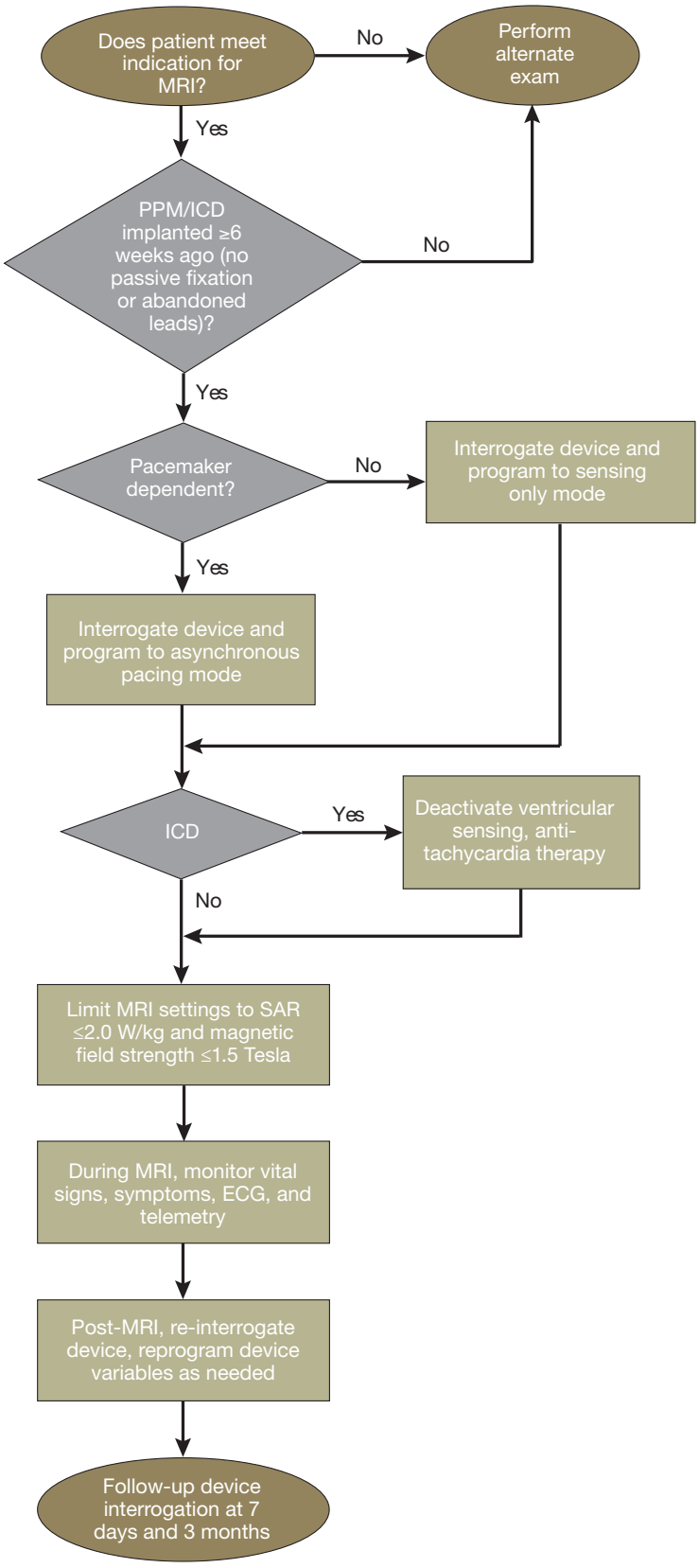

Figure 1. Proposed algorithm for performance of MRI scanners in patients with implanted cardiac devices. ICD: implantable cardioverter defibrillator; MRI: magnetic resonance imaging; PPM: pacemaker.

There were no complications related to the MRI and only mild changes in capture threshold and sensing amplitude among both groups. Therefore, this trial has shown that Medtronic's MR conditional pacing system appears to be safe and effective while exposed to EMI.

The most recently developed MR conditional cardiac device by Medtronic is the Advisa MRI™ SureScan™ Pacemaker, along with CapSureFix MRI SureScan leads, which received FDA approval on February 13, 2013. The most significant improvement over the EnRhythm pacemaker is a lack of restriction on positioning with MRI scans of the chest. This pacing system was assessed by Gimbel et al. in a prospective unblinded randomized clinical trial.[19] Inclusion and exclusion criteria were similar to the EnRhythm pacing system study discussed above.

A total of 263 patients had device implantation, with 2:1 randomization for undergoing MRI at 9 to 12 weeks post-implant. Patients in both control and MRI groups also had their devices interrogated at 1 week and 1 month after MRI scan, 6 months following implantation, and every 6 months thereafter. Sixteen MRI exams of the chest and head were performed, and scan time lasted about 30 minutes. The results of this study showed no complications directly attributed to MRI. Also, changes in the capture threshold were comparable among the two groups and minimal at 1 month following MRI. Thus, this trial demonstrates that the Advisa pacing system may be used safely during MRI and also allows for more optimal imaging of the chest compared to its predecessor. Another benefit that should be noted is that more insurance companies would cover an MRI in a patient with an MR conditional device, and thus the future trend is expected to be towards implantation of such cardiac devices.

Conclusion

As the above studies illustrate, meaningful and valuable information can be obtained by MRI that could provide a diagnosis not identified with other modalities and potentially change a patient's treatment course. It would therefore not be beneficial to exclude the group of patients with implantable cardiac devices from this unique imaging modality. More studies need to be done to fully characterize the extent of the impact of MRI on cardiac devices, particularly on defibrillators, and to refine safety protocols. We are hopeful that with future technological advancements, perhaps with fiberoptic leads and laser-powered generators, the ultimate goal of creating MR-safe devices may be reached, and implantable cardiac devices will no longer preclude MRI scans from being performed and possible diagnoses being missed.

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