Magnetic Resonance Imaging in Patients With Implantable Cardiac Devices

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The use of magnetic resonance imaging (MRI) in patients with implantable cardiac devices, such as pacemakers, cardioverter defibrillators, and loop recorders, has been contraindicated based on concerns regarding the powerful magnetic field generated by MRI. Due to the widespread application and powerful diagnostic capability of MRI, there are instances in which denying a patient with an implantable cardiac device an MRI evaluation may influence the quality of health care received. There are data to suggest that MRI might be considered a relative contraindication instead of an absolute contraindication in device patients when precautions are taken by experienced physicians to lower the risk of adverse events. Despite the potential concerns, several hundred non–pacemaker-dependent patients and several pacemaker-dependent patients have undergone MRI without complications while being monitored under a number of different safety protocols. Various strategies have been used to minimize the risk of performing MRI procedures in device patients. Patient selection must be rigorous and made on a case-by-case basis.

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Historically, the use of magnetic resonance imaging (MRI) in patients with implantable cardiac devices, such as pacemakers, cardioverter defibrillators, and loop recorders, has been absolutely contraindicated and is not approved by the US Food and Drug Administration (FDA). This contraindication is based on a number of concerns regarding the powerful magnetic field generated by MRI. There are data to suggest that MRI might be

considered a relative contraindication instead of an absolute contraindication in device patients when precautions are taken by experienced physicians to lower the risk of adverse events. This article will discuss the current literature regarding MRI in device patients and describe our experience and recommendations for providing MRI in those patients in whom rigorous screening has established that the risk versus benefit ratio is favorable.

Theoretically, the potential risks of MRI on implantable devices include physical and/or programming problems such as device and lead movement, device-lead interface damage secondary to heating, unexpected programming changes, inappropriate therapy, and rapid pacing leading to death.[1,2] It is estimated that each year there are more than 900,000 implantable cardiac devices prescribed worldwide. There have also been an increasing number of MRI systems in use worldwide, with about 35 million magnetic imaging procedures performed yearly.[3,4] Because of the expanding clinical indications for implantable devices and MRI, an ever-increasing number of patients require both of these medical modalities.

Due to the widespread application and powerful diagnostic capability of MRI, there are instances in which denying a patient MRI evaluation may influence the quality of health care received. One study found that 17% of patients with pacemakers were denied MRI in the previous year. This policy may affect more than 1 million patients worldwide.[5]

Studies to determine the safety of MRI in patients with devices are limited. Despite the potential concerns, several hundred non–pacemaker-dependent patients and several pacemaker-dependent patients have undergone MRI without complications while being monitored under a number of different safety protocols. Various strategies have been used to minimize the risk of performing MRI procedures in device patients. Several investigators have manipulated various aspects of the device programming features, such as setting the device to a subthreshold level or in asynchronous mode. Others have limited imaging to non–pacemaker-dependent patients. Furthermore, MRI protocols themselves have been modified to attenuate radiofrequency (RF) power or to limit studies to patients in whom the pulse generator is positioned outside the bore of the MRI system. Finally, the most conservative approach to date has been to explant the pulse generator prior to MRI imaging.[4,6]

Potential Concerns

Several legitimate concerns have been expressed regarding MRI studies in patients with cardiac devices, but most of the feared adverse events have not occurred. It was thought that devices and/or leads might be explanted from patients due to the MRI magnetic force, but this event has not been reported. In addition, the feared malignant arrhythmias have not been seen in controlled settings. The data support the view that MRI in patients with cardiac devices does not cause clinically significant changes to pacing parameters.[6-9]

There are 3 types of magnetic fields associated with MRI that may affect cardiac device function. These are static magnetic fields, responsible for mechanical force and torque and reed switch changes; RF; and various magnetic gradient fields that may cause heating, rapid pacing, alterations to programming, energy damage to circuitry, oversensing, and power on reset. We will examine the theoretical concerns as well as the evidence-based adverse events associated with these magnetic fields. We will also discuss ways to apply special precautions to reduce the risk of adverse events.

Static Magnetic Fields

Mechanical Force and Torque

The static magnetic field and its interaction with the ferrous components of cardiac devices could theoretically cause pacemaker/lead movement and reed switch changes. Static magnetic fields apply mechanical force and torque to device components because of magnetic attraction. In theory, this interaction could cause movement of the device/leads or reed switch closure. In reality, there is a small ferromagnetic mass in cardiac devices and leads.[5,7] The patient may notice a small tug on the device, but no significant movement of the device or leads has been reported and is unlikely to occur. Our recommendation: No special precaution is needed to prevent device/lead movement.

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Reed Switch Changes

The reed switch is a magnetically activated switch found in pacemakers that allows for the so-called *magnet mode*. When a sufficiently strong magnetic field is applied to the reed switch, the switch closes and the pacer goes into the preset magnet mode (VOO at a preset rate). There is some evidence that when the reed switch is subjected to MRI static

magnetic fields, its position cannot be predicted.[10] For example, if a device set at VOO mode at a rate of 60 is placed in a magnetic field, with the reed switch closed, then the pacer will stay in VOO mode but pace at the predetermined "magnet rate." (The only likely change would be pacing rate.) A pacemaker set in OOO or VOO mode to start, with an open or closed reed switch, is unlikely to experience significant clinical consequences during MRI. Our recommendation: Place the pacemaker in OOO or VOO mode prior to MRI.

Radiofrequency and Varying Magnetic Gradient Fields

Heating of Device Leads

Heating of myocardial tissue at the lead cardiac interface during MRI has been a concern. Myocardial tissue damaged by heat may cause changes in pacing threshold values and possibly loss of capture, which may be fatal in pacemaker-dependent patients. In vitro studies have shown marked increases in electrode temperatures during pacing.[5] Animal studies have shown no thermal injury to the myocardium secondary to lead heating in vivo.[5] Any heat-induced changes would be noted as changes in pacing thresholds. Theoretically, these pacing threshold changes might not be noticed immediately if tissue damage does occur, but they may be evident at a later date if fibrosis of the damaged tissue occurs. Our recommendation: Device interrogation should include threshold measurements before and after MRI, with regular follow-up in a pacing clinic 3 to 6 months later.

Device Circuitry Damage

MRI may damage the circuitry of cardiac devices,[11] but it is unlikely to do so. Damage has been noted only in devices placed unknowingly into the MRI without proper pre-MRI programming changes. Pacemaker circuits are protected by a zener diode, which acts as a valve to shunt high voltages away from device circuits. Theoretically, this diode protection may become overwhelmed, with subsequent damage to cardiac device circuitry, but this circumstance has not been reported with MRI. Our recommendation: Perform device interrogation before and after MRI.

Alteration of Programming

Exposure of cardiac devices to MRI may cause programming alterations.[12,13] Pre-1985 pacemaker models use an older programming system that may reprogram when subjected to MRI. (These devices are unlikely to still be in use.) There has been a report of 3 Kappa® pacemakers (Medtronic, Inc., Minneapolis, MN), which are post-1985 devices, that reset to power-on default status (back-up mode) during MRI.[14] Power-on reset pacing or back-up mode is analogous to the device's elective replacement behavior, which is VVI mode. MRI-generated signals may be interpreted as ventricular events, and oversensing may result in inhibition of pacemaker ventricular output. This alteration in reprogramming would be catastrophic for a pacemaker-dependent patient. It has not been seen outside of this report, and no other reports of phantom pacemaker reprogramming associated with modern cardiac devices have been made. Our recommendation: Monitor the patient by electrocardiography (ECG), pulse oximetry, and direct verbal contact. Have resources for transcutaneous pacing, transvenous pacing, and resuscitation available.

Interference With Sensing

Of the possible interactions between MRI magnetic fields and cardiac devices, interference with sensing is the most likely to occur (Figure 1). It is very likely that MRI-generated signals will be interpreted as ventricular fibrillation by implantable cardioverter defibrillators (ICDs),[5,12] and pacemakers will interpret the

Figure 1. *Areas of possible interaction between magnetic resonance imaging and cardiac devices.*
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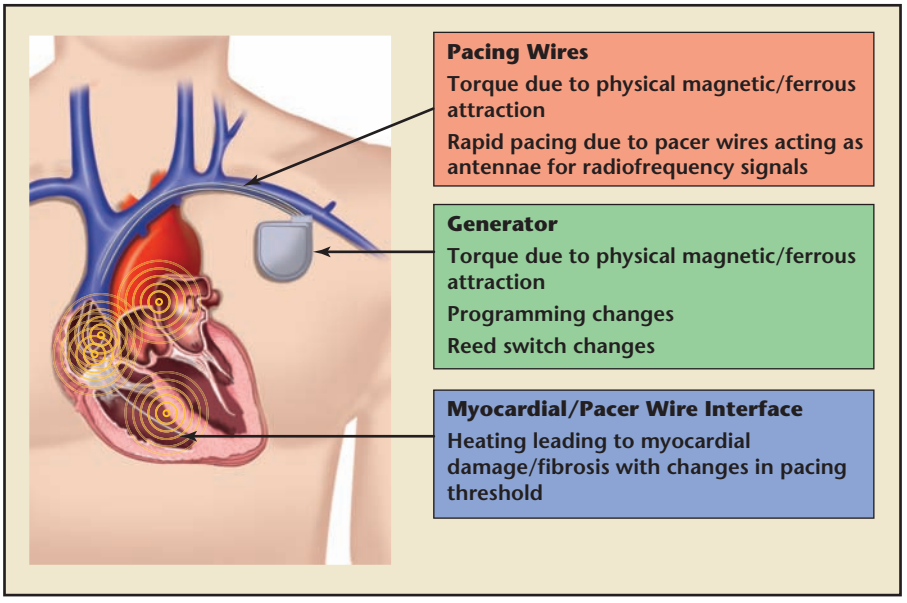

signals in a multitude of ways. We have noted this interaction when ICD sensing is left on and ICD firing capacity is turned off to determine the interpretation of the MRI fields by the ICD. The ICDs invariably interpret MRI noise as ventricular fibrillation. Our recommendation: Turn the ICD off and/or place the pacemaker device in the OOO or VOO mode.

Rapid Pacing

The most alarming of the potential interactions between magnetic fields and cardiac device activity is the induction of rapid pacing. Not only can rapid pacing have devastating effects on the patient, but it is also the alteration we have the least amount of control over (programming changes are unlikely to influence the probability of occurrence). In theory, pacing leads may act as antennae, detecting and amplifying MRI RF signals and producing sufficient energy to pace the heart at high rates—leading to hemodynamic collapse and death. This event could also theoretically happen in pacing leads that are capped and when no generator is present. There is some evidence that it may occur only in the VVI or DDD mode and not in the OOO, DOO, or VOO modes, but it is still theoretically possible in all modes.[13] Our recommendation: Monitor the patient by ECG, pulse oximetry, and direct verbal contact. Have resources for transcutaneous pacing, transvenous pacing, and resuscitation available.

Key Studies Depicting Safety in Device Patients

Several key studies have been instrumental in providing evidence that patients with implantable devices may undergo MRI with a relatively safe risk-to-benefit ratio. Each study explores 1 of the 4 major groups that device patients fall into (non–pacemaker-dependent, pacemaker-dependent, ICD, and loop recorder patients).

Non–Pacemaker-Dependent Patients

Martin and colleagues[6] studied a group of 54 non–pacemaker-dependent patients who underwent a total of 62 MRI studies at 1.5 tesla (T). This study was very liberal as to patient selection and pacemaker settings, allowing for analysis of a broad population of patients. No limitations were placed on the type or duration of the MRI procedure, pacemaker, or lead models, nor on the proximity of the imaged anatomy relative to the pacemaker. Pacemakers were not programmed to the asynchronous mode. Pacemaker-dependent patients were excluded, but it was later found that 1 pacemaker-dependent patient was inadvertently studied (with no complications). There were no clinically relevant complications or malfunctions.

It has been postulated that limiting the distance from the device to the anatomical region being imaged may improve the safety of MRI. This study demonstrated that the distance between the anatomical region being imaged and the device was not associated with clinically relevant changes in pacer parameters, such as threshold changes.[6]

Sommer and colleagues[9] evaluated MRI at 1.5 T in 82 non–pacemaker-dependent patients who underwent 115 MRI examinations. Pacemaker-dependent patients and patients requiring examinations of the thorax were excluded. All pacemakers were reprogrammed to the asynchronous mode prior to MRI. The pacemakers were interrogated immediately before and after MRI and 3 months after the procedure.

There was a statistically significant increase in pacing capture threshold ($P = .017$). In 2 of the 195 leads evaluated, an increase in the threshold valve was detected only at the 3-month follow-up examination. There were no clinically relevant events that would cause a worsening of morbidity or mortality. The authors concluded that extrathoracic MRI of non–pacemaker-dependent patients could be performed with an acceptable risk-benefit ratio under controlled conditions.

Pacemaker-Dependent Patients

Gimbel and colleagues[2] examined 10 pacemaker-dependent patients undergoing 11 MRI scans of the head and neck. All patients were scanned with a head coil that limited RF power deposition. This approach avoided RF exposure to the device and the leads, which should theoretically limit heating within the leads and at the lead-tissue interface. MRI was at 1.5 T, and all devices were set to an asynchronous mode (VOO or DOO). Each device was interrogated immediately before MRI scanning, afterwards, and at 3-month follow-up.

Three patients experienced no change in the capture thresholds. Two patients experienced an increase in the atrial capture threshold of 0.5 V at the 3-month follow-up. One patient had an increase in the ventricular capture threshold of 0.5 V at 3 months. One patient had an increase in the ventricular capture threshold immediately prior to MRI, which returned to baseline at the 3-month follow-up. The remaining patients had a decrease in the output threshold at the immediate post-MRI check, the 3-month follow-up, or both. There was no clinical evidence of device malfunction or alterations in programming.[2]

Implantable Cardioverter Defibrillators

Roguin and colleagues[14] studied the use of MRI in 18 dogs implanted

with ICDs. Four weeks after implantation, the animals underwent a prolonged MRI scan (3-4 hours) and were monitored for arrhythmias. Device interrogation occurred immediately before the procedure, after the procedure, and weekly for the next 4 weeks. All ICDs had intact function. No arrhythmias were detected during the scan. Devices from 1 manufacturer had a decrease in battery voltage, which resolved after a few days. In 1 animal, a failure to capture pacing occurred immediately after the scan, but resolved after 12 hours. In all the other animals, there were no changes in pacing thresholds, impedance, and intraventricular electrogram amplitude or battery life immediately after the procedure or at follow-up.[14]

Nazarian and colleagues[15] studied 24 patients with ICDs who underwent MRI at 1.5 T. There was no device movement or heating. No rapid pacing was induced. All devices were functioning appropriately after MRI, and no changes in device programming were observed. There was no change in pacing parameters, lead threshold, lead impedance, sensing signal amplitudes, or mean battery voltage before the procedure, after the procedure, and at 3-month follow-up. The conclusion was that patients with ICDs can safely undergo MRI if proper precautions are taken.[15]

Implantable Loop Recorder

Gimbel and colleagues[8] studied patients with implantable loop recorders (ILR) undergoing MRI scans. Ten patients with an ILR (Reveal® Plus, Medtronic, Inc.) underwent 11 scans. During the scan, the ILR recorded artifacts. Post-MRI, none of the ILRs showed diminished signal integrity, altered programmed parameters, diminished battery status, or an inability to communicate or to be reprogrammed. No sensations of heating or tugging were noted.[8]

Our Experience

In our practice, we currently provide MRI for device patients in the surrounding community on a case-by-case basis. Thus far, we have provided 40 MRI studies to 22 patients with devices, including 2 pacemaker-dependent patients and 10 ICD recipients, without complications or significant changes to device settings. Our patients and/or their physicians usually hear of this service by word of mouth. We confirm with the physician that the study results will directly impact patient care. We have developed a protocol that allows us to provide an MRI study to patients with a device with an acceptable (low-level) risk. The protocol consists of the following:

- Informed consent is obtained from the patient.
- A good working relationship with the MRI staff is maintained. It is helpful if the same staff is used for each study, if possible.
- An electrophysiologist, pacemaker company representative, and electrophysiology nurse are present during the procedure.
- The pacemaker is interrogated and placed in 000 or asynchronous mode. The ICD is turned off.
- Transcutaneous pacer and resuscitation materials are available in the MRI suite.
- We monitor cardiac rhythm, pulse oximetry, and maintain verbal communication with the patient.
- After the study, the pacer is interrogated.

Device Company and FDA Recommendations

The April 2005 issue of *Pace* contained guest editorials regarding cardiac devices and MRI by Medtronic, Inc., Guidant Corp. (now Boston Scientific, Corp., Natick, MA), and St. Jude Medical, Inc. (St. Paul, MN). The editorials by Medtronic[16] and Guidant[17]were the most conservative of the 3. These companies will not endorse MRI scanning of their devices until the devices have been specifically engineered to undergo MRI imaging and the FDA approves of the procedure. They will continue to provide safety information to physicians who perform the procedure. The statement from St. Jude Medical, Inc., was less conservative, stating, "The company is confident that the likelihood of damaging or reprogramming one of our current devices is remote. . . . When there is an appropriate clinical justification for an MRI study, the theoretical risks can be managed by appropriate programming and monitoring on the part of the clinical team caring for the patient."[18] The FDA's stand is that there is no justification for the routine use of MRI in patients with cardiac devices, but they "recognize that there are pacemaker and ICD patients for whom, on a case-by-case basis, the diagnostic benefit from MRI outweighs the presumed risk."[19,20]

Professional Society Recommendations

There are no recent guidelines regarding MRI in patients with cardiac devices from the American College of Cardiology, the American Heart Association, or the Heart Rhythm Society. The 2007 American College of Radiology guidelines state: "It is recommended that the presence of implanted cardiac pacemakers or implantable cardioverter defibrillators (ICDs) be considered a relative contraindication for MRI. MRI of patients with pacemakers and ICDs ('device patients') is not routine. Should an MRI be considered, it

should be done on a case-by-case and site-by-site basis, and only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise on hand. As of this writing, no cardiac pacing and/or defibrillating devices are labeled safe or conditionally safe for MRI scanning. Pacemaker and/or ICD leads may also present a hazard in the absence of any implant connected to them."[21]

Future of MRI and Cardiac Devices

The major providers of cardiac devices are all working on devices engineered for MRI compatibility. The new technology involves the use of MRI-compatible nonferrous metals and added filters to prevent the pacemaker and leads from picking up MRI signals, which may confuse the device and cause it to react in an erratic manner. In February 2007, Medtronic announced the start of a multicenter clinical study to evaluate the safety and efficacy of the first pacemaker system engineered for safe use in MRI imaging. The system consists of a dual-chamber pacemaker called the EnRhythm® MRI SureScan™ and the CapSureFix® MRI SureScan™ pacing leads. This prospective, unblinded, randomized controlled study will include 350 patients. The other manufacturers are likely to soon follow, as they have been developing similar systems.

Discussion

Several legitimate concerns regarding MRI studies in patients with cardiac devices have been noted. Most of these concerns are theoretical in nature and/or secondary to anecdotal incidents of device malfunction. To date, 6 patient deaths have been attributed to the use of MRI in device patients.[13] Most of these deaths were reported to the FDA and were not described in the peer-reviewed medical literature. The fatalities were poorly characterized, with no ECG data available. In most cases, the clinicians who performed the MRI were unaware that the patient had a cardiac device. Therefore, the necessary precautions needed to reduce risk were not followed. Conversely, no permanent sequela has been reported when patients have been carefully monitored and the device has undergone reprogramming before the scans. Of note, more than 230 patients have been imaged safely using MRI systems operating from 0.350 T to 1.5 T.

Conclusion

Our group at Providence Hospital and Medical Centers in Southfield, Michigan, has established a protocol that follows the recommendations of the FDA and the American College of Radiology. We provide MRI at 1.5 T to patients after careful analysis of the indication for MRI. The need for MRI is confirmed through discussion with the patient, family, primary medical doctor, and ordering physician. Close cooperation with the MRI staff is critical. Strict adherence to an established protocol is key to reducing risk.

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As we become more comfortable with imaging patients who have devices, we must take into consideration

Main Points

- The use of magnetic resonance imaging (MRI) in patients with implantable cardiac devices, such as pacemakers, cardioverter defibrillators, and loop recorders, has been absolutely contraindicated, and is not approved by the US Food and Drug Administration.
- The potential risks of MRI on implantable devices include physical and/or programming problems such as device and lead movement, device-lead interface damage secondary to heating, unexpected programming changes, inappropriate therapy, and rapid pacing leading to death.
- Despite the potential concerns, several hundred non–pacemaker-dependent patients and several pacemaker-dependent patients have undergone MRI without complications while being monitored under a number of different safety protocols.
- Strategies to help avoid adverse effects include setting the device in the proper mode; performing device interrogation before and after the MRI; and monitoring the patient by electrocardiography, pulse oximetry, and direct verbal contact.
- Several clinical studies have provided evidence suggesting that patients with implantable devices may undergo MRI with a relatively safe risk-to-benefit ratio.

a number of factors. First, the number of patients studied is small. Second, it will always be important to stay vigilant and heed the warning from Gimbel and Kanal[22] that failure to identify an adverse event is not equivalent to demonstrating safety. Third, MRI in device patients is not approved by the FDA. Fourth, patient selection must be rigorous and made on a case-by-case basis, with the safety of the patient the primary concern (*Primum non nocere*). ■

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