Journal of Cardiovascular Magnetic Resonance (2007) **9,** 5–13

ISSN: 1097-6647 print / 1532-429X online
DOI: 10.1080/10976640601117056

informa
healthcare

MR in Patients with Pacemakers and ICDs: Defining the Issues

Jerold S. Shinbane, MD, FACC, Patrick M. Colletti, MD, and Frank G. Shellock, PhD, FACC

Keck School of Medicine, University of Southern California, Los Angeles, California, USA

ABSTRACT

There has been great controversy related to performance of magnetic resonance imaging in patients with pacemakers and implantable cardiac defibrillators. Recent questions have been raised regarding whether contraindications are absolute or relative. Although there are theoretical as well as documented issues relating to device malfunction, data suggest that scanning patients with devices may be feasible when important clinical questions need to be addressed by following strict guidelines. Advanced knowledge and understanding of electrophysiologic as well as magnetic resonance imaging-related issues, and a multidisciplinary, collaborative approach is required to further define the role of MR in patients with pacemakers and implantable cardiac defibrillators.

INTRODUCTION

The safe performance of magnetic resonance (MR) requires meticulous attention to the patient and scanning environment, especially when implanted devices with ferromagnetic content, conductive materials, or electronic components are present (1, 2). Due to the proliferation of both MR and implantable cardiac devices, these issues are of great relevance to cardiologists, cardiac electrophysiologists, and radiologists. There has been great controversy related to performance of MR in patients with pacemakers and implantable cardiac defibrillators (ICD) (3–10). Recent questions have been raised regarding whether contraindications are absolute or relative. Decisions require detailed information relating to specifics of the patient, the device, and MR conditions, including the static magnetic field strength, body area imaged, and the level of the radiofrequency energy (RF). Assessment of these issues requires advanced knowledge and understanding of electrophysiologic as well as MR-related issues utilizing a multidisciplinary, collaborative approach for patient management.

Keywords: Device, Implantable Cardiac Defibrillator, Cardiovascular Magnetic Resonance, Pacemaker, Safety.
Dr. Shellock is a consultant for Medtronic, Inc., St. Jude Medical, and Guidant Corp. Drs. Shinbane and Colletti have no conflicts of interest.
Correspondence to:
Jerold S. Shinbane, MD, FACC
Division of Cardiovascular Medicine
Keck School of Medicine
University of Southern California
1510 San Pablo St #300 North, HCC I
Los Angeles, CA 90033
email: shinbane@usc.edu

POTENTIAL EFFECTS OF MR ON CARDIAC DEVICES

There are a variety of mechanisms by which MR can affect pacemakers and ICDs, with some interactions relating to the exposure of the device to the powerful static magnetic field and gradient magnetic fields associated with the MR system, while others relate to the use of RF during MR. Potential interactions can involve multiple components of the device, including the leads, circuitry, reed switch, battery, and capacitors. In patients with ICDs, the effect not only on bradycardia therapies, but also tachyarrhythmia therapies, including antitachycardia pacing, cardioversion and defibrillation therapies must be considered (11). In regard to effects relating to exposure to CMR, advances in pacemaker and ICD technology make it necessary to understand the specific functions activated on a particular device.

Magnetic field interactions include translational attraction and torque of ferromagnetic objects to the static magnet field of the MR system (12, 13). Varying effects are associated with the specifics of the scanner, including the strength of the static magnetic field, the length of the magnet bore, and the spatial relation of the device to the scanner (14). The spectrum of clinical field strengths spans from 0.2 Tesla to 3.0 Tesla with magnetic field interactions tending to increase with increases in field strengths (i.e., relative to an increase in the spatial gradient for a given MR system) (14). In addition to the static magnetic field, the length of the magnet bore can affect device movement. In

one study, short bore scanners caused greater deflection angles than long bore scanners, related to the significant differences in the spatial gradient for each scanner type (14). In one report, studied pacemakers and ICDs had negligible translational forces (15).

The body area of interest for undergoing MR affects the location of the device in relation to the MR system, especially in reference to whether the device is inside or outside of the magnet bore. For example, the use of a dedicated extremity scanner may allow the device to remain outside of the magnet bore, as well as away from the RF and gradient fields, resulting in no significant magnetic field interactions for both pacemakers and ICDs (16). Furthermore, prospective data suggest that peripheral scan locations such as knee and brain scanning do not have significant effects on programmed parameters, pacemaker components, and pacing capture (17–19).

Magnetic fields may also affect bradycardia pacing through effects on the reed switch, leading to asynchronous pacing. Asynchronous pacing may be preferred during scanning in a patient who is pacemaker dependent, but in the setting of a ventricular rhythm which competes with the asynchronously paced rhythm, pacing during ventricular repolarization may extremely rarely lead to ventricular tachyarrhythmias (20, 21). Pacemaker and some ICD reed switches can be activated leading to asynchronous pacing (22). Reed switch activation may not be predictable though, and may vary with orientation to the magnetic field and field strength (23, 24). Some pacemakers may allow inactivation of the reed switch response.

Additionally, gradient or time-varying magnetic fields can potentially induce voltage that can affect pacing function (24, 25). Sensing of these induced currents can inhibit pacing function or lead to a spectrum of temporary responses depending on the specific pacemaker or ICD including: inhibition of single beats, temporary total inhibition of pacing, or mode reversion to asynchronous pacing (26). These effects may theoretically be greater for left sided devices in magnetic fields due to the area bounded by the lead and the device created by left-sided device placement (25). Effects may be greater for unipolar than bipolar leads due to greater sensing of these interference currents. In patients with ICDs, in addition to affecting pacing function, these currents could potentially trigger detection of tachyarrhythmias, if not deactivated prior to scan, although it is unclear whether capacitors can charge in the static magnetic field (25, 27).

MR require the use of RF energy, which can cause lead heating as well as affect device sensing and programming function (28). The degree of heating associated with RF energy is dependent on the whole body averaged specific absorption rate (SAR) used for a given pulse sequence. Notably, the degree of heating may vary between systems using the same field strength and RF energy due to differences in how the SAR is calculated by a particular MR system, and has raised issues related to the need for standardized units (29).

Lead heating is an important issue to consider. In an in vitro study, leads placed in 0.45% NaCl or 2 to 3 mm of gel did not lead to significant heating, but leads placed deep within gel demonstrated significant heating (15). A canine model in this study demonstrated loss of capture for 12 hours in one animal but no evidence of thermal injury on pathology. In one animal study at 1.5 T significant heating occurred with measured temperature rise of up to 20 degrees Celsius with increase in pacing threshold during scanning and changes in pacing threshold after scanning (30). Interestingly though, in this animal model, there were no pathologic or histologic changes seen after scanning. Previously, the cooling effect of blood flow was felt to be important, but the significant heating seen in this in vivo study has lead some authors to comment that this cooling effect is small, and that additionally the differences in size and shape of the human chest compared to the swine chest may lead to increased heating (31). In one prospective human study by Martin et al (8) at 1.5 Tesla, although statistically significant changes in pacing threshold occurred in 9.4% of cases, only 1.9% required a programmed increase in output (8). The authors postulated that pacing threshold changes seen in their study of patients at 1.5 Tesla may have been due to heating at the lead-tissue interface, although no serious clinical events were observed in this study. Lead length is also important, as a resonant lead length tends to be associated with greater heating (32). Although maximal potential heating at the resonant lead length could be theoretically substantial, clinical effects require greater study. Data on abandoned leads are scarce and requires further investigation (33, 34). Additionally, the ramifications of lead length, configuration, and positioning, require greater characterization, especially when considering the spectrum of body sizes from a pediatric to adult population.

Pacemaker and ICD interference may occur as a result of electromagnetic effects of RF energy on sensing and pacing function. Early reports described inhibition of pacing output due to RF energy (35, 36). Additionally, rapid pacing has been reported in ex vivo models and in patients (37–39). Although the actual mechanism is not completely clear, reports have suggested that pacemaker and ICD leads act as antennae subsequently affecting device circuitry leading to rapid pacing (39). MR scanning can affect pacemaker battery voltage, due to unclear mechanisms (40, 41). In one report, these effects were seen immediately after scanning with return of battery voltage at 3 months after MR. The reason for battery voltage change in controversial with some authors relating this to battery depletion (24), although authors have suggested that this may be due to brief power interruption rather than battery voltage depletion (41). This issue is particularly germane in patients nearing or at elective replacement indices and pacemaker dependent patients (24).

Although there are many potential mechanisms by which MR can affect devices, the issues of greatest clinical relevance relate to whether currently implanted devices demonstrate a lack of adverse effect or whether devices to be scanned need to be designed specifically to be safe for patients undergoing MR procedures (15, 17). The feasibility of scanning patients with devices initially occurred through case reports on devices exposed to MR. These case reports have lead to prospective study in patients with pacemakers and ICDs (Table 1), with the majority of these

Table 1. MR in patients with pacemakers and ICDs

Author	Device	Year	Patient/Studies Report Type	MRI Condition	Findings
Iberer (44)	P	1987	1/1 Case		No adverse effect
Alonga (45)	P	1989	1/1 Case Intentional	1.5 T Brain	No adverse effect
Inbar (46)	P	1993	1/1 Case Intentional	1.5 T Brain	No adverse effect
Gimbel (48)	P	1996	5/5 Retrospective Intentional	0.35-1.5T Cardiac Brain C-Spine	Two second pause
Garcia-Boloa (47)	P	1998	1/2 Case Intentional	1.0 T Brain	No adverse effect
Fontaine (39)	P	1998	1/1 Case Intententional	1.5 T Brain C-Spine	Rapid pacing
Sommer (72)	P	1998	18/18 Prospective	0.5 T Brain Cardiac Vascular	Asynchronous mode due to activation of the reed switch in all patients
Sommer (49)	P	2000	45/51 Prospective	0.5 T Multiple	No adverse effect
Valhaus (40)	P	2001	32/34 Prospective	0.5 T Multiple	Decrease in battery voltage recovered at 3 months
Martin (8)	P	2004	54/62 Prospective	1.5 T Multiple	Significant change in pacing threshold in 9.4% of leads, and 1.9% of leads requiring an increase in programmed output.
Del Ojo (50)	P	2005	13/13 Prospective	2.0 T Multiple	No adverse effect.
Rozner (41)	P	2005	2/2 Case Intentional	1.5 T Thorax Lumbar	Transient change to ERI in 1 patient.
Gimbel (53)	P	2005	10/11 Prospective All pacemaker dependent	1.5 T Brain C-Spine	Small variances in pacing threshold were seen in four patients.
Sommer (51)	P	2006	82/115 Prospective All non-pacemaker dependent	1.5 T Extra-thoracic	Significant increase in pacing threshold, decreased lead impedance, and decrease in battery voltage. No inhibition of pacing or arrhythmias and no leads which required an increase in pacing output.
Heatlie (52)	P	2007	5/6 Prospective All non-pacemaker dependent	0.5 T Cardiac	Pacing at maximum voltage at a fixed rate of 100 beats / minute in 1 patient.
Anfinsen (60)	ICD	2002	1/1 Case Inadvertent	0.5 T Brain	Inappropriate sensing, battery voltage transient change to EOL.
Fiek (59)	ICD	2004	1/1 Case Inadvertent	0.5 T Brain	Unable to communicate with device.
Coman (62)	ICD	2004	11/11 Prospective	1.5 T Cardiac Vascular General	Brief asymptomatic pause in 1patient. Unable to communicate with device in 1 patient.
Gimbel (10)	ICD	2005	7/8 Prospective	1.5 T Brain L-Spine	"Power on reset" electrical reset requiring reprogramming in 1 patient.
Roguin (57)	ICD	2005	1/1 Case Intentional	1.5 T Cardiac	No adverse effect.
Wollmann (58)	ICD	2005	1/3 Case Intentional	1.5 T Brain	No adverse effect.
Naehle (27)	ICD	2006	1/1 Intentional	1.5 T Brain	No adverse effect.
Nazarian (61)	P 31 ICD 24	2006	55/68 Prospective	1.5 T	No adverse effect.

Case = case report, p = pacemaker, EOL = end-of-life, ERI = elective-replacement indices.

studies relating to the performance of non-cardiac scans at low field strengths in patients with pacemakers.

HUMAN MR/PACEMAKER DATA

In regard to pacemakers, case reports of fatalities during scanning have been described in patients inadvertently scanned without monitoring. A small number of deaths have been reported, but the specific details and circumstances of these cases have been poorly characterized (2, 42, 43). In a report by Irnich et al (24), a total of 6 deaths were reported from 1992 to 2001. Ventricular fibrillation was the apparent mechanism of death in 3 cases, but again the specific clinical details preceding the events are not described.

The following data represents case reports and studies of patients with pacemakers intentionally scanned (Table 1). Initial

case reports described patients scanned without significant effects (44–47). Gimbel et al (48) reported on 5 patients with one patient experiencing a 2 second pause. Fontaine et al (39) reported on one patient who experienced rapid ventricular pacing after RF pulsing was initiated. Subsequently, series of patients have been imaged under specific MR scanning conditions and assessed for evidence of pacemaker malfunction. Sommer et al (49) assessed 51 MR studies in 45 patients with pacemakers scanned in asynchronous modes at 0.5 Tesla without significant clinical effects (49). Valhaus et al (40) prospectively performed 34 studies in 32 patients with a variety of scan types at 0.5 Tesla and noted a significant change in battery voltage immediately after scanning with recovery of battery voltage at 3 month follow-up. Martin et al (8) prospectively performed 62 studies in 54 patients at 1.5 Tesla, including brain, neck, chest, abdomen, pelvis, and lower extremity scan locations, without adverse patient clinical events, although statistically significant changes in pacing threshold occurred in 9.4% of cases, and 1.9% required a programmed increase in output. Del Ojo et al (50) prospectively studied 13 non-pacemaker dependent patients at 2.0 Tesla with no significant effects on pacing function, pacing threshold, lead impedances, sensation of heat or device motion.

Sommer et al (51) recently reported 115 extrathoracic 1.5 Tesla MR studies in 82 non-pacemaker dependent patients. For patients with heart rates of <60 beats/minute asynchronous pacing was programmed and for heart rates of >60 beats/minute a sense-only mode was programmed. The SAR was limited to 1.5 W/kg. Although there was no inhibition of pacing or arrhythmias, there was a significant increase in pacing threshold, decrease in lead impedance, and decrease in battery voltage. No lead required an increase in programmed output to maintain function. In 6.1% of studies, the post-study interrogation demonstrated pacemaker reset to a synchronous pacing mode. Heatlie et al (52) recently reported 5 non-pacemaker dependent patients who underwent 6 cardiac 0.5 Tesla scans with the pacemakers reprogrammed prior to scanning to sub-threshold output or OOO mode. In one patient, the pacemaker paced at maximum voltage at a fixed rate of 100 beats/minute, which resolved when the patient was taken out of the MR environment prior to the scanning attempt.

In regard to pacemaker dependent patients, Gimbel et al (53) performed 11 MR studies in 10 pacemaker dependent patients, with pacemaker dependence defined as "absence of an underlying escape rate below the lowest programmed rate of the device" (53). Scans were restricted to exclude chest and abdominal scanning and SAR was limited to 1–2 W/kg. Ten brain studies and one C-spine study were performed. All patients were programmed asynchronous mode (VOO or DOO) a 60 beats/minute prior to study. There was no pacemaker malfunction during study. Small variances in pacing threshold were seen in four patients.

Pacemaker dependence is an important issue. Underlying cardiac substrates and antiarrhythmics predisposing to pause-dependent arrhythmias are of concern as well as asynchronous pacing, which may be proarrhythmic. Decisions in regard to programming mode for scanning need to be made based on an individual patient's underlying rhythm, thereby weighing the risks or benefits of asynchronous pacing in an individual patient. Asynchronous pacing in a patient with a competing rhythm present could potentially but extremely rarely lead to proarrhythmia due to R on T phenomenon (24, 53). As there is a spectrum of dependence defined by sinus node function, degree of AV block, pauses and type and reliability of escape rhythms, these decisions need to be made based on an individual patient's history and underlying rhythm by physicians experienced in device programming. These decisions though can be challenging as some patients' automaticity and conduction abnormalities only occur intermittently. Technologies with potential for temporary pacing using MR compatible fiber optic temporary wires or transesophageal temporary pacing have been suggested, but require further investigation (54, 55).

These series reported some significant effects (Table 1), but did not lead to significant adverse clinical outcomes. Although these series reported a lack of significant adverse clinical outcomes, they still did not demonstrate absolute safety for routine use of MR (7, 56).

HUMAN MR/ICD DATA

Data in patients with ICDs are even more preliminary, as fewer patients have undergone MR procedures. Roguin et al (57) reported cardiac MR in a patient with a single chamber ICD with lack of significant effect and diagnostic quality images for follow-up of arrhythmogenic right ventricular dysplasia. Gimbel et al (10) studied 7 patients with ICDs who underwent a total of 8 studies at 1.5 Tesla with no significant changes in pacing, charge time or battery longevity. Wollmann et al (58) reported one patient with an ICD who underwent 3 separate brain MR studies at 1.5 Tesla with no effect on programmed data, ability to interrogate, ability to program, heating or movement of the device. Fiek et al (59) described permanent effect on circuitry of an ICD after brain MR at 0.5 Tesla without ability to communicate with the device post scan. This was an inadvertent scan of a patient with an ICD. Anfinsen et al (60) reported a patient inadvertently studied 8 days after implant of an ICD. Brain MR at 0.5 Tesla caused inappropriate sensing of electromagnetic noise and a battery voltage change to end-of-life parameters with reversion to a normal battery voltage after several capacitor reformations. Although an increased pacing threshold was noted at follow-up 2 weeks and 3 months later, it is unclear whether the rise in pacing threshold was due to scanning in this case or independent changes in a newly implanted lead.

Naehle et al (27) reported the performance of brain MR at 1.5 Tesla for assessment of a brain tumor with a single chamber ICD, with the ICD antitachycardia therapies deactivated and a protocol to minimize radiofrequency energy power, with system integrity assessed after study and at 6 weeks post study including defibrillation testing. There were no sensed events in tachyarrhythmia zones, no electrical reset of programmed features, and normal defibrillation function.

Nazarian et al (61) performed 68 MR studies in both pacemaker (n = 31) and ICD (n = 24) patients. Their protocol

included asynchronous pacing for pacemaker dependent patients and demand pacing for all others, with magnet response and tachyarrhythmia function disabled, and scanning at 1.5 Tesla cardiac and non-cardiac studies with SAR limited to 2.0 W/kg. There were no significant changes in sensing amplitudes, pacing thresholds, or lead impedances. There were diagnostic studies in all non-thoracic studies and 93% of thoracic studies.

In addition to issues raised by these ICD reports, the role of defibrillation threshold testing to assure adequate defibrillation function in an ICD which has been exposed to the MR environment requires further investigation. Several authors have performed defibrillation testing after scanning in order to assure integrity of ICD function after scanning (27, 60, 62). Coman et al (62) prospectively scanned 11 patients with ICDs at 1.5 Tesla, without significant changes in pacing threshold, lead impedance or sensing threshold. All patients underwent defibrillation threshold testing with a greater than 10 joule safety margin with testing. One patient experienced a "brief" asymptomatic pause. One patient's device was in a back-up mode and could not be interrogated post scan and was replaced. Other authors though have not performed defibrillation testing after scanning patients with ICDs, commenting that testing may be "impractical and meet with both patient and clinician resistance" in settings where in settings where post MR interrogation does not demonstrate any abnormalities (10).

These data described above lead to the philosophical decision as to whether currently implanted devices can be scanned or whether the only devices that should be scanned are future devices specifically designed, tested and labeled to be MR safe (3, 4, 63). The designation of "modern era" devices is a somewhat arbitrary distinction with great differences between individual devices and manufacturers leading to the need to define safety or lack of adverse effect on a device by device basis (50). Others have suggested that decisions regarding scanning should be made on an individual case by case risk benefit analysis by the clinician (5, 64). Until devices are designed to be MR compatible, this analysis will need to take into consideration the issues as discussed. In an editorial from FDA authors, Faris et al (7) concluded, "In summary, FDA recognizes that MRI is a unique and powerful diagnostic tool that, as recent studies demonstrate, has the potential for safe application in the pacemaker and ICD populations. However, the removal of the warnings and contraindications for C/MR use with pacemaker or ICD patients will require thorough characterization of the array of safety concerns" (7). In a recent follow-up to this editorial, Faris et al (56) commented, "The FDA continues to believe that extending MRI use to the general pacemaker and ICD patient population through removal or modification of device warnings and contraindications will require thorough characterization of the array of safety concerns related to heating, arrhythmogenesis, and proper device function and validation of the measures taken to mitigate these concerns. Although many of these concerns are best addressed through bench and animal studies, prospectively designed and adequately powered clinical trials will likely be necessary to confirm the results from preclinical testing" (56).

The American College of Radiology White Paper on MR Safety (2) comments, "It is recommended that the presence of implanted cardiac pacemakers and/or autoimplanted cardioverter defibrillators (ICD) be considered contraindications for routine MR imaging. Should an exception be considered, it should be done on a case-by-case and site-by-site basis and only if the site is manned with individuals with the appropriate radiology and cardiology knowledge and expertise on hand" (2). Comprehensive in vitro testing of specific pacemaker and ICD models with connected leads under specified conditions using sophisticated phantoms simulating anatomically relevant orientation with assessment of magnetic field interactions, MR associated heating, effects on device functional parameters, and MR associated induced currents can provide data on specific models and scanning conditions, and serve an important role in the assessment of safety of individual devices (65).

Current nomenclature related to devices and MR do not use the term "MR compatible." The current nomenclature designated by the American Society for Testing and Materials International uses the term "MR conditional" to define a device "demonstrated to pose no known hazards in a specified MR environment with specified conditions of use" and "MR safe" to define a device that "poses no known hazards in all MR environments" (66). Current generation pacemakers and ICDs do not carry these designations. Other electronic devices have been studied with criteria created for their safe application with some devices which have received approval as "MR safe" (67, 68). In addition to the current designations, physicians must balance this with what is felt to be clinically acceptable, especially when dealing with potentially life threatening disease processes such as brain tumors, where MR diagnoses may be essential to patient management. These issues point to the need for the attention to the details of a specific patient's case and assessment of risks and benefits to define what is clinically acceptable in an individual patient's care.

Another issue relates to scanning patients with devices on safety advisories. Although advisories are for specific issues, differentiating device malfunction versus an intrinsic device issue secondary to an advisory may be more challenging. Further prospective case controlled studies with precise definition of patient substrate, device, scanner, and type of scan are necessary to provide greater information on safety for clinical use, especially in regard to pacing parameters as these can vary in during regular clinical follow-up.

PATIENT, DEVICE, AND MR FACTORS

Consideration of MR in a patient with a pacemaker or ICD requires thorough assessment and knowledge of a patient's history, indication for scan, scan type, scan setting, and the type of cardiac device involved (Table 2). A detailed knowledge of electrophysiologically relevant issues related to arrhythmia history, underlying cardiac substrate, device type and function

Table 2. Important information in the evaluation of patients with pacemakers and ICDs for MR

Patient	Device	MR
Device indication	Device location	Body part to be scanned
Underlying rhythm	Device type, functions and era	Magnet field strength
Arrhythmia history	Lead type, configuration, and maturity	Imaging sequences Specific Absorption Rate
Indication for scan	Pre scan device function and programming	Potential scan artifact secondary to device
Alternative imaging options	Generator battery voltage	Patient monitoring Resuscitation equipment
Options for device revision	Device advisories	Staff capable of device management

is required. Degree of pacemaker dependence is an important issue, as there is a spectrum of dependence defined by sinus node function, degree of AV block, pauses and type and reliability of escape rhythms. Underlying cardiac substrates and antiarrhythmics predisposing to pause-dependent arrhythmias are of concern as well as asynchronous pacing, which may be proarrhythmic (24). As mentioned above, decisions in regard to programming mode for scanning need to be made based on an individual patients underlying rhythm thereby weighing the risks or benefits of asynchronous pacing in an individual patient.

In terms of ICDs, the frequency and type of ventricular arrhythmias are also important as some MR studies may be lengthy with suboptimal electrocardiographic monitoring due to interference with ECG lead recordings during scanning. Patient stability and recent arrhythmia events must be taken into account in regard to risk benefit analysis regarding scanning or timing of scanning. Knowledge of system type, lead type and configuration, abandoned leads, device function, battery voltage, and any system advisory are critical details. Individual assessment of options and limitations to device revision and replacement are important, especially regarding such issues as limited vascular access sites, epicardial leads, and challenges to initial device placement and must be taken into account in assessing an individual patient's risk benefit analysis.

Details related to the MR procedure, including the indication for scanning, urgency of scanning, and advantages and disadvantages of other possible imaging modalities must be taken into account. The type of scan, spatial relation of the device to the scanner during the study, magnetic field strength, magnet bore, imaging sequences, and overall time of study are also important factors. In addition to assessment of factors relating to the effect of the scan on the device, other issues relate to the effect of the device on scan quality. Specifically, artifacts caused by devices using certain imaging sequences may render investigation difficult or non-diagnostic (Fig. 1), although image distortion

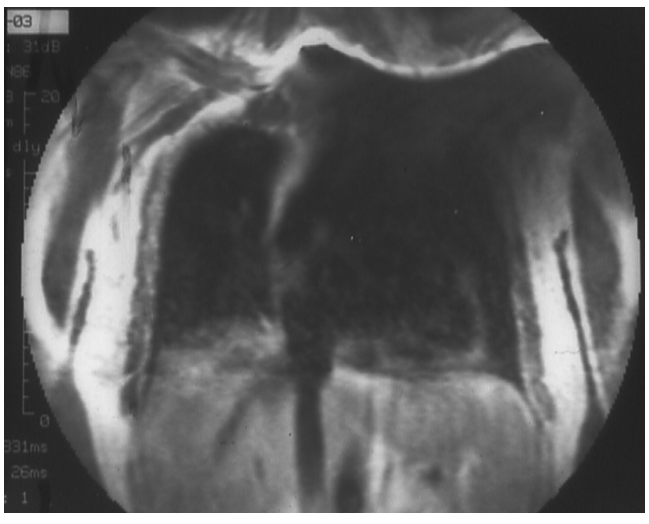

Figure 1. MR of the chest performed on a patient with a non-functioning pacemaker at 0.5 Tesla demonstrating significant artifact.

Table 3. Considerations for patients with pacemakers and ICDs

Indication	Important clinical questions essential to patient management.
	Inability to adequately assess patient with other diagnostic techniques.
Consent	Informed consent relating to potential risks.
Pacemaker Programming	Non-pacemaker dependent patients. *If clinical circumstances necessitate scanning in a pacemaker dependent patient, asynchronous pacing with avoidance of chest or abdomen scanning.
	Programming changes based on individual patient device and history by physician experienced in device programming.
ICD Programming	Program to therapy off for antitachycardia pacing, cardioversion and defibrillation.
Staff	Advanced Cardiac Life Support-trained personnel and equipment.
	Physician experienced in device programming.
Monitoring	Continuously monitor the patient's level of consciousness, heart rate, blood pressure, and oxygen saturation using appropriate MRI-safe equipment. Maintain visual contact throughout the procedure.
	Maintain voice contact throughout the procedure with the patient.
	Instruct the patient and provide means to alert the MR system operator of any unusual sensations or problems so that the scan can be immediately terminated.
Post MR	Evaluation of device function and reprogramming.

predominantly occurs in the region adjacent to the device (15, 57).

Programming immediately prior to introduction to the MR environment requires detailed knowledge of the individual patient's device features, including monitoring histograms and other data storage, bradycardia pacing, antitachycardia pacing, cardioversion and defibrillation therapies. For each feature, decisions need to be made regarding saving histogram data, subsequently clearing histograms, decisions as to whether to program pacing asynchronously, and deactivation of antitachycardia pacing and shock therapies.

The scanning setting is important with the necessary presence of staff with Advanced Cardiac Life Support training, code equipment, preferably with a defibrillator with the ability to provide transcutaneous pacing, device programmer, and staff with training to assess and program devices. Monitoring can be challenging while patients are in the scanner due to ECG artifact and should be supplemented with fiber-optic pulse oximeter monitoring and frequent communication with the patient (69). Interrogation of device function and reprogramming to original settings is necessary after scanning. There are many factors to consider in patients with cardiac devices being assessed for possible MR, requiring great vigilance on the part of the physicians and staff involved in the assessment, scanning, and follow-up (Table 3).

CONCLUSIONS

There is still great controversy regarding MR in patients with pacemakers and ICDs. Although there are theoretical as well as documented issues relating to device malfunction, preliminary data suggests that scanning patients with pacemakers and ICDs may not be absolutely contraindicated. Clinical data though are limited with most existing studies relating to non-cardiac scanning of pacemakers at low field strengths. In regard to higher field strengths, the clinically used field strengths have increased to 3 Tesla, and therefore further research will need to be performed using experimental models and scanners with greater field strengths to assess for device interactions (70). Further investigation and application to patient care will require detailed knowledge of patient, device and scanner (71). Until additional data are available, individualized assessment of risk versus benefit will determine what is in the best interest of an individual patient. Future device designs will need to take into account the ever increasing use of MR for both cardiac and non-cardiac indications. Future scanner designs will need to consider systems and imaging sequences which may decrease potential interactions as well as potential artifact. Authors have proposed such systems as "pacemaker triggered MR scans" which may potentially decrease the chances of pacing during ventricular repolarization, although this system could require design changes in some pacemakers and increase study times (24). The future designers of both devices and scanners will need to be cognizant of relevant interaction issues. Additionally, standardized units of measure for RF power and standardized testing will need to be defined. As assessment for interaction between devices and MR span multiple technologies and specialties, a multidisciplinary effort will be necessary to further define the role of MR in patients with pacemakers and ICDs.

ABBREVIATIONS

ICD	implantable cardiac defibrillator
MR	magnetic resonance imaging
RF	radiofrequency energy
SAR	specific absorption rate

REFERENCES

1. Shellock FG. Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2006 Edition. Los Angeles: Biomedical Research Publishing Group, 2006.
2. Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology White Paper on MR Safety: 2004 update and revisions. AJR Am J Roentgenol 2004;182:1111–4.
3. Kalin R, Stanton MS. Current clinical issues for MR scanning of pacemaker and defibrillator patients. Pacing Clin Electrophysiol 2005;28:326–8.
4. Stanton MS. Industry viewpoint: Medtronic: Pacemakers, ICDs, and MRI. Pacing Clin Electrophysiol 2005;28:265.
5. Levine PA. Industry viewpoint: St. Jude Medical: Pacemakers, ICDs and MRI. Pacing Clin Electrophysiol 2005;28:266–7.
6. Fisher JD. MRI: safety in patients with pacemakers or defibrillators: is it prime time yet? Pacing Clin Electrophysiol 2005; 28:263.
7. Faris OP, Shein MJ. Government viewpoint: U.S. Food & Drug Administration: Pacemakers, ICDs and MRI. Pacing Clin Electrophysiol 2005;28:268–9.
8. Martin ET, Coman JA, Shellock FG, Pulling CC, Fair R, Jenkins K. Magnetic resonance imaging and cardiac pacemaker safety at 1.5-Tesla. J Am Coll Cardiol 2004;43:1315–24.
9. Martin ET. Can cardiac pacemakers and magnetic resonance imaging systems co-exist? Eur Heart J 2005;26:325–27.
10. Gimbel JR, Kanal E, Schwartz KM, Wilkoff BL. Outcome of magnetic resonance imaging (MRI) in selected patients with implantable cardioverter defibrillators (ICDs). Pacing Clin Electrophysiol 2005;28:270–3.
11. Saksena S, Madan N. Management of the patient with an implantable cardioverter-defibrillator in the third millennium. Circulation 2002;106:2642–6.
12. Shellock FG. Biomedical implants and devices: Assessment of magnetic field interactions with a 3.0-Tesla MR system. J Magn Reson Imaging 2002;16:721–32.
13. Baker KB, Nyenhuis JA, Hrdlicka G, Rezai AR, Tkach JA, Shellock FG. Neurostimulation systems: assessment of magnetic field interactions associated with 1.5- and 3-Tesla MR systems. J Magn Reson Imaging 2005;21:72–7.
14. Shellock FG, Tkach JA, Ruggieri PM, Masaryk TJ. Cardiac pacemakers, ICDs, and loop recorder: evaluation of translational attraction using conventional ("long-bore") and "short-bore" 1.5- and 3.0-Tesla MR systems. J Cardiovasc Magn Reson 2003;5:387–97.
15. Roguin A, Zviman MM, Meininger GR, et al. Modern pacemaker and implantable cardioverter/defibrillator systems can be magnetic resonance imaging safe: In vitro and in vivo assessment of safety and function at 1.5 T. Circulation 2004;110:475–82.
16. Shellock FG, O'Neil M, Ivans V, et al. Cardiac pacemakers and implantable cardioverter defibrillators are unaffected by operation

of an extremity MR imaging system. AJR Am J Roentgenol 1999;172:165–70.
17. Loewy J, Loewy A, Kendall EJ. Reconsideration of pacemakers and MR imaging. Radiographics 2004;24:1257–67; discussion 1267–68.
18. Schmiedel A, Hackenbroch M, Yang A, et al. Magnetic resonance imaging of the brain in patients with cardiac pacemakers. Experimental and clinical investigations at 1.5 Tesla. Rofo 2005;177:731–44.
19. Bailey SM, Gimbel JR, Ruggieri PM, Tchou PJ, Wilcoff BL. Magnetic resonance imaging (MRI) of the brain in pacemaker dependent patients. Heart Rhythm 2005;2:S128.
20. Fries R, Steuer M, Schafers HJ, Bohm M. The R-on-T phenomenon in patients with implantable cardioverter-defibrillators. Am J Cardiol 2003;91:752–55.
21. Chiladakis JA, Karapanos G, Davlouros P, Aggelopoulos G, Alexopoulos D, Manolis AS. Significance of R-on-T phenomenon in early ventricular tachyarrhythmia susceptibility after acute myocardial infarction in the thrombolytic era. Am J Cardiol 2000;85:289–93.
22. Lauck G, von Smekal A, Wolke S, et al. Effects of nuclear magnetic resonance imaging on cardiac pacemakers. Pacing Clin Electrophysiol 1995;18:1549–55.
23. Luechinger R, Duru F, Zeijlemaker VA, Scheidegger MB, Boesiger P, Candinas R. Pacemaker reed switch behavior in 0.5, 1.5, and 3.0 Tesla magnetic resonance imaging units: are reed switches always closed in strong magnetic fields? Pacing Clin Electrophysiol 2002;25:1419–23.
24. Irnich W, Irnich B, Bartsch C, Stertmann WA, Gufler H, Weiler G. Do we need pacemakers resistant to magnetic resonance imaging? Europace 2005;7:353–65.
25. Irnich W. Electronic security systems and active implantable medical devices. Pacing Clin Electrophysiol 2002;25:1235–58.
26. Trigano A, Blandeau O, Souques M, Gernez JP, Magne I. Clinical study of interference with cardiac pacemakers by a magnetic field at power line frequencies. J Am Coll Cardiol 2005;45:896–900.
27. Naehle CP, Sommer T, Meyer C, et al. Strategy for safe performance of magnetic resonance imaging on a patient with implantable cardioverter defibrillator. Pacing Clin Electrophysiol 2006;29:113–16.
28. Achenbach S, Moshage W, Diem B, Bieberle T, Schibgilla V, Bachmann K. Effects of magnetic resonance imaging on cardiac pacemakers and electrodes. Am Heart J 1997;134:467–73.
29. Baker KB, Tkach JA, Nyenhuis JA, et al. Evaluation of specific absorption rate as a dosimeter of MRI-related implant heating. J Magn Reson Imaging 2004;20:315–20.
30. Luechinger R, Zeijlemaker VA, Pedersen EM, et al. In vivo heating of pacemaker leads during magnetic resonance imaging. Eur Heart J 2005;26:376–83; discussion 325–27.
31. Vahlhaus C. Heating of pacemaker leads during magnetic resonance imaging. Eur Heart J 2005;26:1243; author reply 1243–44.
32. Yeung CJ, Susil RC, Atalar E. RF heating due to conductive wires during C/MR depends on the phase distribution of the transmit field. Magn Reson Med 2002;48:1096–98.
33. Hartnell GG, Spence L, Hughes LA, Cohen MC, Saouaf R, Buff B. Safety of MR imaging in patients who have retained metallic materials after cardiac surgery. AJR Am J Roentgenol 1997;168:1157–59.
34. Kanal E. Safety of MR imaging in patients with retained epicardial pacer wires. AJR Am J Roentgenol 1998;170:213–14.
35. Erlebacher JA, Cahill PT, Pannizzo F, Knowles RJ. Effect of magnetic resonance imaging on DDD pacemakers. Am J Cardiol 1986;57:437–40.
36. Pavlicek W, Geisinger M, Castle L, et al. The effects of nuclear magnetic resonance on patients with cardiac pacemakers. Radiology 1983;147:149–53.
37. Holmes DR, Jr., Hayes DL, Gray JE, Merideth J. The effects of magnetic resonance imaging on implantable pulse generators. Pacing Clin Electrophysiol 1986;9:360–70.
38. Hayes DL, Holmes DR, Jr., Gray JE. Effect of 1.5 tesla nuclear magnetic resonance imaging scanner on implanted permanent pacemakers. J Am Coll Cardiol 1987;10:782–86.
39. Fontaine JM, Mohamed FB, Gottlieb C, Callans DJ, Marchlinski FE. Rapid ventricular pacing in a pacemaker patient undergoing magnetic resonance imaging. Pacing Clin Electrophysiol 1998;21:1336–39.
40. Vahlhaus C, Sommer T, Lewalter T, et al. Interference with cardiac pacemakers by magnetic resonance imaging: are there irreversible changes at 0.5 Tesla? Pacing Clin Electrophysiol 2001;24:489–95.
41. Rozner MA, Burton AW, Kumar A. Pacemaker complication during magnetic resonance imaging. J Am Coll Cardiol 2005;45:161–2.
42. Avery JK. Loss Prevention case of the month. Not my responsibility! J Tenn Med Assoc 1988;81:523.
43. Coman JA, Martin ET, Ramza BM, Margolis PD, Fair RD. Pacemaker safety during magnetic resonance imaging at 1.5 Tesla. J Am Coll Cardiol 2001;37(Suppl. A):436.
44. Iberer F, Justich E, Stenzl W, Tscheliessnig KH, Kapeller J. Nuclear magnetic resonance imaging of a patient with implanted transvenous pacemaker. Herz 1987;7:196–99.
45. Alagona P, Jr., Toole JC, Maniscalco BS, Glover MU, Abernathy GT, Prida XE. Nuclear magnetic resonance imaging in a patient with a DDD Pacemaker. Pacing Clin Electrophysiol 1989;12:619.
46. Inbar S, Larson J, Burt T, Mafee M, Ezri MD. Case report: nuclear magnetic resonance imaging in a patient with a pacemaker. Am J Med Sci 1993;305:174–75.
47. Garcia-Bolao I, Albaladejo V, Benito A, Alegria E, Zubieta JL. Magnetic resonance imaging in a patient with a dual-chamber pacemaker. Acta Cardiol 1998;53:33–5.
48. Gimbel JR, Johnson D, Levine PA, Wilkoff BL. Safe performance of magnetic resonance imaging on five patients with permanent cardiac pacemakers. Pacing Clin Electrophysiol 1996;19:913–19.
49. Sommer T, Vahlhaus C, Lauck G, et al. MR imaging and cardiac pacemakers: in-vitro evaluation and in-vivo studies in 51 patients at 0.5 T. Radiology 2000;215:869–79.
50. Del Ojo JL, Moya F, Villalba J, et al. Is magnetic resonance imaging safe in cardiac pacemaker recipients? Pacing Clin Electrophysiol 2005;28:274–78.
51. Sommer T, Naehle CP, Yang A, et al. Strategy for safe performance of extrathoracic magnetic resonance imaging at 1.5 tesla in the presence of cardiac pacemakers in non-pacemaker-dependent patients: a prospective study with 115 examinations. Circulation 2006;114:1285–92.
52. Heatlie G, Pennell DJ. Cardiovascular magnetic resonance at 0.5T in five patients with permanent pacemakers. J Cardiovasc Magn Reson 2007;9:15–17.
53. Gimbel JR, Bailey SM, Tchou PJ, Ruggieri PM, Wilkoff BL. Strategies for the safe magnetic resonance imaging of pacemaker-dependent patients. Pacing Clin Electrophysiol 2005;28:1041–46.
54. Greatbatch W, Miller V, Shellock FG. Magnetic resonance safety testing of a newly-developed fiber-optic cardiac pacing lead. J Magn Reson Imaging 2002;16:97–103.
55. Hofman MB, de Cock CC, van der Linden JC, et al. Transesophageal cardiac pacing during magnetic resonance imaging: Feasibility and safety considerations. Magn Reson Med 1996;35:413–22.
56. Faris OP, Shein M. Food and Drug Administration perspective: Magnetic resonance imaging of pacemaker and implantable cardioverter-defibrillator patients. Circulation 2006;114:1232–33.
57. Roguin A, Donahue JK, Bomma CS, Bluemke DA, Halperin HR. Cardiac magnetic resonance imaging in a patient with implantable

cardioverter-defibrillator. Pacing Clin Electrophysiol 2005;28:336–38.
58. Wollmann C, Grude M, Tombach B, et al. Safe performance of magnetic resonance imaging on a patient with an ICD. Pacing Clin Electrophysiol 2005;28:339–42.
59. Fiek M, Remp T, Reithmann C, Steinbeck G. Complete loss of ICD programmability after magnetic resonance imaging. Pacing Clin Electrophysiol 2004;27:1002–04.
60. Anfinsen OG, Berntsen RF, Aass H, Kongsgaard E, Amlie JP. Implantable cardioverter defibrillator dysfunction during and after magnetic resonance imaging. Pacing Clin Electrophysiol 2002;25:1400–02.
61. Nazarian S, Roguin A, Zviman MM, et al. Clinical utility and safety of a protocol for noncardiac and cardiac magnetic resonance imaging of patients with permanent pacemakers and implantable-cardioverter defibrillators at 1.5 tesla. Circulation 2006;114:1277–84.
62. Coman JA, T. ME, Sandler DA, Thomas RT. Implantable cardiac defibrillator interactions with magnetic resonance imaging at 1.5 tesla. J Am Coll Cardiol 2004;43:138A.
63. Gimbel JR, Kanal E. Can patients with implantable pacemakers safely undergo magnetic resonance imaging? J Am Coll Cardiol 2004;43:1325–27.
64. Smith JM. Industry viewpoint: Guidant: Pacemakers, ICDs, and MRI. Pacing Clin Electrophysiol 2005;28:264.
65. Shellock FG, Fischer L, Fieno D. Cardiac pacemakers and implantable cardioverter defibrillators: in vitro C/MR evaluation at 1.5-Tesla. J Cardiovasc Magn Reson 2007;9:21–31.
66. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. American Society for Testing and Materials (ASTM) International 2003;F2503–05.
67. Shellock FG. MR imaging and electronically activated devices. Radiology 2001;219:294–95.
68. Shellock FG, Hatfield M, Simon BJ, et al. Implantable spinal fusion stimulator: Assessment of MR safety and artifacts. J Magn Reson Imaging 2000;12:214–23.
69. Birkholz T, Schmid M, Nimsky C, Schuttler J, Schmitz B. ECG artifacts during intraoperative high-field C/MR scanning. J Neurosurg Anesthesiol 2004;16:271–76.
70. Nahrendorf M, Hiller KH, Hu K, Zeijlemaker V, Griswold M, Bauer WR. Pacing in high field cardiac magnetic resonance imaging. Pacing Clin Electrophysiol 2004;27:671–74.
71. Nazarian S, Roguin A, Zviman MM, et al. Evaluation of a safety protocol for clinically indicated magnetic resonance imaging of patients with permanent pacemakers and implantable defibrillators at 1.5-Tesla. J Amer Coll Cardiol 2005;45:14A.
72. Sommer T, Lauck G, Schimpf R, et al. C/MR in patients with cardiac pacemakers: in vitro and in vivo evaluation at 0.5 tesla. Rofo 1998;168:36–43.