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Safety of serial MRI in patients with implantable cardioverter defibrillators

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Abstract

Objective—While patients with cardiac implantable electronic devices could benefit from magnetic resonance (MR) imaging, the presence of such devices has been designated as an absolute contraindication to MR. Although scanning algorithms are proposed for cardiac implantable electronic devices, their safety remains uncertain. To address this issue, the safety of serial cardiac MR scans was evaluated in patients with implantable cardioverter defibrillators (ICDs).

Methods—Three serial cardiac MR scans were prospectively performed at 1.5 T on 10 patients (9 men) of median age 56 years (range 51–68) with ICDs. ICD interrogation was performed before and after the MR scan and at a follow-up of median 370 days (range 274–723). Image quality was also assessed.

Results—In all patients MR scanning occurred without complications. There were no differences between preand post-MR pacing capture threshold, pacing lead or high voltage lead impedance, or battery voltage values. During follow-up there were no occurrences of ICD dysfunction. Although most patients had image artifacts, the studies were generally diagnostic regarding left ventricular function and wall motion. Delayed enhancement imaging was of good quality for inferior wall and inferolateral infarcts, but ICD artifacts often affected the imaging of anterior wall infarcts.

Conclusion—Serial MR scans at 1.5 T in patients with ICDs, when carefully performed in a monitored setting, have no adverse effects on either patient or device. When required, single or multiple MR scans at 1.5 T may therefore be considered for clinical diagnostic purposes in these patients.

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INTRODUCTION

Magnetic resonance (MR) imaging is an important clinical tool for the evaluation of many disease states. In the heart, in particular, cardiac MR provides high resolution imaging of tissue characteristics and regional and global left ventricular function. Cardiac MR is proving highly useful for the detection and diagnosis of specific forms of cardiomyopathy. Many patients who could potentially benefit from MR have cardiac implantable electronic devices (CIED) in place. It remains highly controversial whether MR is safe for such patients, even when taking into account the diagnostic value of MR imaging. The device manufacturers and US Food and Drug Administration (FDA) list such devices as contraindications to MR imaging.[1–4]

While a number of recent publications have evaluated the safety of MR imaging in patients with CIEDs, the safety of multiple cardiac MR imaging procedures among such patients has not been previously reported.[5–7] Given the fact that a patient needing multiple MR scans is not infrequent and, furthermore, that multiple MR scans may more rigorously test the safety of the procedure, we tested the hypothesis that even multiple sequential cardiac MR scans would not damage or impair implantable cardioverter defibrillator (ICD) function or patient well-being.

METHODS

We prospectively performed 30 cardiac MR scans on 10 patients (nine men) of median age 56 years (range 51–68) who had an ICD implanted for primary or secondary prevention according to the current guidelines.8 The study protocol included cardiac MR imaging at enrolment and follow-up scans at 3, 6 and 12 months. The patients were subjects in a study of ischaemic cardiomyopathy; the study's potential requirement for MR imaging was approved by the institutional review board of the University of Miami and all study subjects signed an informed consent form. Patients who were pacemaker-dependent (intrinsic heart rate <40 beats/min) were excluded from the study. All patients with an ICD who underwent MR signed a second informed consent form regarding the indications, risks and benefits of MR imaging with cardiac devices. The risks outlined in the consent process included (but were not limited to) ICD dysfunction and/or damage, arrhythmia, device dislodgement, thermal injury and death.[9]

ICD interrogation

ICD interrogation was performed before and immediately after MR scanning. Data collected from each device interrogation included pre- and post-MR scan sensing and pacing threshold, pacing lead impedance, high voltage lead impedance and battery voltage.

Safety features

Before the MR scan, all devices were reprogrammed to VVI-40 and all ICD therapies were turned off to avoid known side effects of electromagnetic interference during the scan. During this period all patients were continuously monitored with continuous ECG telemetry and pulse oximetry, blood pressure measurements every 5 min (Veris MR Vital Signs Monitor, Medrad Inc, Warrandale, Pennsylvania, USA) and verbal symptom monitoring.

Pacemaker-dependent patients, patients with devices manufactured before 2000 and patients with non-transvenous epicardial or abandoned (capped) leads were excluded from this substudy.6 Rate response, premature ventricular contraction response, ventricular sense response, conducted atrial fibrillation response, magnet mode and tachyarrhythmia monitoring and therapies were disabled. Post-MR scan pacing and tachyarrhythmia functions were reprogrammed to original settings.

Cardiac MR protocol

Cardiac MR (CMR) was performed on a 1.5 T scanner (Signa HDx, GE Healthcare, Waukesha, Wisconsin, USA) using an echo speed gradient of 33 mT/m and slew rate of 120 T/m/s with an eight-channel cardiac-phased array coil to provide optimal signal to noise. Imaging was performed using ECG gating and breathholding with respiratory monitoring. Visual and voice contact were maintained with the patient throughout the procedure. Scan sequences were limited to an estimated whole body averaged specific absorption rate of <2.0 W/kg, which was calculated by the scanner console using patient weight. The protocol consisted of

1. Sagittal and axial pilot images.
2. Retrospectively gated segmented k-space fast gradient echo (FASTCARD, GE Medical Systems, Milwaukee, Wisconsin, USA) cine images were acquired in 2-, 3- and 4-chamber view and short axis planes. The sequence parameters were TE 3 ms, TR 6 ms; 8 views per segment; receiver bandwidth 32–83 kHz; flip angle 158; section thickness 8 mm with 2 mm gap; 40 cm field of view (FOV); imaging matrix of 2563128. Steady-state free precession cine sequences were not used because of unacceptable artifacts from the ICD device.
3. Segmented k-space fast gradient echo tagged short axis sequence with grid pattern, with the same parameters as the cine images;
4. Short axis first-pass resting perfusion using 0.2 mmol/kg of Magnevist (Bayer Healthcare, Wayne, New Jersey, USA) intravenous injection were acquired using an ultra-short realtime fast imaging sequence employing steady-state acquisition (MR Echo, GE Healthcare). MR Echo combined with contrast enables acquisition of real-time cardiac images without the use of cardiac gating or breath holding using the following parameters: TE 1.2 ms, TR 2.7 ms, receiver bandwidth 83 kHz, flip angle 208, section thickness 10 mm with 5 mm gap, 40 cm FOV, imaging matrix 1283128, 6–8 slices.
5. Short axis, 2-, 3- and 4-chamber delayed myocardial enhancement imaging starting 10 min after gadolinium infusion; same positions and FOV as the cine images were acquired using the following parameters: inversion time 200–300 ms, R-wave trigger delay 400 ms, TE 1.1 ms, 20 views per segment, receiver bandwidth 83 kHz, flip angle 208, section thickness 8 mm with 2 mm gap, 40 cm FOV, imaging matrix 1923160.

Image quality

All images were reviewed by a radiologist (JF) to determine image quality. Each of four short axis series (cine, tagged, perfusion and delayed enhancement) for each subject and scan date was reviewed to determine how many, if any, of the myocardial segments were not analysable according to the AHA 16 segment model.

Statistical analysis

Statistical analysis was performed with PASW 17.0 software (SPSS). The Student t test was used for evenly distributed variables and the ManneWhitney test was used to determine significance in variables with skewed distribution. The significance level was set at $p<0.05$.

RESULTS

The study included 10 patients and, at the time of analysis, all patients had undergone three MR scans. The baseline characteristics of these patients are shown in table 1. Patients reported no adverse symptoms during MR and no scans required termination before completion. The patients were followed for a median of 370 days (range 274–723) after the first MR scan.

ICD interrogation

The mean pre- and post-scan pacing threshold values were not significantly different in the MR scans (first scan: 1.9961.12 V vs 2.0061.11 V, p1/40.97; second scan: 1.9161.14 V vs 1.9261.12 V, p1/40.88; third scan: 1.7461.2 V vs 1.7861.2 V, p1/40.85; table 2). Additionally, there were no significant differences between mean pre- and post-scan pacing lead or high voltage (HV) lead impedance values in the MR scans (first scan: pacing: 528695 ohm vs 507684 ohm, p1/40.45; HV: 5068.3 ohm vs 5168.4 ohm, p1/40.68; second scan: pacing: 5276102 ohm vs 538688 ohm, p1/40.73; HV: 5269.2 ohm vs 5366.1 ohm, p1/40.79; third scan: pacing: 524689 ohm vs 520688 ohm, p1/40.97; HV: 5167.9 ohm vs 5166.3 ohm, p1/40.97). Furthermore, we did not find any significant differences between preand post-battery voltage values in the MR scans (first scan: 3.0560.22 V vs 3.0460.21 V, p1/40.61; second scan: 3.0360.23 V vs 3.0360.23 V, p1/40.75; third scan: 3.0160.24 V vs 3.0060.24 V, p1/40.65). Detailed results of the statistical analysis are shown in table 2. The mean values between scans differed due to the different subgroups in the scans since most ICD settings are individual and dependent on the device manufacturer. No clinically relevant individual changes between pre- and post-scan ICD interrogation values were detected. Individual results from each ICD interrogation are shown in more detail in table 3. After scanning the ICD was successfully reprogrammed to pre-MR parameters and therapies in all patients.

Image quality

Of the 10 subjects, at least one segment on one image series was not analysable in eight. For all patients and scans combined, a median of two of 16 segments in cine sequences, two segments in tagged sequences, zero segments in perfusion sequences and five segments in delayed enhancement sequences were nonanalysable. Artifacts most often affected the anterior wall and septum with variable involvement of the lateral wall. The artifacts were

most severe in the apical region of the left ventricle with relatively less involvement of the basal region. Calculation of ejection fraction and ventricular volumes from cine imaging was feasible, occasionally requiring estimations of blood pool myocardial boundary in the region of the anterior wall. Delayed enhancement image quality was adequate for inferior wall and inferolateral infarcts, but anterior wall infarcts were often not well visualised due to artifacts.

DISCUSSION

The expanding indications for MR scanning and CIEDs have resulted in an increasing patient population with CIEDs being referred for MR. It has been estimated that patients with CIEDs have a 50–75% likelihood of having a clinical indication for MR over the lifetime of their device.10 Owing to this clinical dilemma, several clinical studies have assessed the safety of MR in patients with CIEDs.[5–7]

Previous reports have focused on the safety of single MR imaging studies. In this study we report the safety of serial cardiac MR imaging in a subset of 10 patients with ischaemic cardiomyopathy, all of whom underwent three MR imaging studies. Moreover, we also report the long-term safety of serial cardiac MR imaging in this patient population with a median follow-up of 370 days. During this period we did not observe any adverse patient or device events after 30 MR imaging studies.

CIED and MR manufacturers advise against MR in patients with these devices.[4–11] There were reported deaths associated with MR in patients with CIEDs during the 1980s. However, these deaths were poorly characterised and no ECG data were available. Worldwide, no deaths have been reported in the last decade during physician-supervised MR studies.10 Nevertheless, CIED and MR manufacturers continue to advise against MR in patients with these devices.[4–11] The reasons for these recommendations include numerous potential hazards including MRrelated radiofrequency (RF) pulses being interpreted as ventricular fibrillation and causing the device to attempt therapy with adverse consequences for the device and/or patient; lead tip heating causing changes in sensing and pacing thresholds and lead impedances; and a decrease in battery voltage with shortening of device battery life. To prevent mistaken therapy delivery, all ICD therapies were disabled prior to MR scanning. Our results have bearing on the potential risk of RF energy to scar myocardium with subsequent alteration of impedances and thresholds since we identified no significant changes in any of these parameters after as many as three cardiac MR scans during a median follow-up of 370 days. Adhering to the recommended guideline of limiting specific absorption rate to <2 W/kg is thus unlikely to produce significant thermal injury at the lead tip-myocardial interface. Finally, Naehle et al described a small but significant decrease in battery voltage in patients with ICD after single MR examinations. [7] They comment that this may have consequences on charge time and/or device lifetime. In our study we did not observe any significant changes in battery voltage.

An AHA Scientific Statement recognises that safe MR imaging involves careful patient screening, accurate evaluation of the CIEDs, a thoughtful analysis of the risks and benefits of the procedure, informed consent and adequate physician supervision. [9] The Writing Group states that CIEDs should still be considered a strong relative contraindication to

routine MR imaging, that patients with CIEDs should not undergo MR if an alternative diagnostic test is available and that MR should only be considered in cases in which the potential benefit to the patient clearly outweighs the risks.9 Similarly, a position paper published in the European Heart Journal affirms that the risk of MR may be acceptable in selected patients in whom diagnostic benefit from MR may outweigh its risks, provided that specific scanning and monitoring conditions are followed.[10]

Recently, the FDA approved the commercial distribution of the Revo MRI SureScan pacing system (Medtronic, Minneapolis, Minnesota, USA) as an MR Conditional pacemaker system designed to allow patients to undergo MRI under specified conditions. A complete system, consisting of a Medtronic Revo MRI SureScan pulse generator implanted with two CapSureFix MRI SureScan leads, is required for use in the MRI environment according to the FDA approval letter.[12] This device, however, is not pertinent to our study because (1) the SureScan system is not an ICD, and (2) the SureScan system is not FDA approved for MR scans in which the magnet isocentre is located between the C1 and T12 vertebral bodies as is necessary for CMR or other MR scans of the thoracic region. It is possible that ‘standard’ ICD systems could eventually be considered MRI ‘conditional’ when other diagnostic modalities are inadequate and a thorough informed consent procedure has been followed.

The Heart Rhythm Society Expert Consensus on transvenous lead extraction gave a class IIb indication for lead extraction for patients who require specific imaging techniques (eg, MRI) that cannot be imaged due to the presence of the CIEDs when there is no other available imaging alternative for the diagnosis.[13] We believe that with the safety data presented in this study and reported by others,[5–7] a physician-supervised MR study poses lower risks than lead extraction with subsequent device reimplantation. It is important to clarify that patients with abandoned leads might still need device and lead extraction if performance of MRI is considered essential for adequate patient care.

The primary purpose of our study was the evaluation of MR safety in the presence of an ICD. CMR is a particularly stringent test since the ICD is near the magnet isocentre for cardiac imaging and thus receives high levels of RF energy. In parallel with the relative utilisation of MRI in different organs, we anticipate that a majority of indications for MR in patients with ICD will be for non-cardiac imaging. In general, the further away the target organ is from the ICD, the less problematic image artifacts will be. Since CMR was the diagnostic test of our particular research study, however, we did evaluate CMR image quality in the presence of an ICD. Due to the close proximity of the heart and the ICD, artifacts were identified in a majority of subjects and were of variable severity. When present, artifacts were usually located in the left ventricular anterior wall and septum, particularly in the apical and middle thirds of the left ventricle, and in the most cephalic portion of the right ventricular outflow tract. This distribution is attributable to the relative positions of the heart and the ICD generator. A median of two segments were affected in cine imaging, so calculation of ventricular metrics from these images was generally feasible. Artifacts were more severe on delayed enhancement images. Inferior and inferolateral wall infarcts were generally well imaged, but the visualisation of anterior wall infarct enhancement was often non-diagnostic. We are currently investigating techniques to

improve CMR image quality in patients with devices. Until such techniques are available, we believe that knowledge of infarct location should be considered when deciding on the feasibility of CMR for viability assessment in patients with ICD. It is noteworthy that our results would not necessarily apply to CMR in patients with non-ICD pacemakers, the generators of which are generally smaller than ICD units. The ICD lead itself appeared as a hypointense focus and did not cause appreciable artifacts.

Study limitations

There are several limitations to our study, one of which is the small number of included patients (n1/410) and scans (n1/430). Our study was restricted to patients who were not pacemaker dependent. We did not evaluate levels of cardiac biomarkers as a potential indicator of tissue damage. Defibrillator testing thresholds to assess the integrity of the ICD was not routinely performed. However, we believe that periodic measurement of sensing and pacing threshold, pacing lead impedance, high voltage lead impedance and battery voltage are reliable indicators of ICD integrity. Finally, MR scans of patients with metallic implants or foreign bodies are subject to a variety of artifacts that may degrade image quality, as described above.

CONCLUSION

Our study provides long-term safety data of serial cardiac MR studies in patients with an ICD for the first time. Although our study is not able definitively to address the absolute safety of MR in patients with CIEDs, it suggests that there is a relatively low risk of one or multiple clinically indicated MR scans in patients with ICDs. Our findings help validate the concept that MR may be safely performed in a monitored setting with no apparent adverse effects to patient or device when other diagnostic modalities are inadequate and a thorough informed consent procedure has been followed.

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Table 1

Demographics and device information of study patients

	Age/ gender	ICD make and model	Lead information	Follow-up (days)
1	54/M	St Jude Current VR RF 1207-36	Medtronic 6947 Sprint Quattro	420
2	67/M	Medtronic Marquis DR 7274	Medtronic 6947 Sprint Quattro	366
3	54/M	BS Teligen 100	Medtronic 6947 Sprint Quattro	302
4	68/M	BS Teligen 100	Guidant Reliance Active Fix Dual Col 0185	723
5	66/M	Medtronic Maximo VR 7232	Medtronic 6947 Sprint Quattro	274
6	51/M	BS Teligen 100	Guidant Reliance Active Fix Dual Col 0185	530
7	54/M	Medtronic Maximo II VR D284VRC	Medtronic 6947 Sprint Quattro	329
8	51/M	Medtronic Maximo II VR D284VRC	Medtronic 6947 Sprint Quattro	342
9	62/M	Medtronic Virtuoso DR D154AWG	Medtronic 6944 Sprint Quattro	373
10	58/F	St Jude Atlas + DR V-243	St Jude Riata 1571/65	418

ICD, implantable cardioverter defibrillator.

Table 2

Difference in ICD interrogation data pre-and post-MR scan

	MR scan #1 pre-MR	MR scan #1 post-MR	p Value	MR scan #2 pre-MR	MR scan #2 post-MR	p Value	MR scan #3 pre-MR	MR scan #3 post-MR	p Value
Pacing capture threshold (V)	1.99±1.12	2.00±1.11	0.97	1.91±1.14	1.92±1.12	0.88	1.74±1.2	1.78±1.2	0.85
Pacing lead impedance (ohm)	528±95	507±84	0.45	527±102	538±88	0.73	524±89	520±88	0.97
High voltage lead impedance (ohm)	50±8.3	51±8.4	0.68	52±9.2	53±6.1	0.79	51±7.9	51±6.3	0.97
Battery voltage (V)	3.05±0.22	3.04±0.21	0.61	3.03±0.23	3.03±0.23	0.75	3.01±0.24	3.00±0.24	0.65

Values are presented as mean±SD.
Mann-Whitney two-sided p values.
ICD, implantable cardioverter defibrillator.