ORIGINAL ARTICLE

Safety of Magnetic Resonance Imaging in Patients with Cardiac Devices

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ABSTRACT

BACKGROUND

Patients who have pacemakers or defibrillators are often denied the opportunity to undergo magnetic resonance imaging (MRI) because of safety concerns, unless the devices meet certain criteria specified by the Food and Drug Administration (termed "MRI-conditional" devices).

METHODS

We performed a prospective, nonrandomized study to assess the safety of MRI at a magnetic field strength of 1.5 Tesla in 1509 patients who had a pacemaker (58%) or an implantable cardioverter–defibrillator (42%) that was not considered to be MRI-conditional (termed a "legacy" device). Overall, the patients underwent 2103 thoracic and nonthoracic MRI examinations that were deemed to be clinically necessary. The pacing mode was changed to asynchronous mode for pacing-dependent patients and to demand mode for other patients. Tachyarrhythmia functions were disabled. Outcome assessments included adverse events and changes in the variables that indicate lead and generator function and interaction with surrounding tissue (device parameters).

RESULTS

No long-term clinically significant adverse events were reported. In nine MRI examinations (0.4%; 95% confidence interval, 0.2 to 0.7), the patient's device reset to a backup mode. The reset was transient in eight of the nine examinations. In one case, a pacemaker with less than 1 month left of battery life reset to ventricular inhibited pacing and could not be reprogrammed; the device was subsequently replaced. The most common notable change in device parameters (>50% change from baseline) immediately after MRI was a decrease in P-wave amplitude, which occurred in 1% of the patients. At long-term follow-up (results of which were available for 63% of the patients), the most common notable changes from baseline were decreases in P-wave amplitude (in 4% of the patients), increases in atrial capture threshold (4%), increases in right ventricular capture threshold (4%), and increases in left ventricular capture threshold (3%). The observed changes in lead parameters were not clinically significant and did not require device revision or reprogramming.

CONCLUSIONS

We evaluated the safety of MRI, performed with the use of a prespecified safety protocol, in 1509 patients who had a legacy pacemaker or a legacy implantable cardioverter–defibrillator system. No long-term clinically significant adverse events were reported. (Funded by Johns Hopkins University and the National Institutes of Health; ClinicalTrials.gov number, NCT01130896.)

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A majority of patients who undergo implantation of a pacemaker or implantable cardioverter–defibrillator (ICD) subsequently have a clinical indication for magnetic resonance imaging (MRI).[1] Small studies have reported on the safety of MRI in patients who have a pacemaker or ICD[2-20]; a recent larger study evaluated only nonthoracic examinations.[21] Other studies have specifically investigated the safety of MRI in patients who have pacemakers that, according to the Food and Drug Administration (FDA), have been shown to pose no known hazard under certain specified conditions of use; such devices are termed "MRI-conditional."[22-25] However, the vast majority of pacemaker and ICD systems in current use are not labeled specifically as MRI-conditional and are termed "legacy" systems. The presence of a legacy system is considered by the FDA[26,27] and device manufacturers[28-30] to be a contraindication to MRI. The Centers for Medicare and Medicaid Services has determined that access to MRI improves outcomes for Medicare beneficiaries who have MRI-conditional devices. However, because of the lack of adequate data, access to MRI is extremely limited for patients who have legacy systems.[31] Here, we report the results of a large, prospective study that evaluated the safety of an MRI protocol in patients with legacy pacemaker or ICD systems.

Methods

Study Design and Oversight

The study was funded by Johns Hopkins University and the National Institutes of Health. The institutional review board at Johns Hopkins University approved the protocol, which is available with the full text of this article at NEJM.org. The authors vouch for the accuracy and completeness of the data and analyses and for the fidelity of the study to the protocol. Preliminary data from the first 55 enrolled patients (who underwent a total of 68 MRI examinations) and subsequently from the first 406 enrolled patients (who underwent a total of 522 MRI examinations) in the current study have been reported previously.[8,13]

Patient Selection

Candidates who had an ICD or a pacemaker and a clinical indication for MRI were referred by primary care and subspecialty physicians and were enrolled during the period from February 2003 through January 2015. Patients were excluded from participation in the study if they had undergone lead implantation within the previous 4 weeks, if they had permanent surgical epicardial leads or permanent nonfunctional leads, if they had subcutaneous ICD systems, or if they were pacing-dependent and had an ICD without asynchronous pacing capability. No exclusions were made because of clinical instability. Written informed consent was obtained from all participants, with the exception of participants who had altered mental status and had been referred for MRI of the head, in which case the participant's next of kin provided consent.

Device Interrogation and Programming

Our institutional safety protocol has been described previously.[8,13,32] MRI examinations were supervised by a registered nurse who had experience in cardiac device programming and training in cardiac life support and who had immediate access to an electrophysiologist (which represented the majority of examinations) or were supervised directly by an electrophysiologist. Device parameters — variables that indicate lead and generator function and interaction with surrounding tissue, including battery voltage, capture thresholds, pacing lead impedance, and sensing — were measured at baseline and within minutes after the MRI. The device was reprogrammed to an asynchronous pacing mode for patients who had an intrinsic heart rate of less than 40 beats per minute. An inhibited pacing mode was used for all other patients. Pacing features and functions to treat tachyarrhythmia, including magnet mode (a programmable feature in some pacemakers that allows for the disabling of the asynchronous pacing response to magnet application), premature ventricular complex detection, noise discrimination, rate response, and ventricular sense response, were deactivated. After completion of the MRI, the devices were reprogrammed to the original settings. Long-term follow-up interrogation at 6 months was recommended.

Magnetic Resonance Imaging

Imaging was performed with the use of MRI scanners with the commonly used magnetic

field strength of 1.5 Tesla (Magnetom Avanto and Magnetom Aera, Siemens). Symptoms, such as pain, warmth, and palpitations, were monitored with the use of an in-room speaker system. Blood pressure, measured noninvasively, was assessed every 3 minutes. Continuous electrocardiographic monitoring was performed. The frequency and stability of the pulse oximetry waveform was used as a surrogate for the heart rhythm when electrocardiographs showed MRI-related artifacts. MRI was performed according to standard institutional protocols for the region of interest. The specific absorption rate of MRI sequences, a measure of power absorbed per mass of tissue, was limited to less than 2.0 watts per kilogram in the first 55 patients enrolled in the study.[8] However, given the lack of association between the specific absorption rate and changes in device parameters[5,33] and the unreliability of the specific absorption rate to guide MRI safety recommendations,[34] no restrictions beyond standard specific absorption rate limits were applied in subsequently enrolled patients. Repeat scanning was performed as clinically indicated.

OUTCOME ASSESSMENTS

Study outcome assessments included adverse events and changes in device parameters. Anticipated prespecified adverse events, which were assessed immediately after the MRI, included generator failure, power-on reset (in which device settings are reset automatically to a backup mode as if the power to the device had been shut off and then turned on again), changes in pacing threshold or sensing that require system revision or programming changes, battery depletion, cardiac arrhythmia, inhibition of pacing, inappropriate delivery of antitachycardia pacing or shock, and patient-reported events, such as discomfort, pain, a warm sensation in the location of the device, and palpitations. Device parameters, which were assessed immediately after the MRI in all the patients and at long-term follow-up in patients who returned for reassessment, included P-wave amplitude; right ventricular and left ventricular R-wave amplitude; atrial, left ventricular, and right ventricular lead impedance; atrial, right ventricular, and left ventricular capture threshold; and battery voltage. Given the expected variation in lead parameters on repeat measurement,[15,22,35-38] percent changes from baseline were categorized as no change (≤20% change), expected change (>20 to 50% change), and notable change (>50% change).

STATISTICAL ANALYSIS

Continuous variables are summarized as medians and interquartile ranges, and discrete variables as absolute numbers and percentages. Lead parameters were compared with the use of the Wilcoxon signed-rank test, with MRI examination as the unit of analysis. Absolute changes from baseline and percent changes from baseline in device parameters are summarized as medians and interquartile ranges. We calculated the percent change from baseline using the median and interquartile range for the distribution of percent change relative to baseline values for device parameters. The number of comparisons for each device parameter is unique, primarily because of variability in several factors, including the number of leads, the presence or absence of intrinsic P or R waves, the presence or absence of atrial arrhythmia, and pulse widths during the measurement of capture threshold at the follow-up interrogation. The associations between changes in device parameters that occurred either immediately after the MRI or at long-term follow-up and the number of repeat scans, lead length, type of device, and anatomical region of imaging were assessed with the use of the nonparametric k-sample test on the median (unordered groups) or a nonparametric test for trend (ordered groups). All tests were two-tailed, and analyses were performed with the use of Stata software, version 12.

RESULTS

CHARACTERISTICS OF STUDY PARTICIPANTS, MRIS, AND DEVICES

A total of 2103 MRI examinations were performed in 1509 patients, 880 (58%) of whom had a pacemaker and 629 (42%) of whom had an ICD. The baseline characteristics of the participants are shown in Table 1. Of the 1509 patients, 137 (9%) were pacing-dependent (22 of whom had an ICD with asynchronous programming mode capability). Tables S1 and S2 in the Supplementary Appendix, available at NEJM.org, list the generator models and lead models that the study

Table 1. Characteristics of the Participants at Baseline and Imaging and Lead Information.*

Characteristic	Value
Participants	
No. of participants	1509
Median age (IQR) — yr	69.3 (57.7–78.1)
Female sex — no. (%)	548 (36)
Median ejection fraction (IQR) — %	50 (30–60)
Coronary artery disease — no. (%)	501 (33)
Previous coronary-artery bypass surgery — no. (%)	233 (15)
Previous aortic-valve replacement — no. (%)	54 (4)
Previous mitral-valve replacement — no. (%)	35 (2)
Pacemaker — no. (%)	880 (58)
Implantable cardioverter–defibrillator — no. (%)	629 (42)
Cardiac resynchronization therapy — no. (%)	163 (11)
Reason for device implantation — no. (%)†	
Symptomatic bradycardia	469 (31)
Tachycardia–bradycardia syndrome	99 (7)
Complete heart block‡	163 (11)
Primary prevention of sudden death	398 (26)
Secondary prevention of sudden death	139 (9)
Median time since generator implantation (IQR) — mo	29 (12–52)
Median time since lead implantation (IQR) — mo	
Right atrial lead	40 (15–75)
Right ventricular lead	39 (15–75)
Left ventricular lead	26 (10–56)
Dependence on pacing during MRI — no. (%)	137 (9)
MRIs	
No. of examinations	2103
Scan category — no. (%)	
First scan	1509 (72)
Second scan	320 (15)
Third or subsequent scan	274 (13)
Region of imaging — no. (%)	
Arm or leg§	196 (9)
Head or neck	1091 (52)
Thorax	257 (12)
Abdomen or pelvis	559 (27)
Lead length — no./total no. (%)¶	
Right atrial lead	
≤45 cm	257/891 (29)
46–50 cm	164/891 (18)
>50 cm	470/891 (53)
Right ventricular lead	
≤55 cm	358/1123 (32)
56–60 cm	502/1123 (45)
>60 cm	263/1123 (23)
Left ventricular lead	
≤85 cm	33/102 (32)
86–90 cm	43/102 (42)
≥90 cm	26/102 (25)

* IQR denotes interquartile range, and MRI magnetic resonance imaging.
† The reason for the device was unknown to study personnel in 357 participants (24%) at the time of presentation for MRI. In addition, not all reasons for device implantation were mutually exclusive.
‡ Complete heart block refers to conduction block.
§ Transmit–receive coils were used in 57 MRIs of the knee (3%).
¶ Lead length is presented as the number of leads of a given length divided by the number of leads with implantation data and the percentage.

participants had received and the estimated number of active implants for each model in the United States, which total more than 2.8 million generators and more than 6.9 million leads. A total of 1189 of the 1509 patients (79%) underwent a single MRI examination. Repeat MRI examination was performed in 320 patients (21%): 196 (13%) underwent two examinations, 64 (4%) three examinations, 27 (2%) four examinations, 15 (1%) five examinations, and 18 (1%) six or more examinations.

ASSESSMENTS AFTER MRI

Device interrogation was performed at baseline and immediately after the MRI for all 2103 examinations (100%). Long-term follow-up results were available after 1327 examinations (63%), which were performed in 958 patients (63%); the median time to follow-up was 1 year (interquartile range, 0.5 to 1.7). Telephone follow-up conducted in September 2015 for the 551 patients in whom long-term interrogation results were unavailable revealed that 124 of the patients (23%) had died and 125 (23%) were alive and had no device-related problems. The remaining 302 patients (55%) did not respond to telephone follow-up. A comparison of baseline characteristics and changes in device parameters that occurred immediately after the MRI between patients with and those without long-term follow-up is provided in Table S3 in the Supplementary Appendix.

SAFETY AND DEVICE FUNCTION IMMEDIATELY AFTER MRI

A summary of the adverse events that occurred during the study is shown in Table S4 in the Supplementary Appendix. Power-on reset occurred during a total of nine MRI examinations (0.4% of the examinations; 95% confidence interval [CI], 0.2 to 0.7) in eight patients (0.5% of patients; 95% CI, 0.2 to 0.9) (Table 2). Patient 4,

Table 2. Nine Events of Power-On Reset in Eight Patients.*

Patient Number and Device Type	Examination No., Region of Imaging	Generator Manufacturer, Implantation Yr	Other System Components, Lead Length, Implantation Yr	Rhythm Changes	Generator Function Fully Restored	Scan Completed	Clinical Consequences
4, ICD	1, Thorax	Medtronic (7271), 1999	RA lead (6940), 52 cm, 1999 RV lead (6945), 65 cm, 1999	No	Yes	No	Pulling sensation in chest during MRI reported by patient
52, Pacemaker	1, Brain 5, Brain	Medtronic (8968), 1997 Medtronic (8968), 1997	RV lead (5032), 58 cm, 1997 RV lead (5032), 58 cm, 1997	No No	Yes No, VVI pacing†	Yes Yes	None Battery ERI before MRI, replacement required after MRI
113, Pacemaker	1, Brain	Medtronic (8160), 1999	RV lead (5024), 58 cm, 1999	No	Yes	Yes	None
165, Pacemaker	2, Abdomen	Medtronic (303), 2002	RA lead (5092), 53 cm, 2002 RV lead (5092), 58 cm, 2002	Yes	Yes	No	MRI aborted owing to pacing dependence and resultant brief pause after power-on reset
265, Pacemaker	1, Brain	Medtronic (DR401), 2003	RA lead (5076), 45 cm, 2003 RV lead (5076), 52 cm, 2003	No	Yes	Yes	None
413, Pacemaker	1, Brain	Medtronic (7960), 2009	RA lead (5534), 45 cm, 2009 RV lead (5034), 58 cm, 2009	No	Yes	Yes	None
705, Pacemaker	1, Abdomen	Medtronic (303), 2000	RA lead (5076), 45 cm, 2000 RV lead (5076), 52 cm, 2000	No	Yes	Yes	None
1141, Pacemaker	1, Abdomen	Medtronic (900), 2006	RV lead, model and length unavailable (implanted outside United States), 2006	No	Yes	Yes	None

* Numbers shown in parentheses are model numbers. All scans were performed in the Magnetom Avanto scanner, with the exception of the scans for Patients 165, 705, and 1141, which were performed in the Magnetom Aera scanner. ERI denotes elective replacement indicator, ICD implantable cardioverter–defibrillator, RA right arterial, and RV right ventricular.
† VVI, or ventricular inhibited pacing, is a programmed mode that inhibits ventricular pacing when intrinsic ventricular activation is sensed.

who had an ICD, described a pulling sensation in his chest during the MRI. The examination was terminated, and power-on reset of the ICD was noted. The device had not attempted to deliver tachyarrhythmia therapy. The event of power-on reset was transient, and generator function was able to be fully restored. Patient 52, who had a pacemaker, had two events of power-on reset. The first of these events was transient. The patient subsequently underwent four examinations without the occurrence of an adverse event. At the fifth MRI examination, with less than 1 month of battery life remaining in the device before the MRI was performed, the device reset to ventricular inhibited pacing with end-of-life battery status, could not be reprogrammed, and was replaced. Patient 165, who had a pacemaker and was pacing-dependent, had a pause after programming reversion to an inhibited pacing mode as a result of power-on reset. The MRI was aborted and programming was restored; there were no clinical sequelae. The remaining five patients, all of whom had pacemakers, completed the examinations despite having transient events of power-on reset. None of the patients who had a transient event of power-on reset had device dysfunction at long-term follow-up.

Five other MRI examinations were terminated prematurely. One was aborted when a patient who had an adequate heart rate at baseline and whose device was programmed to a nonasynchronous mode had bradycardia (<40 beats per minute) that resulted from functional inhibition of pacing with electromagnetic interference. Another examination was stopped as a result of frequent, nonsustained ventricular tachycardia in a patient who was undergoing MRI before undergoing catheter ablation of ventricular tachycardia. The remaining three MRI examinations were aborted because of the extent of image artifact and the futility of the examination to provide useful diagnostic information. No other examinations were stopped because of clinical symptoms or changes in heart rate, oxygenation, or other variables.

In pacemakers without magnet-mode programming capability, reed switch activation by MRI led to transient, asymptomatic asynchronous pacing at the pacemaker-specific magnet rate (typically 85 pulses per minute) without any clinically significant symptoms or sequelae. Premature atrial and ventricular beats and occasional nonsustained episodes of ventricular tachycardia, as well as an episode of paroxysmal atrial fibrillation, were observed. However, no arrhythmias were temporally associated with MRI sequence initiation, rhythmicity, or termination.

CHANGES IN DEVICE PARAMETERS IMMEDIATELY AFTER MRI AND AT LONG-TERM FOLLOW-UP

No change in device parameters that occurred either immediately after the MRI or at long-term follow-up in any patient was large enough to result in lead or system revision or device reprogramming. The distribution of differences between device parameters at baseline and those obtained immediately after the MRI or at long-term follow-up is shown in Table 3. The absolute changes from baseline and percent changes from baseline in device parameters are provided in Table S5 in the Supplementary Appendix. Immediately after the MRI, the most common notable changes in device parameters (>50% change from baseline) were decreases in P-wave amplitude, which occurred in 1% of the patients. At long-term follow-up, the most common notable changes from baseline were decreases in P-wave amplitude (in 4% of the patients), increases in atrial capture threshold (4%), increases in right ventricular capture threshold (4%), and increases in left ventricular capture threshold (3%). In total, 96% (95% CI, 95 to 97) of all the MRIs were performed without the occurrence of either an event (e.g., power-on reset or early termination of the examination) or a notable change in lead setting immediately after the MRI. Table S6 in the Supplementary Appendix summarizes changes in device parameters that can be expected to occur between two interrogations (up to 50% change from baseline) and notable changes (>50% change from baseline), as well as persistent versus new changes at long-term follow-up. Many of the changes in device parameters that occurred immediately after the MRI resolved at long-term follow-up, and new changes were more common than persistent changes.

DETERMINANTS OF CHANGES IN DEVICE PARAMETERS

Associations between changes from baseline in device parameters either immediately after the MRI or at long-term follow-up and the number of repeat scans, lead length, type of device, and

Table 3. Changes in Device Parameters.*

Time of Assessment and Variable	No. of Patients†	Baseline Setting	Decrease from Baseline				≤20% Change from Baseline	Increase from Baseline			
			>50%	41–50%	31–40%	>20–30%		>20–30%	31–40%	41–50%	>50%
		median (IQR)	*number of patients (percent)*								
Immediately after MRI											
P-wave amplitude	1347	3.0 (2.0–4.6) mV	13 (1)	26 (2)	35 (3)	97 (7)	1049 (78)	32 (2)	53 (4)	28 (2)	14 (1)
RV R-wave amplitude	1799	11.2 (8.0–14) mV	5 (<1)	4 (<1)	15 (1)	117 (6)	1583 (88)	20 (1)	35 (2)	12 (1)	8 (<1)
LV R-wave amplitude	72	11.4 (7.0–19.7) mV	0	0	2 (3)	5 (7)	61 (85)	2 (3)	2 (3)	0	0
Atrial lead impedance	1559	473 (413–540) ohms	0	0	1 (<1)	2 (<1)	1553 (100)	3 (<1)	0	0	0
RV lead impedance	2021	532 (448–640) ohms	0	0	1 (<1)	4 (<1)	2014 (100)	2 (<1)	0	0	0
LV lead impedance	202	629 (512–769) ohms	0	0	0	1 (<1)	201 (100)	0	0	0	0
Atrial capture threshold	1338	0.8 (0.5–1.0) V	2 (<1)	28 (2)	37 (3)	32 (2)	1143 (85)	17 (1)	36 (3)	34 (2)	9 (<1)
RV capture threshold	1969	0.8 (0.7–1.0) V	3 (<1)	32 (2)	45 (2)	54 (3)	1669 (85)	39 (2)	65 (3)	47 (2)	15 (<1)
LV capture threshold	200	1 (0.8–1.5) V	1 (<1)	3 (2)	4 (2)	7 (4)	164 (82)	10 (5)	7 (4)	4 (2)	0
Battery voltage	1578	2.8 (2.8–3.0) V	0	0	0	0	1577 (100)	0	0	1 (<1)	0
At long-term follow-up after MRI‡											
P-wave amplitude	826	3.1 (2.0–4.7) mV	29 (4)	42 (5)	39 (5)	91 (11)	498 (60)	33 (4)	37 (4)	25 (3)	32 (4)
RV R-wave amplitude	1072	11.2 (8.0–13.8) mV	8 (1)	21 (2)	54 (5)	101 (9)	732 (68)	53 (5)	46 (4)	24 (2)	33 (3)
LV R-wave amplitude	26	19.7 (10.0–25.0) mV	0	0	1 (4)	0	20 (77)	3 (12)	1 (4)	1 (4)	0
Atrial lead impedance	1021	475 (416–548) ohms	0	1 (<1)	6 (1)	22 (2)	975 (96)	11 (1)	3 (<1)	1 (<1)	2 (<1)
RV lead impedance	1286	535 (447–644) ohms	1 (<1)	3 (<1)	9 (1)	26 (2)	1214 (94)	25 (2)	3 (<1)	1 (<1)	4 (<1)
LV lead impedance	106	675 (538–830) ohms	0	1 (1)	0	2 (2)	100 (94)	3 (3)	0	0	0
Atrial capture threshold	725	0.8 (0.5–1.0) V	4 (1)	28 (4)	47 (6)	37 (5)	469 (65)	19 (3)	43 (6)	48 (7)	30 (4)
RV capture threshold	1105	0.8 (0.7–1.0) V	10 (1)	41 (4)	66 (6)	71 (6)	693 (63)	48 (4)	63 (6)	65 (6)	48 (4)
LV capture threshold	105	1 (0.8–1.4) V	0	5 (5)	5 (5)	6 (6)	64 (61)	4 (4)	10 (10)	8 (8)	3 (3)
Battery voltage	930	2.8 (2.8–3.0) V	0	0	0	4 (<1)	925 (100)	1 (<1)	0	0	0

* Percentages have been rounded. LV denotes left ventricular, mV millivolts, and V volts.

† The number of comparisons for each device parameter is unique, owing primarily to variability in the number of leads, the absence of intrinsic P-R waves, the presence of atrial arrhythmia, and the pulse widths during the measurement of capture threshold at the follow-up interrogation.

‡ Long-term (median, 1 year; IQR, 0.5 to 1.7) follow-up results were available for 958 patients (63%) who underwent a total of 1327 MRIs.

anatomical region of imaging are shown in Table S7 in the Supplementary Appendix. Patients with ICDs had significantly greater immediate changes in P-wave amplitude and right ventricular R-wave amplitude and significantly greater long-term change in battery voltage than patients with pacemakers. In contrast, the change in long-term P-wave amplitude was significantly greater among patients with pacemakers than among patients with ICDs. Long-term changes in right ventricular R-wave amplitude were significantly smaller among patients with right ventricular leads of 60 cm or shorter than among patients with leads longer than 60 cm. Long-term changes in atrial capture threshold were significantly greater among patients with atrial leads longer than 50 cm than with leads of 50 cm or shorter, and long-term changes in right ventricular capture threshold were greater among patients who underwent three or more MRIs than among those who underwent two MRIs.

DISCUSSION

In this large, prospective study, we evaluated the safety of MRI in patients with implanted legacy devices. The most important event that was found to be attributable to MRI was the occurrence of power-on reset in approximately 1 in 200 examinations. During events of power-on reset, the device is susceptible to inhibition of pacing output and activation of antitachycardia therapies.[39,40] Of the 9 MRI examinations in which events of power-on reset occurred, 1 examination was associated with mild physical symptoms, 1 (which occurred near the end of the battery life of the device) resulted in an inability to reprogram the device and in the consequent replacement of the device, and 1 was associated with transient inhibition of pacing.

Small changes in lead sensing, impedances, and capture thresholds immediately after the MRI among patients with devices have been reported previously[5,7,13,33] and were attributed to heating at the lead-tissue interface. Previous reports have also suggested that MRI of the thorax may present a greater risk of safety issues than MRI of nonthoracic regions owing to greater power deposition over the region containing the device.[7,41] In our smaller study that was reported previously,[14] we noted an association between thoracic imaging and changes in long-term right ventricular sensing and capture threshold. However, the current larger study, in which the follow-up period was longer, does not suggest any association between the region of imaging and detrimental changes in device parameters. The primary detrimental associations were a larger reduction in right atrial and right ventricular lead sensing immediately after the MRI with ICD systems than with pacemakers, as well as a larger reduction in long-term right ventricular lead sensing with longer lead length than with shorter lead length. The association of ICD systems with greater long-term battery drain was probably confounded by increased tachyarrhythmia and pacing needs in patients with ICDs.

The study protocol required that an asynchronous pacing mode be programmed for pacing-dependent patients to avoid inappropriate inhibition of pacing resulting from detection of electromagnetic interference. In contrast, an inhibited pacing mode was used for patients without pacing dependence to avoid inappropriate pacing resulting from tracking of electromagnetic interference. Deactivation of other pacing functions ensured that sensing of electromagnetic interference did not lead to unwarranted pacing. Tachyarrhythmia monitoring and therapies were deactivated to avoid delivery of unwarranted therapies. In this study, 137 pacing-dependent patients (22 of whom had an ICD with asynchronous programming mode capability) underwent MRI without safety issues. It is vital, however, to emphasize the need for appropriate device programming, monitoring by qualified personnel, and the availability of an external pacing backup for such patients. If power-on reset occurs, the device reverts to an inhibited pacing mode. Therefore, in pacing-dependent patients, the device may transiently cease pacing because of electromagnetic interference, and electrocardiographic monitoring and pulse oximetry are warranted so that the scanning can be stopped if inhibition of pacing occurs.

Another study of the safety of MRI in patients with legacy devices is the MagnaSafe Registry, the results of which were reported recently in the *Journal*.[21] The MagnaSafe Registry was a prospective, multicenter study that excluded patients who had a clinical indication for thoracic imaging but was otherwise similar to our study. In the MagnaSafe Registry, no patient who was screened appropriately and whose device was reprogrammed

had device or lead failure. The MagnaSafe Registry and our study thus provide complementary evidence that MRI scanning can be performed safely in patients with legacy devices, provided that an appropriate protocol is followed.

Several limitations of our study should be noted. First, the data were acquired at a single center and may not be generalizable to other clinical settings and MRI facilities. Second, we were unable to obtain long-term follow-up information, either in person or by telephone, from 302 patients (20% of all enrolled patients); therefore, we cannot be certain whether device-related malfunctions or dysrhythmias occurred in these patients after the device interrogation that was performed immediately after the MRI. Third, we did not perform defibrillation threshold testing in patients who had an ICD and were undergoing an MRI, a decision that we believe was justifiable, given the absence of clinically important changes in sensing and pacing parameters, previous evidence of preserved ventricular fibrillation defibrillation threshold after an MRI,[42,43] the questionable usefulness of defibrillation threshold testing,[44] and the potential for the occurrence of serious side effects associated with routine testing.[45] Fourth, although we studied many devices, the numbers of each individual device model were small. Fifth, device technology is constantly in evolution, and interactions of future systems with electromagnetic interference cannot be ruled out. Finally, the MRIs were performed at a field strength of 1.5 Tesla. These findings should not be extrapolated to MRI scanners that operate at higher or even lower field strengths.

In conclusion, we studied the safety of MRI performed on 1.5-Tesla MRI scanners in 1509 patients who had legacy cardiac pacemakers or legacy ICD systems, using a prespecified safety protocol. In only one case — a patient who had a pacemaker battery that was near the end of its battery life — device programming failure occurred, which resulted in the need for replacement of the device. Changes in device parameters were infrequent, and none resulted in long-term clinically significant adverse events.

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