ORIGINAL ARTICLE

Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator

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ABSTRACT

BACKGROUND

The presence of a cardiovascular implantable electronic device has long been a contraindication for the performance of magnetic resonance imaging (MRI). We established a prospective registry to determine the risks associated with MRI at a magnetic field strength of 1.5 tesla for patients who had a pacemaker or implantable cardioverter–defibrillator (ICD) that was "non–MRI-conditional" (i.e., not approved by the Food and Drug Administration for MRI scanning).

METHODS

Patients in the registry were referred for clinically indicated nonthoracic MRI at a field strength of 1.5 tesla. Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning. The primary end points were death, generator or lead failure, induced arrhythmia, loss of capture, or electrical reset during the scanning. The secondary end points were changes in device settings.

RESULTS

MRI was performed in 1000 cases in which patients had a pacemaker and in 500 cases in which patients had an ICD. No deaths, lead failures, losses of capture, or ventricular arrhythmias occurred during MRI. One ICD generator could not be interrogated after MRI and required immediate replacement; the device had not been appropriately programmed per protocol before the MRI. We observed six cases of self-terminating atrial fibrillation or flutter and six cases of partial electrical reset. Changes in lead impedance, pacing threshold, battery voltage, and P-wave and R-wave amplitude exceeded prespecified thresholds in a small number of cases. Repeat MRI was not associated with an increase in adverse events.

CONCLUSIONS

In this study, device or lead failure did not occur in any patient with a non–MRI-conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla, was appropriately screened, and had the device reprogrammed in accordance with the prespecified protocol. (Funded by St. Jude Medical and others; MagnaSafe ClinicalTrials.gov number, NCT00907361.)

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The use of magnetic resonance imaging (MRI) poses potential safety concerns for patients with an implanted cardiac device (cardiac pacemaker or implantable cardioverter–defibrillator [ICD]). These concerns are a consequence of the potential for magnetic field–induced cardiac lead heating, which could result in myocardial thermal injury and detrimental changes in pacing properties.[1-3] As a result, it has long been recommended that patients with an implanted cardiac device not undergo MRI scanning, even when it otherwise may be considered to be the most appropriate diagnostic imaging method for the patient's clinical care.[4]

Over the past two decades, cardiac devices have been designed to reduce the potential risks associated with MRI.[5,6] Such devices, if they have been shown to pose no known hazard under certain specified conditions, are labeled "MRI-conditional" by the Food and Drug Administration (FDA) Center for Devices and Radiological Health. However, it is estimated that 2 million people in the United States and an additional 6 million worldwide[7] have devices that have not been shown to meet these criteria and are therefore considered "non–MRI-conditional." At least half the patients with such devices are predicted to have a clinical indication for MRI during their lifetime after device implantation.[8]

The MagnaSafe Registry was established to determine the frequency of cardiac device–related clinical events and device setting changes among patients with non–MRI-conditional devices who undergo nonthoracic MRI at a magnetic field strength of 1.5 tesla, as well as to define a simplified protocol for screening, monitoring, and device programming for such patients.

Methods

Study Design

The MagnaSafe Registry was a prospective, multicenter study involving patients with a non–MRI-conditional pacemaker or ICD who underwent a clinically indicated, nonthoracic MRI examination at 1.5 tesla. The rationale, design, and protocol have been described previously.[9] The protocol, which is available with the full text of this article at NEJM.org, was written after consultation with personnel at the Center for Devices and Radiological Health of the FDA, who requested that thoracic scans be excluded because of a higher perceived risk of adverse outcomes. An investigational device exemption was obtained in April 2009 for the purpose of data collection. All participating centers obtained approval from a local or independent institutional review board.

None of the funders of the study had any role in the design of the study protocol, in the collection or analysis of the data, or in the writing of the manuscript. The authors had full access to the data, performed the analyses, and vouch for the completeness and accuracy of the data and for the fidelity of the study to the protocol.

Study Participants

Patients were included in the registry if they were 18 years of age or older and had a non–MRI-conditional pacemaker or ICD generator, from any manufacturer, that was implanted after 2001,[10] with leads from any manufacturer (without implantation date limitation), and if the patient's physician determined that nonthoracic MRI at 1.5 tesla was clinically indicated (see Tables S1 and S2 in the Supplementary Appendix, available at NEJM.org, for a list of pacemaker and ICD manufacturers and models). The exclusion criteria were an abandoned or inactive lead that could not be interrogated, an implanted device other than a pacemaker or an ICD, an MRI-conditional pacemaker, a device implanted in a nonthoracic location, or a device with a battery that was near the end of its battery life (with a device interrogation display that read "elective replacement indicator"). In addition, pacing-dependent patients with an ICD were excluded because it was not possible to independently program tachycardia and bradycardia therapies for all ICD models at the time of study design. All participants provided written informed consent.

Reimbursement

During the first 2 years of the study, the Centers for Medicare and Medicaid Services National Coverage Determination (NCD) stated that a patient with a pacemaker or an ICD was not eligible for coverage for MRI. In March 2011, a change to the NCD was granted that allowed reimbursement for patients enrolled in a prospective registry designed to determine the risk associated with MRI.[11]

MRI Protocol and Monitoring

All studies were performed in a 1.5-tesla MRI scanner; there was no vendor restriction (a list of manufacturers and models is included in Table S3 in the Supplementary Appendix). A physician, nurse practitioner, or physician assistant with car-

diac device expertise and training in advanced cardiac life support was in attendance. Blood pressure, pulse oximetry, and cardiac rhythm were monitored with an MRI-compatible system from the time of device reprogramming until restoration of baseline values. Further details are provided in the MagnaSafe Protocol section of the Supplementary Appendix.

DEVICE INTERROGATION AND PROGRAMMING

Prescanning device interrogation was performed with the use of a standardized protocol (Fig. 1).[9] If the patient was asymptomatic and had an intrinsic heart rate of at least 40 beats per minute, the device was programmed to a no-pacing mode (ODO or OVO). Symptomatic patients or those with an intrinsic heart rate of less than 40 beats per minute were determined to be pacing-dependent, and the device was reprogrammed to an asynchronous pacing mode (DOO or VOO). For non–pacing-dependent patients with an ICD, all bradycardia and tachycardia therapies were inactivated before the MRI. Pacing-dependent patients with an ICD were excluded, because not all ICD models allowed for independent inactivation of tachycardia and bradycardia therapies. After the MRI, baseline settings were restored, full device interrogation was repeated, and if necessary, the device was reprogrammed to maintain adequate pacing and sensing. Further details are provided in the MagnaSafe Protocol section of the Supplementary Appendix.

PRIMARY AND SECONDARY END POINTS

The primary end points, which were assessed during or immediately after the MRI examination, were death, generator or lead failure requiring immediate replacement, loss of capture (for pacing-dependent patients with pacemakers), new-onset arrhythmia, and partial or full generator electrical reset. The secondary end points, which were assessed immediately after the MRI examination and at the final follow-up, were a battery voltage decrease of 0.04 V or more, a pacing lead threshold increase of 0.5 V or more,[12] a P-wave amplitude decrease of 50% or more, an R-wave amplitude decrease of 25% or more and of 50% or more,[13] a pacing lead impedance change of 50 ohms or more,[14] and a high-voltage (shock) lead impedance change of 3 ohms or more.

Patients with any secondary end-point event were required to undergo repeat device interrogation within 7 days, at 3 months (±30 days), and at 6 months (±30 days) after the MRI to determine whether the device settings had returned to baseline. If a secondary end-point event did not occur, a single device interrogation was required at between 3 and 6 months after the MRI (±30 days). Patients who had a primary end-point event were seen in follow-up at the discretion of the supervising physician. Further details and definitions of end points are provided in the Supplementary Appendix.

STATISTICAL ANALYSIS

A case was defined as an instance in which a patient who provided informed consent entered the scanner and underwent MRI of one or more anatomical regions during a single examination session. If the patient returned on a subsequent day for repeat MRI, a separate informed consent was obtained and the data were entered as a unique case.

The mean (±SD) yearly rate of device replacement due to spontaneous malfunction has been estimated to be 0.46±0.22% for pacemakers and 2.07±1.16% for ICDs.[15] Using these estimates and assuming a device failure rate during or after MRI of 0, we determined that 1000 cases in which patients had a pacemaker (pacemaker cases) and 500 cases in which patients had an ICD (ICD cases) would be needed to yield a 95% confidence interval of 0 to 0.5% for pacemakers and 0 to 1.0% for ICDs.

Data were analyzed separately for the pacemaker and ICD cohorts with the use of R statistical software, version 3.2.3.[16] The decision not to perform statistical comparisons between the pacemaker and ICD cohorts was made before enrollment began. The Wilson score method without continuity correction was used to calculate 95% confidence intervals for single proportions for primary end-point events. The linear association between lead age and each of the secondary end points was assessed with Pearson's product moment correlation coefficient.

RESULTS

STUDY PATIENTS AND FOLLOW-UP

From April 2009 through April 2014 at 19 centers in the United States, clinically indicated nonthoracic MRI was performed in a total of 1000 pacemaker cases (818 patients) and 500 ICD cases (428 patients). The baseline characteristics of the patients are shown in Table 1. Follow-up data, which included data from a full device interrogation, were available in 1395 cases (93%) at 6 months. Additional information about the study population is provided in the Supplementary Appendix.

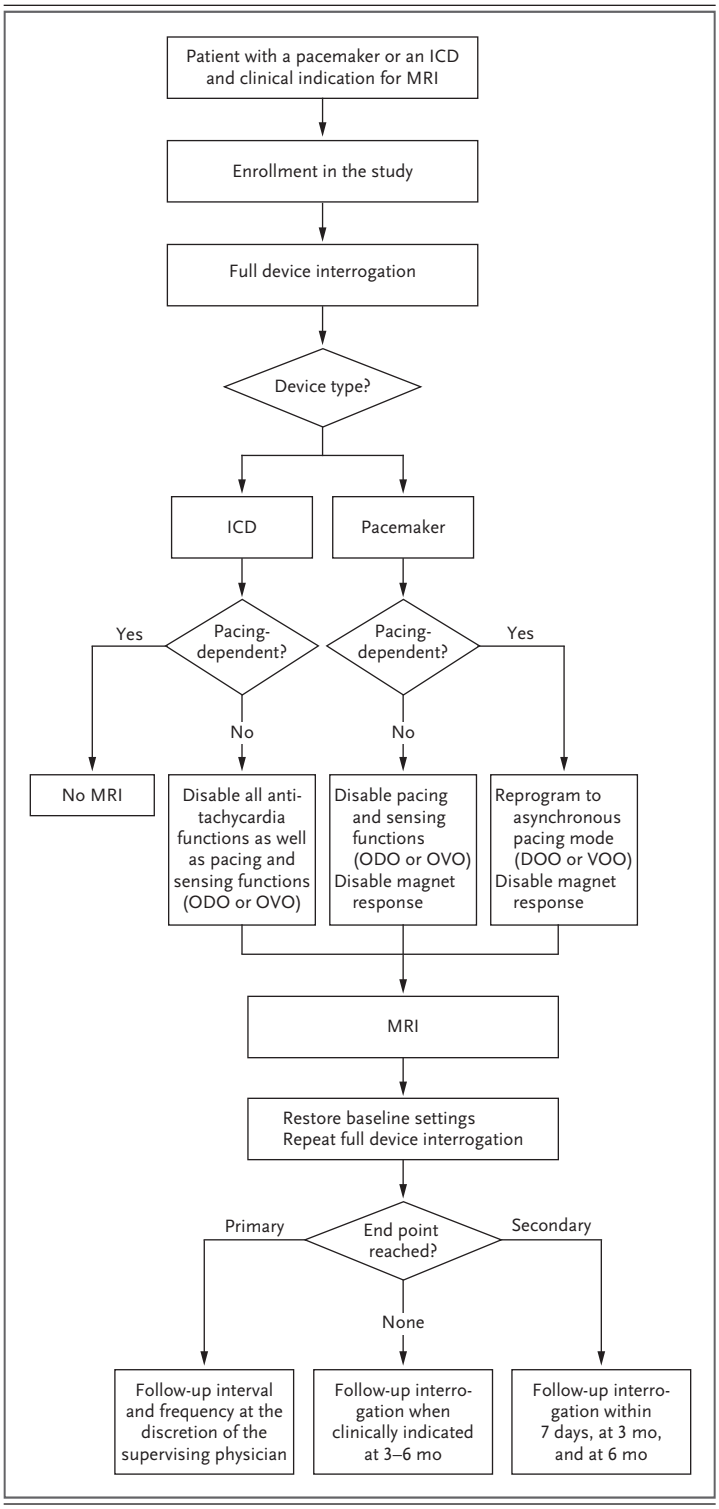

Figure 1. MagnaSafe Registry Study Flow Chart.

Patients were enrolled in the MagnaSafe Registry if they had a pacemaker or an implantable cardioverter–defibrillator (ICD) and were determined to have a clinical indication for MRI. Pre-MRI device interrogation was performed for all patients in accordance with a standardized protocol.[9] For patients with a pacemaker or an ICD, pacing dependence was defined as having an intrinsic rhythm lower than 40 beats per minute or having symptoms of presyncope or lightheadedness at a heart rate of 40 beats per minute or higher. For patients with a pacemaker who were determined not to be pacing-dependent, the device was programed to a no-pacing mode (pacing mode ODO or OVO) before MRI. For patients who were determined to be pacing-dependent, the device was programmed to an asynchronous pacing mode (DOO or VOO) at the previously programmed lower rate limit. For patients with an ICD who were determined not to be pacing-dependent, the device was programmed with all bradycardia and all tachycardia functions in an inactive mode (pacing off and tachycardia sensing and treatment functions off). Pacing-dependent patients with an ICD were excluded from the study because not all ICD models allowed for independent inactivation of tachycardia and bradycardia therapies. Blood pressure, pulse oximetry, and cardiac rhythm were monitored with an MRI-compatible system from the time of device reprogramming. For all patients, post-MRI device interrogation was performed before external monitoring was discontinued. If the difference between post-MRI and pre-MRI values did not exceed prespecified limits, the baseline device settings were restored and the patient was scheduled for routine clinically indicated follow-up device interrogation within 3 to 6 months. However, if any change limit was exceeded, then the patient was scheduled for follow-up within 1 week and at 3 months and 6 months. When necessary, devices were reprogrammed to maintain an appropriate safety margin for pacing or sensing thresholds. Patients who had a primary end-point event (new-onset arrhythmia or a full or partial device electrical reset during MRI) were seen in follow-up at the discretion of the supervising physician. Further details are provided in the Supplementary Appendix. This figure has been adapted with permission from Russo.[9]

MRI PROCEDURAL DATA

A total of 75% of the MRI examinations were performed on the brain or the spine. The mean time patients spent within the magnetic field was 44 minutes. During the MRI examination, four patients reported symptoms of generator-site discomfort; one patient with an ICD was removed from the scanner when a sensation of heating was described at the site of the generator implant, and the patient did not complete the examination. No patient with generator-site symptoms had the device placed within the "field of view" (the MRI imaging area), had a study end-point event, or reached the specific absorption rate limit set by the FDA for the scanned body site.

PRIMARY END POINTS

There were no deaths, lead failures requiring immediate replacement, or losses of capture during the MRI examination among patients who were

Table 1. Characteristics of the Patients at Baseline and MRI Scanning Information.*

Characteristic	Pacemaker (N=1000)	ICD (N=500)
Patient age — yr	72.5±13.6	65.1±12.8
Female sex — no./total no. (%)	420/999 (42.0)	150/489 (30.7)
Body-mass index†	27.8±5.8	29.1±6.5
Coronary artery disease — no./total no. (%)	310/993 (31.2)	284/496 (57.3)
Type 1 or type 2 diabetes mellitus — no./total no. (%)	185/994 (18.6)	181/498 (36.3)
Mechanical prosthetic heart valve — no./total no. (%)	36/981 (3.7)	18/482 (3.7)
Antiarrhythmic therapy — no. (%)‡	102 (10.2)	82 (16.4)
Leads — no.	1926	997
Pacing-dependent — no./total no. (%)§	282/994 (28.4)	NA¶
Time since generator implantation — yr	3.2±2.4	2.7±1.7
Time since implantation for all leads — yr	4.6±3.9	3.7±2.9
Time since most recent lead implantation — yr	4.5±4.0	3.6±2.8
Duration of MRI — min	45±21	41±20
Previous MRI with an implanted cardiac device — no./total no. (%)‖	225/997 (22.6)	89/495 (18.0)
SAR limit reached — no./total no. (%)**	118/989 (11.9)	44/493 (8.9)
First-level operating mode required — no./total no. (%)	3/989 (0.3)	2/493 (0.4)
MRI scans obtained — no./total no. (%)††		
Brain	402/1145 (35)	189/564 (34)
Cervical spine	169/1145 (15)	80/564 (14)
Lumbar spine	310/1145 (27)	138/564 (24)
Extremity or joint‡‡	102/1145 (9)	66/564 (12)
Abdomen or pelvis	51/1145 (4)	30/564 (5)
Other§§	111/1145 (10)	61/564 (11)

* Plus–minus values are means ±SD. Baseline data are presented as cases (a case was defined as an instance in which a patient who provided informed consent entered the scanner and underwent MRI of one or more anatomical regions during a single examination session), because some patients underwent more than one MRI procedure during enrollment in this registry. Denominators for some variables are smaller than the total sample because of missing data that could not be recovered or verified. Means ±SD for the following variables reflect numbers smaller than the total sample: body-mass index (985 pacemaker cases, 498 implantable cardioverter–defibrillator [ICD] cases), time since generator implantation (999 pacemaker cases, 500 ICD cases), time since implantation for all leads (1919 of 1929 leads among pacemaker cases, 994 of 997 leads among ICD cases), time since most recent lead implantation (997 pacemaker cases, 499 ICD cases), and duration of MRI (960 pacemaker cases, 472 ICD cases). NA denotes not applicable.

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

‡ Antiarrhythmic therapy included sotalol, propafenone, dronedarone, flecainide, amiodarone, and dofetilide.

§ If no intrinsic rhythm was detected when the device was reprogrammed to 40 beats per minute or if symptoms were noted at a heart rate of 40 beats per minute or higher (presyncope or lightheadedness in the sitting or supine position), the patient was considered to be "pacing-dependent" and the device was programmed to an asynchronous pacing mode (DOO or VOO) at the previously programmed lower rate limit.

¶ Pacing-dependent patients with an ICD were excluded from study entry.

‖ This category includes cases in which the patient had had a previous MRI of any anatomical location after device implantation. These include cases in which a previous MRI had been performed before the patient had enrolled in the MagnaSafe Registry, as well as cases in which a previous MRI that had been performed was included in the MagnaSafe Registry.

** The specific adsorption rate (SAR) is a measure of the radiofrequency power absorbed per kilogram of body mass during MRI scanning. The SAR indicates the potential for tissue heating. The Food and Drug Administration has set SAR limits that vary according to the region of the body that is scanned.

†† A scan is defined as the result of an imaging examination of a specific, standardized anatomical region. In some patients, more than one anatomical area was scanned during a single MRI examination.

‡‡ MRI examinations of the extremities and joints included the shoulder, arm, elbow, wrist, hand, hip, knee, leg, ankle, and foot.

§§ Other scanning locations and descriptions included the ear, neck, orbits, and peripheral magnetic resonance angiography.

Table 2. Primary End Points.

End-Point Event	Pacemaker		ICD	
	Events/Cases	% (95% CI)	Events/Cases	% (95% CI)
Death during the MRI examination	0/1000	0 (0–0.4)	0/500	0 (0–0.8)
Generator failure requiring immediate replacement	0/1000	0 (0–0.4)	1/500*	0.2 (0.04–1.1)
Lead failure requiring immediate replacement†	0/1926	0 (0–0.2)	0/997	0 (0–0.4)
Loss of capture during the MRI examination‡	0/280	0 (0–1.4)	NA	NA
Observed atrial arrhythmia	5/1000	0.5 (0.2–1.2)	1/500	0.2 (0.04–1.1)
Observed ventricular arrhythmia	0/1000	0 (0–0.4)	0/500	0 (0–0.8)
Electrical reset§	6/1000	0.6 (0.3–1.3)	0/500	0 (0–0.8)

* One patient required immediate replacement of an ICD generator when antitachycardia therapy was inappropriately left in the active mode during the MRI examination (with bradycardia therapy disabled). However, no ICD shocks were delivered. On explantation and subsequent off-site examination by the manufacturer, the device was found to be fully functional.
† Data for this event are presented as numbers and percentages of leads rather than cases.
‡ Data are for cases in which the patient had a pacemaker, was found to be pacing-dependent on initial device interrogation, and was paced in an asynchronous mode during the MRI examination. Patients who had an ICD and were found to be pacing-dependent on initial interrogation were excluded from study entry.
§ In six cases, a partial electrical reset of the device occurred. There were no cases in which full electrical reset of the device occurred.

appropriately screened and had their device reprogrammed for imaging (Table 2). In one patient with an ICD who was not pacing-dependent, antitachycardia therapy was left in the active mode during the MRI (a protocol violation). During the post-MRI evaluation, the ICD could not be interrogated, and immediate generator replacement was required. Further details are provided in the Supplementary Appendix.

Four patients had atrial fibrillation and two patients had atrial flutter during or immediately after the MRI (Table S4 in the Supplementary Appendix). Five of these patients had a history of paroxysmal atrial fibrillation and were receiving warfarin; two were receiving antiarrhythmic therapy. Three of the patients returned to sinus rhythm before leaving the MRI environment, and the remaining three patients returned to sinus rhythm within 49 hours. No ventricular arrhythmias were noted.

In six cases (five patients), the patient had partial generator electrical reset; in all six cases, the patients had pacemakers that had been implanted 5.7 to 9.7 years before the MRI (Table S5 in the Supplementary Appendix). Settings in the device memory that were reset included patient and device or lead identification information. No appropriately screened and reprogrammed device underwent a full electrical reset.

SECONDARY END POINTS

The results with regard to the secondary end points and measured differences between post-MRI and pre-MRI device settings for both pacemakers and ICDs are shown in Table 3 and as a histogram in Figure S1 in the Supplementary Appendix. A decrease of 50% or more in P-wave amplitude was detected in 0.9% of pacemaker leads and in 0.3% of ICD leads; a decrease of 25% or more in R-wave amplitude was detected in 3.9% of pacemaker leads and in 1.6% of ICD leads, and a decrease of 50% or more in R-wave amplitude was detected in no pacemaker leads and in 0.2% of ICD leads. An increase in pacing lead threshold of 0.5 V or more was detected in 0.7% of pacemaker leads and in 0.8% of ICD leads.

A pacing lead impedance change of 50 ohms or more was noted in 3.3% of pacemakers and in 4.2% of ICDs. For both pacemakers and ICDs, any decrease in pacing lead impedance from baseline occurred in 54% of atrial leads and in 55% of ventricular leads, and any increase occurred in 19% of atrial and 22% of ventricular leads. However, when the change in pacing lead impedance was compared as a continuous variable with the change in P-wave or R-wave voltage or pacing lead threshold, no clinically significant correlations were noted (Table S6 in the Supplementary Appendix).

LEAD AND DEVICE AGE AND CLINICAL END POINTS

Among patients who had undergone placement of a new generator or lead within 90 days before the MRI, there were no primary end-point events, and secondary end-point events were limited to a change in pacing lead impedance in 2 of 53 new pacemaker leads and in 1 of 27 new ICD leads.

Table 3. Measured Changes in Device Setting Values (Post-MRI minus Pre-MRI).*

Setting	Pacemaker					ICD				
	Leads or Cases†	Mean Change (±SD)	95% CI	Prespecified Threshold	Leads or Cases Exceeding Threshold†	Leads or Cases†	Mean Change (±SD)	95% CI	Prespecified Threshold	Leads or Cases Exceeding Threshold†
	no.	*ohms*			*no. (%)*	*no.*	*ohms*			*no. (%)*
Pacing lead impedance										
All leads	1902	−8.6±22.0	−9.6 to −7.6‡	±50	62 (3.3)	984	−5.5±22.3	−6.9 to −4.1‡	±50	41 (4.2)
Atrial leads	887	−7.3±17.6	−8.4 to −6.1‡	±50	11 (1.2)	359	−2.8±18.7	−4.7 to −0.9‡	±50	8 (2.2)
LV leads	21	−18.0±27.1	−30.3 to −5.7‡	±50	3 (14.3)	128	−8.9±28.9	−14.0 to −3.9‡	±50	10 (7.8)
RV leads	994	−9.6±25.0	−11.2 to −8.1‡	±50	48 (4.8)	497	−6.5±22.6	−8.5 to −4.5‡	±50	23 (4.6)
High-voltage lead impedance	NA	NA	NA	—	—	611	0.0±2.5	−0.2 to 0.2	±3	100 (16.4)
RV lead impedance	NA	NA	NA	—	—	413	0.1±2.4	−0.2 to 0.3	±3	52 (12.6)
SVC lead impedance	NA	NA	NA	—	—	198	−0.1±2.6	−0.5 to 0.3	±3	48 (24.2)
	no.	*volts*			*no. (%)*	*no.*	*volts*			*no. (%)*
Pacing lead threshold										
All leads	1813	0.0±0.2	−0.004 to 0.01	+0.5	13 (0.7)	951	0.0±0.2	0.003 to 0.02‡	+0.5	8 (0.8)
Atrial leads	800	0.0±0.2	−0.02 to 0.004	+0.5	4 (0.5)	331	0.0±0.2	−0.005 to 0.03	+0.5	4 (1.2)
LV leads	21	0.0±0.3	−0.1 to 0.1	+0.5	1 (4.8)	126	0.0±0.2	−0.02 to 0.05	+0.5	2 (1.6)
RV leads	992	0.0±0.2	0.003 to 0.02‡	+0.5	8 (0.8)	494	0.0±0.1	0.001 to 0.03‡	+0.5	2 (0.4)
Battery voltage	802	0.0±0.0	−0.001 to 0.0001	−0.04	3 (0.4)	333	0.0±0.0	−0.013 to −0.008‡	−0.04	24 (7.2)
	no.	*percent*			*no. (%)*	*no.*	*percent*			*no. (%)*
P-wave amplitude	790	2.5±30.9	0.4 to 4.7‡	−50	7 (0.9)	346	3.9±32.5	0.5 to 7.4	−50	1 (0.3)
R-wave amplitude	844	−0.2±13.7	−1.1 to 0.7	−25, −50	33 (3.9), 0	496	−0.3±13.8	−1.5 to 0.9	−25, −50	8 (1.6), 1 (0.2)

* Measurements of changes in settings are expressed as the difference between post-MRI and pre-MRI interrogation values for cases in which an interrogation yielded a numerical value. For example, a numerical value for battery voltage was obtained in 802 (80%) of pacemaker cases and 333 (67%) of ICD cases. Device interrogation for the remaining cases was obtained but yielded a descriptive result rather than a numerical value for battery voltage. LV denotes left ventricular, RV right ventricular, and SVC superior vena cava.

† For battery voltage, total numbers and percentages pertain to cases; for all other settings, total numbers and percentages pertain to leads (for P-wave amplitude, only right atrial leads with an intrinsic rhythm that could be measured are included; for R-wave amplitude, only right ventricular or left ventricular leads with an intrinsic rhythm that could be measured are included). The total number of leads among patients enrolled in the study was 1926 for pacemakers and 997 for ICDs. The number of leads used for the determination of secondary end-point events may be smaller than the total number among enrolled patients owing to missing data that could not be recovered or verified.

‡ The 95% confidence interval for the measured setting does not include 0.

Table 4. Cases in Which a Secondary End-Point Event Occurred Immediately after MRI or by the Final Follow-up.*

End Point	Pacemaker		ICD	
	Immediate	Long-Term	Immediate	Long-Term
	number/total number (percent)			
Battery voltage decrease ≥0.04 V	3/802 (0.4)	0/802	24/333 (7.2)	14/333 (4.2)
Pacing lead threshold increase ≥0.5 V	13/1813 (0.7)	5/1813 (0.3)	8/951 (0.8)	3/951 (0.3)
P-wave amplitude decrease ≥50%	7/790 (0.9)	2/790 (0.3)	1/346 (0.3)	0/346
R-wave amplitude decrease ≥50%	0/844	0/844	1/496 (0.2)	0/496
Pacing lead impedance change ≥50 ohms	62/1902 (3.3)	26/1902 (1.4)	41/984 (4.2)	22/984 (2.2)
High-voltage lead impedance change ≥3 ohms	NA	NA	100/611 (16.4)	61/611 (10.0)

* Data for battery voltage decrease are numbers and percentages of cases; data for all other end points are numbers and percentages of leads (for P-wave amplitude, only right atrial leads with an intrinsic rhythm that could be measured are included; for R-wave amplitude, only right ventricular or left ventricular leads with an intrinsic rhythm that could be measured are included). An immediate secondary end-point event or change in device setting was defined as a change that was noted when pre-MRI device interrogation values were compared with immediate post-MRI values on the day of the examination. A long-term secondary end-point event was a persistent change in device setting noted at the final follow-up. Cases in which an immediate change in setting occurred and in which the patient did not have a follow-up interrogation at 6 months were counted as long-term events. Follow-up data at 3 to 6 months were obtained for 85% of pacemaker cases and 79% of ICD cases in which an immediate change in setting occurred. Follow-up data at 6 months were obtained for 93% of all cases.

Among patients with leads that had been placed more than 10 years before MRI, there were no primary end-point events, and secondary end-point events were noted in 1 of 31 ICD leads (impedance change of ≥50 ohms) and in 14 of 172 pacemaker leads (1 with a P-wave amplitude decrease of ≥50%, 1 with a pacing threshold increase of ≥0.5 V, and 11 with an impedance change of ≥50 ohms). When the continuous variables of pacing lead threshold change, P-wave amplitude change, R-wave amplitude change, and impedance change were compared separately with the time since lead placement, no clinically significant correlations were found (Table S7 in the Supplementary Appendix).

PATIENTS WITH REPEAT MRI EXAMINATIONS

The maximum number of MRI examinations performed in patients in the MagnaSafe Registry was 11 in one patient with a pacemaker and 7 in one patient with an ICD (Table S8 in the Supplementary Appendix). The median interval between MRIs among patients who underwent more than one MRI examination was 153 days in patients with a pacemaker (range, 3 to 1309 days) and 91 days in patients with an ICD (range, 1 to 1376 days). In the examination of secondary end points, we found no clinically important differences between cases in which the patient underwent a single MRI and cases in which patients had undergone a previous MRI (Table S9 in the Supplementary Appendix).

PERSISTENT CHANGES IN DEVICE SETTINGS

Patients whose cardiac device exceeded the limit for a change in setting at the time of the MRI (a secondary end-point event) were asked to return for a repeat interrogation within 7 days and at 3 months and 6 months (pacemakers, 11% of cases; ICDs, 26% of cases). The proportions of cases in which there were persistent changes in device settings at the final follow-up are shown in Table 4. A higher incidence of long-term setting changes was seen with ICDs than with pacemakers. A long-term battery voltage decrease of 0.04 V or more occurred in 4.2% of ICD cases, and a long-term high-voltage lead impedance change of 3 ohms or more occurred in 10.0% of ICD cases.

DISCUSSION

In this study, we investigated the use of nonthoracic MRI at 1.5 tesla in patients with an implanted non–MRI-conditional cardiac device (pacemaker or ICD). We implemented a specific protocol for device interrogation, device programming, patient monitoring, and follow-up that was designed to reduce the risk of patient harm from MRI effects. In our study, no patient who was appropriately screened and had the device reprogrammed in accordance with our protocol had a device or lead failure. In one case, an ICD that was not properly reprogrammed before the MRI could not be inter-

rogated after the procedure, and immediate generator replacement was required. In six cases, atrial arrhythmias occurred, each lasting less than 49 hours; six partial electrical resets occurred that were detected and corrected during post-MRI reprogramming. Changes in device settings were common, but relatively few exceeded our prespecified threshold criteria for a clinically important change; the most common change was a 3-ohm change in ICD high-voltage (shock) lead impedance (16.4% of cases).

When pre-MRI and post-MRI battery voltage measurements were compared, a small decrease was noted for both pacemakers and ICDs. The radiofrequency energy generated during MRI scanning creates a temporary decrease in battery voltage, which has typically been reported to resolve after several weeks. In our study, all pacemaker voltage decreases of 0.04 V or more had resolved at the last follow-up, although some ICD voltage decreases of 0.04 V or more had not.

At the time that the study was being designed, we did not anticipate the demand for repeat MRI for patients with an implanted cardiac device. If exposure to a strong radiofrequency field resulted in substantial thermal injury at the lead–myocardial interface,[1] these patients should be at the greatest risk for a cumulative detrimental change in pacing properties. The only indication of such an effect in our study was a higher rate of high-voltage (shock) lead impedance changes among patients who had had previous MRI than among those who had not had previous MRI (21.5% vs. 14.9%).

Several smaller studies examining the risk associated with MRI in patients with an implanted device have reported varying effects on cardiac device settings.[17-31] On the basis of this early experience, position statements recommended caution in the performance of MRI in patients with an implanted cardiac device.[32,33] Subsequently, a larger prospective study examined 555 cases of scanning (including thoracic imaging) to assess the risk associated with MRI; no adverse clinical events occurred among the patients who underwent MRI, and the observed setting changes did not require device revision or reprogramming.[7]

Although it has been suggested that implanted generators and leads may be removed and then replaced to allow for MRI, such procedures may have greater risks than those associated with nonthoracic MRI in the current study. The rate of major complications among patients undergoing generator replacement with or without the placement of an additional transvenous lead was 4 to 15% in a prospective registry.[34] In addition, single-center and multicenter studies have shown a rate of major complications associated with elective laser-assisted lead extraction that is in the range of 0.4 to 2%.[35-38] Thus, device removal and replacement seem unlikely to be safer than proceeding with scanning for patients with a pacemaker or an ICD who require a nonthoracic MRI, provided a protocol similar to the one used in our study is followed.

The limitations of this study should be considered carefully. This registry represents a heterogeneous experience, with generators and leads from multiple manufacturers and initial as well as repeat examinations at 1.5 tesla. Thus, the results may not be predictive of findings with all device–lead combinations or higher MRI field strengths. Also, because patients younger than 18 years of age and MRI examinations of the thorax were excluded and the number of left ventricular leads was relatively small, it may not be possible to extrapolate the current data to a pediatric population, to patients undergoing MRI of the chest, or to patients with cardiac resynchronization devices. Finally, we excluded pacing-dependent patients with an ICD, because not all such patients had a device that was capable of providing pacing function while allowing for inactivation of tachycardia therapy. Therefore, our method should not be applied to pacing-dependent patients with an ICD unless independent programming of the bradycardia and tachycardia functions is possible.

In conclusion, we investigated the use of nonthoracic MRI at 1.5 tesla in patients with an implanted non–MRI-conditional cardiac device. No patient who was appropriately screened and had the cardiac device reprogrammed according to our protocol had device or lead failure. Substantial changes in device settings were infrequent and did not result in clinical adverse events.

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