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ORIGINAL INVESTIGATIONS

Full-Body MRI in Patients With an Implantable Cardioverter-Defibrillator

Primary Results of a Randomized Study

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ABSTRACT

BACKGROUND Magnetic resonance imaging (MRI) of patients with conventional implantable cardioverter-defibrillators (ICD) is contraindicated.

OBJECTIVES This multicenter, randomized trial evaluated safety and efficacy of a novel ICD system specially designed for full-body MRI without restrictions on heart rate or pacing dependency. The primary safety objective was >90% freedom from MRI-related events composite endpoint within 30 days post-MRI. The primary efficacy endpoints were ventricular pacing capture threshold and ventricular sensing amplitude.

METHODS Subjects received either a single- or dual-chamber ICD. In a 2:1 randomization, subjects either underwent MRI at 1.5-T of the chest, cervical, and head regions to maximize radiofrequency exposure up to 2 W/kg specific absorption rate and gradient field exposure to 200 T/m/s per axis (MRI group, n = 175), or they underwent a 1-h waiting period without MRI (control group, n = 88). A subset of MRI patients underwent ventricular fibrillation induction testing post-MRI to characterize defibrillation function.

RESULTS In 42 centers, 275 patients were enrolled (76% male, age 60.4 ± 13.8 years). The safety endpoint was met with 100% freedom from the composite endpoint ($p < 0.0001$). Both efficacy endpoints were met with minimal differences in the proportion of MRI and control patients who demonstrated a ≤0.5 V increase in ventricular pacing capture threshold (100% MRI vs. 98.8% control, noninferiority $p < 0.0001$) or a ≤50% decrease in R-wave amplitude (99.3% MRI vs. 98.8% control, noninferiority $p = 0.0001$). A total of 34 ventricular tachyarrhythmia/ventricular fibrillation episodes (20 induced; 14 spontaneous) occurred in 24 subjects post-MRI, with no observed effect on sensing, detection, or treatment.

CONCLUSIONS This is the first randomized clinical study of an ICD system designed for full-body MRI at 1.5-T. These data support that the system is safe and the MRI scan does not adversely affect electrical performance or efficacy. (Confirmatory Clinical Trial of the Evera MRI System for Conditionally-Safe MRI Access; NCT02117414) (J Am Coll Cardiol 2015;65:2581–8) © 2015 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

ICD = implantable cardioverter-defibrillator

MRI = magnetic resonance imaging

RF = radiofrequency

VPCT = ventricular pacing capture threshold

The implantable cardioverter-defibrillator (ICD) was approved in 1985 for the prevention of sudden cardiac death. Subsequent multicenter studies demonstrated the efficacy of ICDs to reduce mortality for both primary and secondary prevention (1–3). Many advances have been made in this therapy over the past 30 years, including the addition of pacing therapy and downsizing of the device, which allowed for pectoral implantation and transvenous leads. Magnetic resonance imaging (MRI), however, has remained contraindicated for ICD patients, because of the presumed risks associated with such scans in this patient group (4). For these reasons, there are presently no U.S. Food and Drug Administration–approved MRI-safe ICD systems, even though MRI has been performed safely in certain circumstances. The lack of MRI access to device patients has become a growing issue, as MRI usage as a diagnostic tool has evolved to become the preferred imaging modality in many clinical situations (5–7). It is now estimated that more than one-half of ICD patients will need MRI over a 10-year period (8).

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Over the past several years, a few pacemaker systems have been modified to allow for safe MRI (9–11). The issues required for safe MRI for ICDs are more complex, because in addition to pacing functionality, the risk of inducing or undersensing ventricular arrhythmias may be increased. Therefore, accurately sensing ventricular fibrillation and successful defibrillation are required. A comprehensive pre-clinical series of experiments showed the safety of such a system in animal studies, bench testing, and computer simulation (12). The present study represents the first human randomized study of an MRI-safe ICD system designed for full-body imaging.

METHODS

TRIAL DESIGN AND OVERSIGHT. This multicenter, international, parallel-group, randomized trial evaluated the safety and efficacy of patients who received a novel ICD system and who were subjected to an MRI examination. All participants met Class I or II indication for receiving a de novo ICD, with no restrictions on pacemaker dependence. All subjects provided written informed consent. The trial was sponsored by the manufacturer, Medtronic, Inc. (Minneapolis, Minnesota). The Declaration of Helsinki was followed, as well as laws and regulations of participating countries. The ethics committee at each participating institution approved the protocol. Trained center personnel collected the data, and data integrity was maintained via programmatic edit checks and source data verification by the sponsor.

STUDY DEVICE. Consenting patients received pectoral implantation of an Evera MRI ICD (MR-ICD, Medtronic) connected to commercially-available defibrillator leads (model 6935M or 6947M [Medtronic], 55- and 62-cm lead lengths). Per physician discretion, patients received a single- or dual-chamber ICD. For the dual-chamber ICD, a commercially-available pacing lead (model 5076, Medtronic) that has been demonstrated to be safe for MRI scanning (13) was used.

The MR-ICD had specific design and material modifications to reduce interaction with the MRI environment that have been described elsewhere (12). Briefly, ferromagnetic material was reduced, a hall sensor replaced the mechanical reed switch, filters to prevent gradient and radiofrequency (RF) energy coupling were added, and battery circuitry protection was added. Additionally, a programmable SureScan mode was included to provide asynchronous or disabled pacing and to disable tachyarrhythmia detection during the MRI scanning procedure. SureScan mode is designed to be preserved during a full electrical reset, and it times out after 6 h to mitigate the risk of therapies being inadvertently left disabled after scanning is completed. The system was designed and tested to be MRI-conditional when utilizing this device with specific SureScan lead models and lengths in a 1.5-T MRI environment.

RANDOMIZATION. After successful MR-ICD implantation, patients were randomly assigned 2:1 to undergo MRI (MRI group) or to undergo a 1-h waiting period without MRI (control group) 9 to 12 weeks after implant. Randomization assignments were centrally

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allocated by computer-generated, center-stratified blocked groups.

Subjects were evaluated post-implant at 2 months, at 9 to 12 weeks for MRI/waiting visit, and then at 1-week and 1-month post-MRI/waiting, 6 months post-implant, and every 6 months thereafter. Routine device measurements were collected, including pacing capture threshold, sensing amplitudes, and impedance values for each lead.

MRI SCAN. MRI scans were performed with 1.5-T systems from any of the 4 most common MRI manufacturers: Siemens (Berlin, Germany), Philips (Eindhoven, the Netherlands), GE Healthcare (Little Chalfont, United Kingdom), and Toshiba (Tokyo, Japan). To test the safety of MRI comprehensively and to include clinically-relevant evaluations, 10 MRI head, cervical spine, and chest scan sequences were performed (Table 1). The scan protocol included MRI scans with maximized RF energy deposition up to specific absorption rate levels of 2 W/kg body and scans with maximized gradient slew rates (up to 200 T/m/s per axis). The body coil served as the RF transmit coil in all cases. Static magnetic field exposure was approximately 50 min, with cumulative active MRI scan times of approximately 20 min (gradient and RF field exposure). Pulse oximetry, electrocardiography, and verbal communication provided monitoring. An external defibrillator was required to be immediately available during the scan, and qualified personnel were required to be present to manage any potential emergency situation.

The assessment of image quality was an ancillary objective of the study, and only some cardiac sequences in the protocol, such as k-space segmented fast gradient echo cine acquisitions, were chosen for this assessment. Representative examples of cardiac imaging are shown in Figure 1 and the Online Appendix.

POST-MRI INDUCTION TESTING. Because defibrillation is a primary function of ICDs, a subset of patients in the MRI group consented to undergo induction testing post-MRI to characterize ventricular arrhythmia sensing and detection as part of a preplanned substudy. In addition, subjects in the MRI group were required to undergo induction testing at the 1-month post-MRI visit for either of the following conditions: 1) a >30% decrease in ventricular sensing amplitude was observed compared with immediately pre-MRI; or 2) ventricular sensing amplitude measured <3 mV.

PRIMARY OBJECTIVES. The trial had 3 primary objectives. The primary safety objective was to demonstrate >90% freedom from MRI-related events. The occurrence of any of the following was considered an MRI-related event: 1) sustained ventricular tachyarrhythmia (ventricular tachycardia [VT]/ventricular fibrillation [VF]) during SureScan mode; 2) complication within 30 days and related to the MRI; or 3) loss of capture within 30 days of MRI. All events were reviewed by a clinical events committee. There were 2 primary efficacy endpoints: ventricular pacing capture threshold (VPCT) and ventricular sensing amplitude changes from the MRI/waiting period to 1-month post-MRI/waiting period. VPCT, measured at 0.4 ms in both the MRI and control groups, was defined as a failure if it increased by >0.5 V. Sensing amplitude was considered a failure if a >50% decrease in R-wave amplitude (or >25% decrease if <3 mV) was noted.

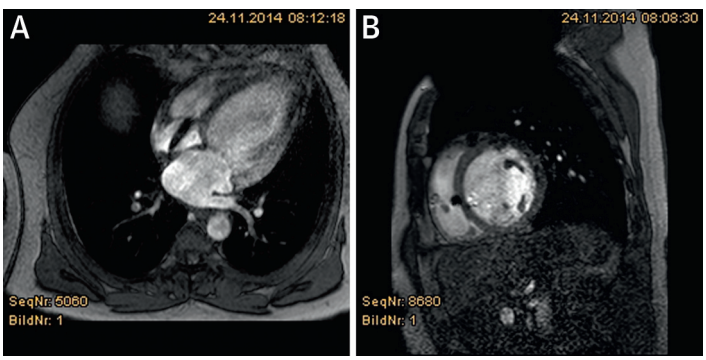
VT/VF DETECTION ANCILLARY OBJECTIVE. All device-detected VT and VF episodes (induced or spontaneous) with stored electrogram available and nonsustained VT/VF episodes of at least 16 beats

TABLE 1 MRI Examination Sequences for Study Scan

Body Region	Sequence Name
Cardiac	SSFP cine, short-axis, 10 slices
	SSFP cine, short-axis, 3 slices
	Delayed enhancement inversion recovery, short-axis, 10 slices No contrast media given
	K-space segmented fast gradient echo cine, short-axis, 3 slices
	SSFP cine, horizontal long-axis, 1 slice
	SSFP cine vertical long-axis, 1 slice
	K-space segmented fast gradient echo cine, horizontal long-axis, 1 slice
Thoracic spine	T2 fast spin echo, sagittal plane
Cervical spine	T2 fast spin echo, sagittal plane
Head	Diffusion-weighted imaging, transverse plane

MRI = magnetic resonance imaging; SSFP = steady state free precession.

FIGURE 1 Image Quality Scan Sequences



Representative cardiac images from a study patient implanted with an Evera MRI system (Medtronic, Inc., Minneapolis, Minnesota). Horizontal long-axis **(A)** and short-axis **(B)** cine k-space segmented fast gradient echo acquisitions.

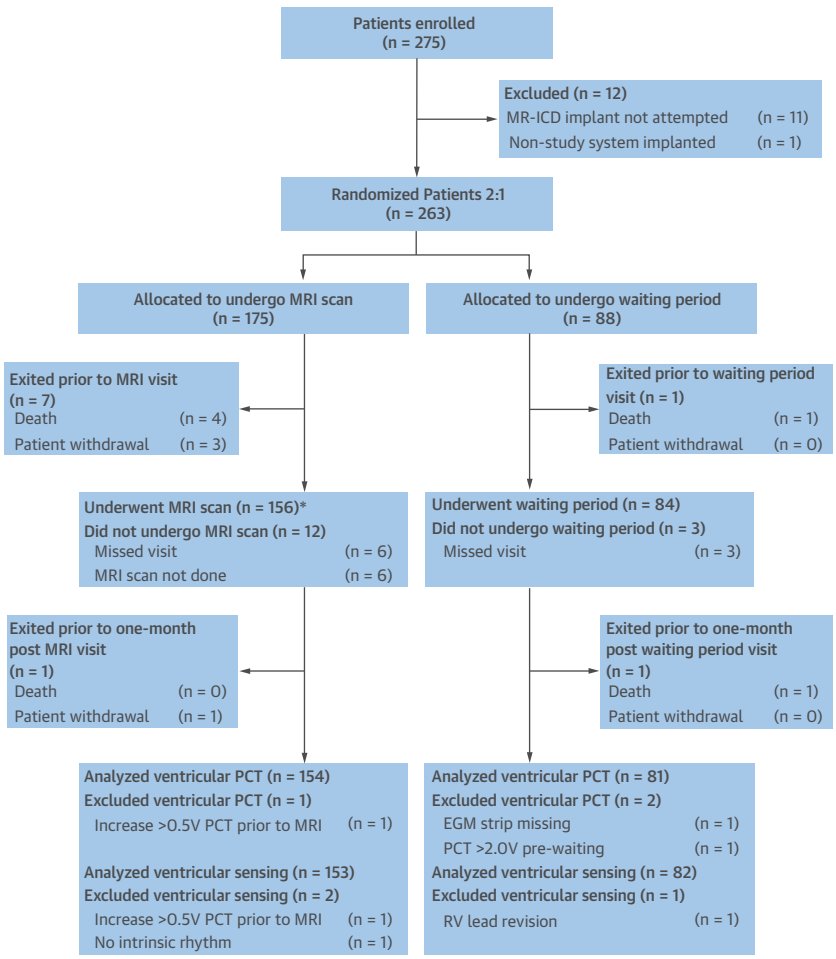
were adjudicated by an episode review committee. Episodes that were classified as polymorphic VT/VF, and with at least 4 intervals ≥300 ms, with 1 interval ≥600 ms, or with the pre-detection time lasting more than 10 s, were further evaluated for VF undersensing and amount of detection delay. A clinically-significant detection delay was defined as ≥5 s.

STATISTICAL ANALYSIS. All primary endpoints were tested using a 1-sided test with an α-level of 0.025. For the primary safety objective, a 1-proportion binomial exact test was used. The Farrington-Manning test of 2 independent proportions was used to test the primary efficacy endpoints. The noninferiority margins were 10% (VPCT) and 8% (sensing). Mean change was tested using paired Student *t* tests. Continuous variables are reported as mean ± SD.

RESULTS

Patient enrollment began April 17, 2014, and concluded September 11, 2014, with 275 patients enrolled at 42 centers located in 13 countries within North and South America, Europe, Asia, and the Middle East. In the trial, 263 patients successfully received an MR-ICD (Figure 2) and were randomized to undergo MRI (n = 175) or a waiting period without MRI (n = 88). Baseline characteristics are presented in Table 2; this was a typical group of patients undergoing ICD implantation. The mean follow-up

FIGURE 2 Primary Objectives Analysis Population



This is a flow chart of enrolled patients through the primary ventricular PCT and ventricular sensing endpoints. *A total of 147 of 156 MRI scanned patients were included in the primary safety objective analysis. Patients not included missed the 1-month post-MRI visit (n = 8) or withdrew (n = 1). EGM = electrocardiogram; ICD = implantable cardioverter-defibrillator; MR = magnetic resonance; PCT = pacing capture threshold; RV = right ventricular; other abbreviations as in Figure 1.

TABLE 2 Baseline Demographic and Clinical Characteristics

	MRI Group (n = 175)	Control Group (n = 88)	Total (n = 263)
Age, yrs	60.5 ± 13.5	60.1 ± 14.3	60.4 ± 13.8
Sex			
Male	135 (77.1)	66 (75.0)	201 (76.4)
Female	40 (22.9)	22 (25.0)	62 (23.6)
NYHA functional class			
I	15 (8.6)	14 (15.9)	29 (11.0)
II	93 (53.1)	43 (48.9)	136 (51.7)
III	23 (13.1)	12 (13.6)	35 (13.3)
IV	1 (0.6)	1 (1.1)	2 (0.8)
Subject does not have heart failure	29 (16.6)	12 (13.6)	41 (15.6)
Classification not available	14 (8.0)	6 (6.8)	20 (7.6)
ICD indication			
Primary prevention	130 (74.3)	64 (72.7)	194 (73.8)
Secondary prevention	45 (25.7)	24 (27.3)	69 (26.2)
Atrial fibrillation	48 (27.4)	18 (20.5)	66 (25.1)
ICD system configuration			
VR ICD (vs. DR ICD)	92 (52.6)	51 (58.0)	143 (54.4)
6935M (vs. 6947M)	119 (68.0)	60 (68.2)	179 (68.1)

Values are mean ± SD or n (%).

DR = dual chamber; ICD = implantable cardioverter-defibrillator; MRI = magnetic resonance imaging; NYHA = New York Heart Association; VR = single chamber.

duration of randomized patients was 4.5 ± 1.3 months.

SAFETY. Full-body MRI examinations were performed in 156 patients representing the MRI group, and 147 included in the safety objective analysis were followed to 1-month post-MRI or longer. Patients not included in the safety analysis either missed the 1-month post-MRI visit (n = 8) or withdrew (n = 1), but they were all seen at the 1-week post-MRI visit. None of these patients experienced an MRI-related complication. The safety endpoint was met (100% complication-free rate) with no sustained ventricular tachyarrhythmia episodes during MRI, and no MRI-related complications or loss of capture ($p < 0.0001$).

A total of 5 MRI-related observations occurred in 5 patients. No action was required for 2 patients who reported implant site warmth and 1 who reported back pain during scanning. One patient, reporting a burning sensation in the forehead, received x-rays to exclude the presence of a metallic foreign body. One patient experienced atrial tachycardia at a rate of 150 beats/min during the scan, associated with asynchronous pacing. The scan was stopped, and the patient's rhythm was converted to normal rhythm using atrial antitachycardia pacing noninvasively through the MR-ICD. Scanning was continued and was completed uneventfully. The patient subsequently experienced multiple other atrial tachycardia episodes during the follow-up period, so presumably was predisposed to this arrhythmia.

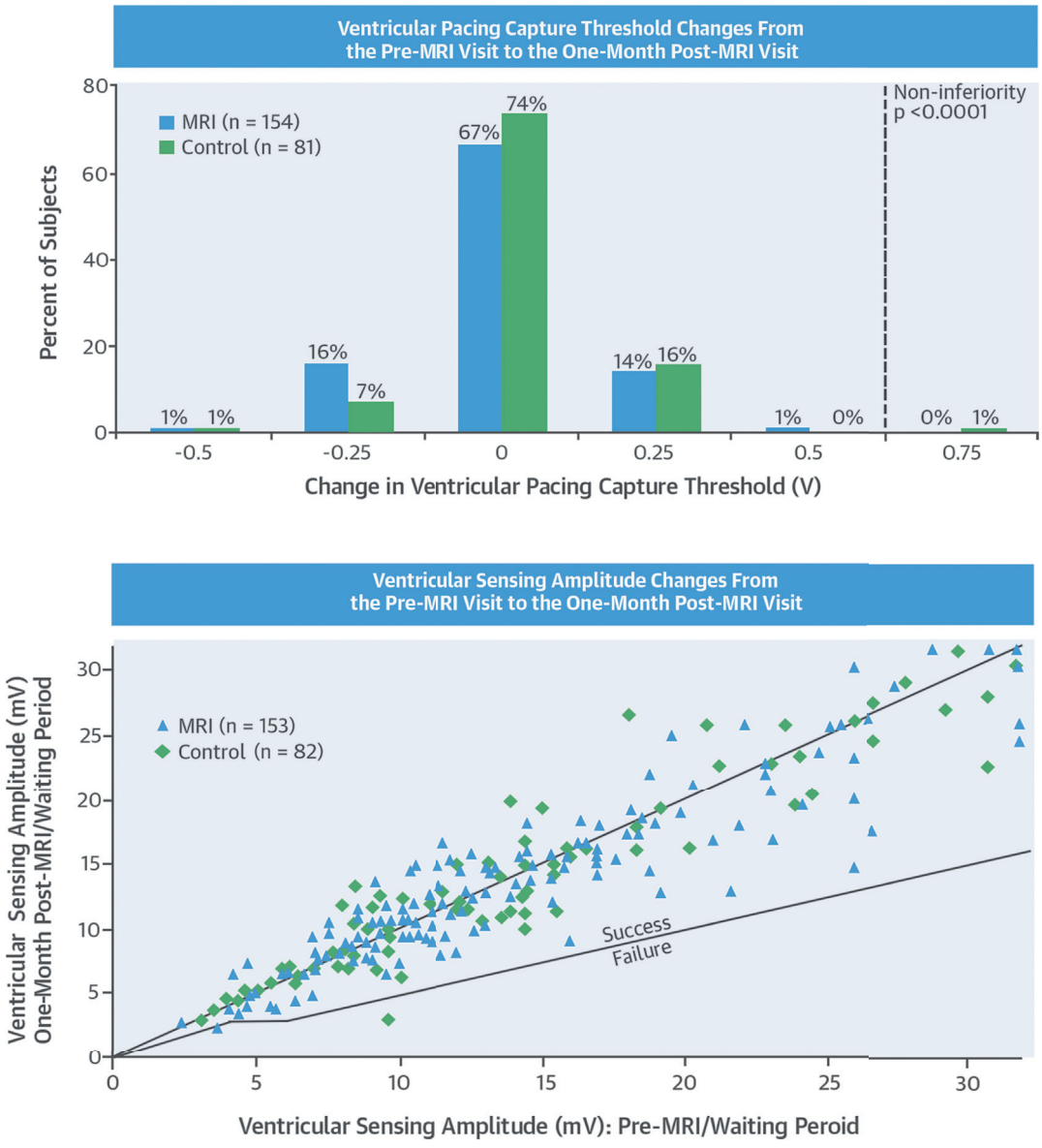
Twelve patients died during the study, of which 4 were in the control group and 8 in the MRI group. In the latter group, 5 of these subjects died before undergoing MRI, 1 died 30 days post-MRI due to small cell lung carcinoma, 1 died 109 days post-MRI due to acute respiratory distress, and the last died 187 days post-MRI due to VT. All deaths were reviewed and adjudicated by the clinical events committee, and none were considered to be related to the MR-ICD system or MRI procedure.

VENTRICULAR LEAD PERFORMANCE. VPCT before and post-MRI/waiting period are shown in the **Central Illustration**. On average, the MRI group's VPCT did not change (0.00 ± 0.16 V), whereas the control group changed very little (0.02 ± 0.16 V). There were no significant differences between the MRI and control groups in the proportion of patients who met the VPCT endpoint (100.0% MRI, 98.8% control; $p < 0.0001$); thus, the pre-specified primary endpoint for noninferiority was met. A total of 28 randomized patients (21 [12%] MRI and 7 [8%] control subjects) did not contribute data to the analysis, primarily due to MRI examinations not being performed for various reasons and death (**Figure 2**).

R-wave amplitudes before and post-MRI/waiting period are shown in the **Central Illustration**. Mean changes were small for both MRI (-0.10 ± 2.67 mV) and control (0.04 ± 2.59 mV) subjects. There was no significant difference between the MRI and control groups in the proportion of patients meeting the R-wave amplitude endpoint (99.3% MRI, 98.8% control; $p = 0.0001$) (**Central Illustration**); thus, the pre-specified primary endpoint for noninferiority was met.

There were several other electrical properties of the ICD systems that were included as secondary endpoints for this trial. Ventricular pacing impedances from MRI/waiting period to 1-month post-MRI/waiting period were stable in both the MRI (468 ± 83 ohms [Ω] vs. 464 ± 83 Ω; $p = 0.12$) and control (475 ± 97 Ω vs. 476 ± 100 Ω; $p = 0.81$) groups. The proportion of MRI and control patients who demonstrated defibrillation impedances within the standard ranges was also very similar. The right ventricular defibrillation impedance between 20 and 100 Ω was observed in 100% of MRI subjects and 98.8% of control subjects, ($p < 0.0001$ for noninferiority). The superior vena cava defibrillation impedance between 20 and 100 Ω at 1-month post MRI/waiting period visit was 100% in both groups.

CENTRAL ILLUSTRATION **Full-Body MRI Scanning in Patients With Implantable Cardioverter-Defibrillators**



Gold, M.R. et al. J Am Coll Cardiol. 2015; 65(24):2581–8.

(Top) Ventricular pacing capture threshold changes from the pre-magnetic resonance imaging (MRI) visit to the 1-month post-MRI visit. The data to the right of the **vertical dashed line** represents the percentage of patients with a >0.5 V increase in ventricular pacing capture threshold, which was the pre-specified endpoint to be tested. **(Bottom)** Ventricular sensing amplitude changes from the pre-MRI visit to the 1-month post-MRI visit. **Points above the line** labeled success/failure (a 25% decrease from 0 to 4 mV pre-MRI/waiting, and a 50% decrease for ≥4 mV) represent successful subjects. The other **line** is the line of unity.

A total of 34 episodes of VT/VF occurred after MRI in 24 subjects. Of those, 20 were induced on the basis of protocol requirements and 14 were spontaneous events. None (0.0%) were noted to have a significant detection delay. The longest observed detection delay due to undersensing was 0.19 s, which is an expected occurrence in any ICD.

ATRIAL LEAD PERFORMANCE. There were 120 patients implanted with a dual-chamber ICD. At the 1-month post-MRI/waiting period visit, there were

minimal differences in the proportion of MRI and control patients evaluated who demonstrated a ≤0.5 V increase in atrial pacing capture threshold at 0.4 ms (98.7% MRI, 100% control subjects; non-inferiority $p = 0.006$), with mean changes of 0.01 ± 0.18 V and -0.02 ± 0.13 V, respectively. The proportion of patients who demonstrated a ≤50% decrease in P-wave amplitude was very similar between groups (97.4% MRI, 97.1% control; non-inferiority $p = 0.005$). Atrial pacing impedances from MRI/waiting period to 1-month post-MRI/waiting period were stable in both the MRI ($481 \pm 62\ \Omega$ vs. $483 \pm 60\ \Omega$; $p = 0.71$) and control ($486 \pm 50\ \Omega$ vs. $489 \pm 49\ \Omega$; $p = 0.63$) groups and with minimal differences observed.

DISCUSSION

This is the first randomized trial in humans of the safety and efficacy of full-body MRI on an ICD system that was designed specifically for this purpose. The primary finding was that no adverse effects were noted with a standardized, comprehensive MRI protocol. Moreover, pacing and sensing were not significantly affected by MRI, with normal arrhythmia detection and defibrillation function documented following these examinations (**Central Illustration**). These findings support the pre-clinical studies (12), which indicated that the modifications made in this system allow for safe MRI at 1.5-T when used in the prescribed manner.

Although adverse effects of MRI on conventional pacemaker and ICD systems are well documented (14–16), the magnitude of this problem with contemporary devices has been questioned in some studies. Specifically, several single-center trials have shown that such imaging can be performed safely in certain situations (17,18). Although adverse events are low in these reports, these studies typically restricted scans to nonthoracic regions, excluded pacemaker-dependent patients, and included a small proportion of ICD patients compared with pacemaker patients (19). By including a wide variety of cardiovascular implantable electronic device system components, imaging techniques, and patient positions in these studies, an evaluation of safety is difficult to assess.

MRI scans have been restricted to outside of the thoracic region to decrease the risk of lead electrode tip heating (20). Moreover, these previous studies were performed in selective patients at highly-experienced centers. We now show that the modifications of the ICD system employed in this trial allow for safe 1.5-T MRI with <2.0 W/kg specific absorption rate and with no restrictions on scan location, heart rate, rhythm, or pacemaker dependency. Importantly, this study was performed in a large number of centers in diverse geographies with highly-variable scanning experience.

There have been several concerns regarding the risks of MRI among ICD patients (12). These include the induction of ventricular arrhythmias during the MRI procedure, adverse changes in pacing or sensing as a consequence of MRI, and abnormal defibrillation function. No patient in this study had a ventricular arrhythmia during the MRI procedure. Moreover, pacing and sensing function were stable, with minimal changes documented in the 1-month period following MRI and no significant difference compared with a nonimaged control group. One of the theoretical effects of MRI on ICDs is the possible interference with tachyarrhythmia detection. To our knowledge, this is the first prospective study to evaluate sensing and detection following MRI. These include both spontaneous and induced VT/VF episodes in a subset of patients. We found no effect on sensing of VT/VF and therapy delivery, with only a minimal delay to detection, which is within normal limits.

The use of a dedicated mode (SureScan) during ICD imaging facilitates programming of the device into a compatible state for the MRI procedure. Asynchronous pacing is available to support pacing-dependent patients. SureScan disables tachyarrhythmia sensing and defibrillation therapies. However, accidental permanent deactivation of devices for elective procedures has been associated with patient deaths (21). Thus, to mitigate this safety risk, an obligatory 6-h timeout of these settings ensures that inadvertent long-term inactivation of ICD therapy is avoided. The SureScan settings are stored in nonvolatile device memory to maintain these settings during an electrical reset. Finally, filters were added to the telemetry circuitry to reduce the likelihood of device damage caused by MRI. These design changes contribute to patient safety and proper device operation during MRI, compared with conventional ICDs.

STUDY LIMITATIONS. This study should be interpreted with certain methodological limitations. Only a single MRI system and 2 DF4 lead models of limited lengths were tested on 1.5-T MRI machines, so these findings should not be extrapolated to other systems, leads, or lead lengths; nonpectoral implantation sites; or 3T scanners until further research is completed. Scans were performed a period of time after implant, and therefore, scanning prior to the lead maturation period was not assessed. The follow-up was short as it was designed to assess the early effect of MRI on ICD function. Therefore, the long-term effect on ICD

function cannot be determined, although observational clinical trials do not indicate a delayed effect of MRI on device function. Finally, the study restricted patients with de novo implants, so safety with more chronic leads was not assessed.

CONCLUSIONS

This is the first-in-human randomized study of an ICD system designed for full-body MRI at 1.5-T. The data support that the system is safe with MRI examinations, showing no evidence of any adverse effect on the electrical performance or the ability to treat ventricular arrhythmias.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Although diagnostic MRI can be performed safely in some patients with ICDs, it is usually contraindicated because of the risk of causing device malfunction. In a randomized clinical trial, patients with an ICD specifically designed for compatibility safely tolerated MRI even when pacemaker-dependent und undergoing whole-body MRI scans.

TRANSLATIONAL OUTLOOK: Larger studies are needed to ensure that low incidence complications, such as sustained ventricular arrhythmias or perturbations of defibrillation energy thresholds, can be reliably avoided when patients with this type of ICD are subjected to high-intensity MRI.

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APPENDIX For supplemental figures, please see the online version of this article.