Safety of magnetic resonance imaging scanning in patients with cardiac resynchronization therapy–defibrillators incorporating quadripolar left ventricular leads

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BACKGROUND Magnetic resonance imaging (MRI) scanning of magnetic resonance (MR)-conditional cardiac implantable cardioverter-defibrillators (ICDs) can be performed safely following specific protocols. MRI safety with cardiac resynchronization therapy–defibrillators (CRT-Ds) incorporating quadripolar left ventricular (LV) leads is less clear.

OBJECTIVE The purpose of this study was to evaluate the safety and effectiveness of ICDs and CRT-D systems with quadripolar LV leads after an MRI scan.

METHODS The ENABLE MRI Study included 230 subjects implanted with a Boston Scientific ImageReady ICD (n = 39) or CRT-D (n = 191) incorporating quadripolar LV leads undergoing nondiagnostic 1.5-T MRI scans (lumbar and thoracic spine imaging) a minimum of 6 weeks postimplant. Pacing capture thresholds (PCTs), sensing amplitudes (SAs), and impedances were measured before and 1 month post-MRI using the same programmed LV pacing vectors. The ability to sense/treat ventricular fibrillation (VF) was assessed in a subset of patients.

RESULTS A total of 159 patients completed a protocol-required MRI scan (MRI Protection Mode turned on) with no scan-related complications. All right ventricular (RV) and left LV PCT and SA effectiveness endpoints were met: RV PCT 99% (145/146 patients), LV PCT 100% (120/120), RV SA 99% (145/146), and LV SA 98% (116/118). In no instances did MRI result in a change in pacing vector or lead revision. All episodes of VF were appropriately sensed and treated.

CONCLUSION This first evaluation of predominantly CRT-D systems with quadripolar LV leads undergoing 1.5-T MRI confirmed that scanning was safe with no significant changes in RV/LV PCT, SA, programmed vectors, and VF treatment, thus suggesting that MRI in patients having a device with quadripolar leads can be performed without negative impact on CRT delivery.

KEYWORDS Cardiac resynchronization therapy; Implantable cardioverter-defibrillator; Magnetic resonance imaging; Quadripolar lead; Ventricular fibrillation

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Introduction

Most patients with an indication for an implantable cardioverter-defibrillator (ICD) are projected to undergo magnetic resonance imaging (MRI),[1] which is the imaging modality of choice for a wide range of diseases. Previous studies have reported the safety of MRI in patients with an MRI-conditional pacemaker or ICD[2] and, recently, the safety of performing MRI scans in those with nonconditional cardiovascular implantable electronic device systems.[3] However, left ventricular (LV) leads used in cardiac resynchronization therapy (CRT) devices may present unique MRI risks due to their placement through the coronary sinus (CS) and

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tributary cardiac veins, with its thinner walls and lower flow rate potentially providing less cooling than leads placed in the heart, as well as the lack of active fixation on LV leads with resulting dislodgment risk. Some recent publications included a limited number of CRT patients within a larger study,[4,5] but most studies to date have included only bipolar LV leads with limited thoracic or chest MRI locations. Exception are the studies of Sheldon et al,[6] who included 1 patient with a quadripolar lead, and Vago et al,[7] who performed cardiac MRI on 13 patients implanted with MRI-conditional CRTs during biventricular pacing (DOO) and right atrial pacing (AOO) with no reported device complications. The use of quadripolar LV leads has become standard of care.[8,9] Although the MRI compatibility of clinically approved quadripolar leads has been evaluated using clinical modeling,[10] little has been reported on the outcome of MRI scans in patients with CS LV quadripolar leads to confirm the findings of computer modeling. Because delivery of optimal resynchronization may depend on specific pacing vector programming with avoidance of apical pacing vectors and scar preferred,[11] changes in LV vectors as a result of MRI scanning may significantly affect optimal CRT delivery and the ability to sense and treat ventricular fibrillation (VF) episodes. The ENABLE MRI Study was a prospective, nonrandomized study conducted as an investigational device exemption in the United States and postmarket study in Europe, Israel, and Asia Pacific at 45 investigational sites. The objective was to confirm the safety (MRI scan-related complications) and effectiveness (RV and LV lead thresholds/sensing) of the Boston Scientific (St Paul, MN) ImageReady MR-Conditional Defibrillation System in the 1.5-T MRI environment under labeled conditions in patients with an ICD or cardiac resynchronization therapy–defibrillator (CRT-D) with LV quadripolar leads. A VF induction substudy assessed the ability to sense and treat VF after MRI scanning.

Methods

Trial design

The study was conducted to support premarket regulatory agency submissions for approval of the Boston Scientific ImageReady MR-Conditional Defibrillation System in a 1.5-T MRI environment as well as postmarket requirements in certain geographic locations. The first subject was enrolled on February 15, 2016. The study had 2 phases. Phase I enrolled 237 patients for primary endpoint analysis, and phase II enrolled an additional 261 patients for postapproval follow-up. This publication reports Phase I results. The protocol was approved by the institutional review board at each participating center, and all subjects provided written informed consent. Phase I subjects were required to undergo a nonmedically necessary 1.5-T MRI scan. A subset of 25 subjects participated in a VF substudy mandated by the US Food and Drug Administration to confirm the ability to sense and treat VF after MRI exposure. A study design schematic and modified CONSORT diagram are shown in Figures 1 and 2, respectively.

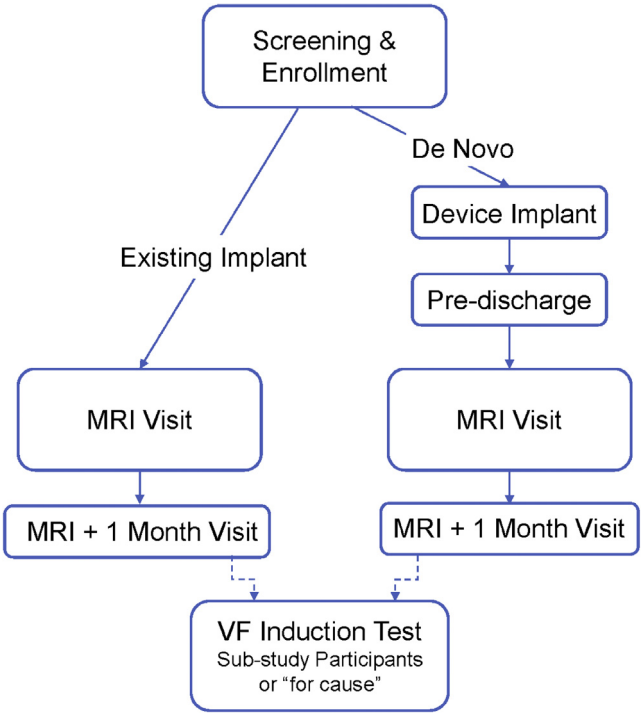

Figure 1 ENABLE MRI Study design. *Dotted lines* indicate that only a subset of patients underwent ventricular fibrillation (VF) induction testing. MRI = magnetic resonance imaging.

Study devices

The Boston Scientific Image-Ready MR-Conditional Defibrillation Systems included in the study consisted of ICDs or CRT-Ds from the NG3 next generation family of pulse generators incorporating Fineline II Sterox/Sterox EZ or Ingevity MRI pace/sense lead families for the right atrial lead and Reliance 4-Front or Endotak Reliance DF4 defibrillation lead families for the right ventricular (RV) lead. All CRT-Ds incorporated quadripolar leads (Boston Scientific Acuity X4 IS4) (Table 1). Prestudy modeling and performance testing had been performed according to Tier 3 modeling as described in the International Organization for Standardization ISO/TS 10974 "Assessment of the Safety of MRI for Patients with an Active Implantable Medical Device" utilizing virtual human body models and simulation software. To provide MRI Protection Mode to these models, the pulse generator firmware was added to implement a special operating mode called MRI Protection Mode. In MRI Protection Mode, the hardware was configured to protect internal circuitry from coupled MR energy and prevent unintended conduction through patient lead electrodes. The pacing mode was disabled, and magnet detection was ignored. The firmware and Programmer Software Application were updated such that when MRI Protection Mode was enabled, daily diagnostics were suspended until after exit from MRI Protection Mode in order to prevent potential corruption of data due to coupled MRI, including disabling automated

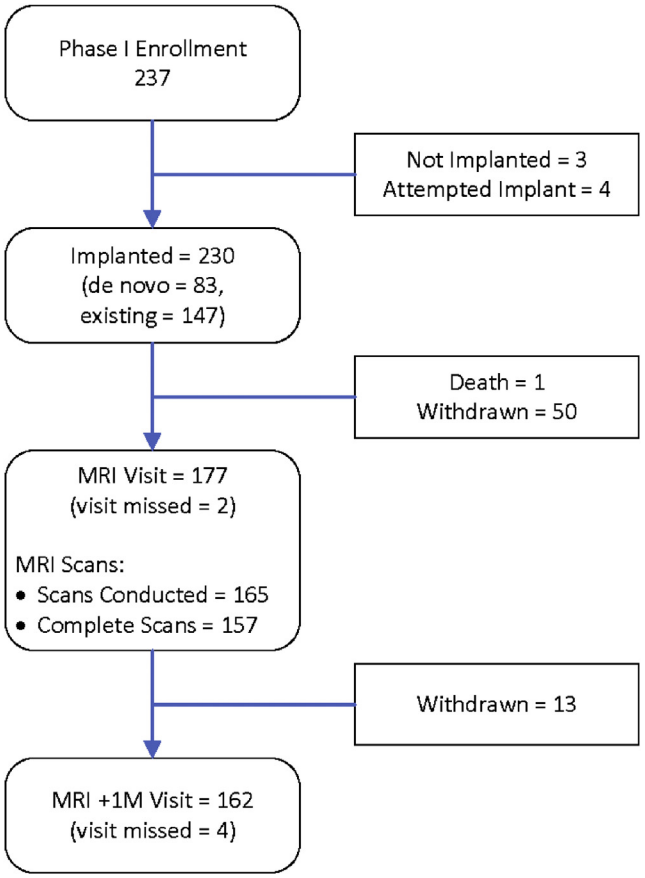

Figure 2 Modified CONSORT flow diagram of patient enrollment, allocation, and disposition status. 1M = 1 month; MRI = magnetic resonance imaging.

device features and monitoring, beeper, radiofrequency (RF) telemetry, pacing, and tachycardia detection and therapy. The ability to asynchronously pace during MRI Protection Mode was added before commercialization in the United States.

Inclusion criteria

Subjects were eligible if they were awaiting or had already been implanted with an ICD or CRT-D pulse generator in the left or right pectoral region and were able to undergo MRI scanning without intravenous sedation (oral sedation allowed). Subjects had to be capable of providing informed consent and participating in all study testing/visits (age $\geq$18 years).

Exclusion criteria

Patients with active or abandoned implanted cardiovascular implantable electronic devices, components, or accessories such as pulse generators, leads, lead adapters, or extenders; those with metallic objects representing a contraindication to MRI; and subjects requiring medically necessary MRI before completing the 1-month follow-up visit were excluded. A history of syncope related to bradyarrhythmia, sinus pauses >2 seconds, permanent or intermittent complete atrioventricular (AV) block, progressive AV nodal block, or trifascicular block were other reasons for exclusion. Patients with inability to tolerate the absence of pacing or resynchronization therapy in a supine position or the absence of tachycardia therapy for the duration the device was in MRI Protection Mode; planned lead revision or extraction within 30 days of enrollment; dialysis; mechanical heart valve; known/suspected sensitivity to dexamethasone acetate; subjects on the heart transplant list or with life expectancy <12 months; and women who were or might become pregnant were excluded.

Study follow-up and duration

Subjects with *de novo* implants underwent a screening and enrollment visit ($\leq$30 days preimplant) followed by implant and predischarge clinic visits (3–72 hours postimplant). Subjects attended an MRI visit (6–9 weeks postimplant) and another visit 1 month (30 $\pm$ 7 days) post-MRI. Subjects with an existing implant underwent screening and enrollment visits, followed by MRI (<6 weeks from enrollment) and 1-month visit (30 $\pm$ 7 days post-MRI).

MRI protocol

All patients were required to undergo a nonmedically necessary 1.5-T MRI under conditions according to the investigational device's MR-conditional instructions for use. The conditions include scanning in a 1.5-T, horizontal closed-bore machine, as well as operating the MR scanner within Normal Mode RF and gradient exposure limits, without restriction on the make or model of the scanner. In order to include sites with different scanner makes and models, and to expose patients to clinically relevant sequences at a given site, the specific scanning parameters (eg, TR, TE, flip angle, etc) were not prescribed. Instead, each site was instructed to follow the guidance of types and durations of sequences (Supplemental Table 1). This enabled sites to use their own sequences while ensuring relatively high exposure to RF- and gradient-intensive fields because of the types of scans and their relative durations in the guidance. These study-defined RF-intensive and gradient-intensive scans were performed in the thoracic spine and lumbar spine regions, respectively, because those landmarks

Table 1 Implanted devices

Lead/PG	Device	
RA lead	Ingevity MRI Fineline II Sterox/Sterox EZ	
RV lead	Reliance 4-Front Endotak Reliance	
LV lead	Acuity X4	
	PG header	Device name
VR ICD	VR ICD (DF4) CRT-D (IS1/DF4/IS4)	Origen Inogen Dynagen Autogen
CRT-D		

CRT-D = cardiac resynchronization therapy–defibrillator; ICD = implantable cardioverter-defibrillator; LV = left ventricle; PG = pulse generator; RA = right atrium; RV = right ventricle.

correspond to the highest anticipated RF- and gradient-intensive exposures for the implanted systems.

Before the MRI scan, the patient underwent a required 5-minute monitoring of intrinsic heart rhythm to confirm that the subject was not pacemaker dependent. The device was then programmed to an MRI Protection Mode, which suspends certain functions including bradycardia pacing and sensing, tachycardia detection and therapy, RF telemetry, and battery voltage monitoring, among other functions (the ability to asynchronously pace during MRI Protection Mode was added before commercialization in the United States). The following parameters were monitored during the full duration of the device being in MRI Protection Mode: telemetry-based ECG, pulse oximetry with waveform monitoring (finger plethysmography), automatic noninvasive blood pressure monitoring, and visual and auditory communication with the subject. Scan duration, duration of RF and gradient scans, and duration in MRI Protection Mode were recorded.

Primary safety endpoint

The primary safety endpoint was the MRI scan-related complication-free rate between the MRI and 1-month follow-up visit. All subjects who underwent any portion of the study-required MR scan sequences were included in this endpoint. An MRI scan-related complication was defined as any adverse event resulting in death, serious injury, correction using invasive intervention, or permanent loss of device function related to the MRI (ie, after the patient was placed in the bore of the magnet and any RF and/or gradient fields had been applied). All reported complications were adjudicated by an external Clinical Events Committee.

Primary effectiveness endpoint

MRI may induce damage to tissue surrounding the lead distal electrode fixated in the myocardium due to RF field-induced heating. Potential damage was assessed by evaluating PCT and SA of RV and quadripolar LV leads before and 1 month post-MRI. Outcomes were considered successful if the following criteria were met: RV thresholds $\leq$0.5-V increase; RV sensing $\geq$5.0 mV and $\geq$50% prescan; LV thresholds $\leq$1.0-V increase; and LV sensing $\geq$5.0 mV and $\geq$50% prescan.

VF episode detection substudy

MRI may affect the ability to sense and treat ventricular tachycardia (VT)/VF. A subset of 25 subjects (20 CRT-D, 5 ICD) participated in an induction substudy. All met the exclusion criteria: unstable heart failure requiring hospitalization in the past 30 days, inability to tolerate intravenous sedation/general anesthesia, any planned revascularization procedure, or RV lead R wave $<$5 mV. All spontaneous and induced VT/VF episodes were evaluated by an ECG core laboratory. If the first VF induction attempt induced monomorphic or polymorphic VT/VF that spontaneously terminated before charging, a second induction was performed. The performance objective was to sense/detect induced or spontaneous VF post-MRI with a detection delay $<$5 seconds above the detection time expected based on VF rate and programming.

Statistical analysis

Statistical analysis was conducted using SAS Version 9.4 or higher (SAS Institute, Cary, NC). All subjects who completed any portion of the study-required MRI without a medically necessary scan before the MRI + 1-month visit were included in the primary safety endpoint analysis. MRI-related complication-free rate was calculated using Kaplan-Meier (K-M) methodology with a 97.5% one-sided lower confidence limit (LCL) of the complication-free rate calculated via log–log methodology for all subjects compared to the performance goal of 90%. Subjects who failed to reach 31 days of follow-up without experiencing an endpoint event before their end of follow-up were censored at the time their follow-up ended. Effectiveness endpoints were designed to detect a permanent increase in PCT or decrease in SA post-MRI. Effectiveness endpoints were measured at the MRI and the MRI +1-month follow-up visits with 3 separate consecutive sets of lead measurements collected at each visit. The average was used to determine whether a chronic effect/permanent change was induced by the scan.

Results

Follow-up duration and endpoint evaluation

Two hundred thirty-seven subjects were enrolled. Baseline demographics are given in Supplemental Table 2. Subjects were predominantly male (72.6%), with an average age 65 years. Hypertension (71.1%) and hyperlipidemia (58.3%) were the most frequent comorbidities. Of the 237 enrolled subjects, 230 underwent device implantation: CRT-D (*de novo* or pre-existing) in 191 (83%) and single-chamber ICD in 39 (17%). Average follow-up was 6.9 months (maximum 14.4 months). Subjects with existing implants averaged 15.6 months of PG implant vs 8.9 months for *de novo* implants. Of the 230 implanted subjects, 177 attended the MRI visit and 165 (72%) were scanned (12 did not undergo MRI). One hundred fifty-seven subjects (95%) underwent a complete scan, and 8 had an incomplete scan (3 due to patient discomfort, inability to fit in the scanner, or nausea; 5 due to problems with the scanner or site error/oversight). Analysis between the 165 patients who were scanned and the 65 patients who were withdrawn without scans showed similar baseline demographics/comorbidities, except for a higher incidence of chronic pulmonary disease in nonscanned patients (Supplemental Table 3). Mean time in MRI Protection Mode was 60.1 $\pm$ 16.7 minutes (range 29–84 minutes). Target scan duration range was 28.5–35 minutes based on the defined durations for the scan sequences. Average total duration of the RF-intensive scan sequences was 12.49 $\pm$ 0.67 minutes (range 7.5–16.4 minutes), and average total duration of gradient-intensive scan sequences was 18.61 $\pm$ 1.02 minutes (range 12.83–21.78 minutes).

Primary safety endpoint: MRI scan-related complication-free rate

Of the 230 implanted subjects, 159 were evaluable for the primary safety endpoint. The MRI scan-related complication-free rate through 31 days post-MRI scan was 100% (one-sided 97.5% LCL 100% > performance goal 90%). One unanticipated adverse device event (UADE) occurred in a patient while the device was programmed to MRI Protection Mode (pacing mode off). This patient experienced asystole in the MRI scanner room (zone 4) before entering the MRI bore. Per protocol, the patient had undergone 5 minutes of intrinsic heart rhythm monitoring before the scan and additional monitoring once the device was programmed to MRI Protection Mode, including telemetry-based ECG monitoring. The patient received 2–3 minutes of cardiopulmonary resuscitation until the device was reprogrammed back to pacing mode, and the patient recovered fully. Because the study endpoint of the MRI scan-related complication-free rate was designed to capture complications specifically during the scan procedure after the application of RF and/or magnetic gradients began, this UADE was not included in this study endpoint, although it was reported to the Food and Drug Administration. Its implications for clinical practice are further examined in the Discussion.

Five deaths occurred during follow up, none of which were adjudicated to be MRI related. Three were adjudicated by the Clinical Events Committee as noncardiac (1 designated as "system-related, unknown cause of death"; 2 adjudicated as unknown cause of death, neither MRI nor system related).

Primary effectiveness endpoints: RV and LV lead values

RV lead values

RV threshold/sensing endpoints were analyzed in 146 subjects with paired measurements. The RV PCT success rate occurred in 145 of 146 patients (99%) (95% one-sided LCL 96.8% > performance goal 87%) (Figure 3A). Changes in RV PCT prescan to MRI visit + 1-month follow-up were normally distributed (median 0 V; 80% subjects between –0.1 and 0.1 V) (Figure 3A). One subject had an RV threshold increase of 1.07 V postimplant due to microdislodgment. Lead revision was not undertaken because the implanter elected to manage with monitoring/reprogramming, with no adverse events reported. This patient was not part of the defibrillation testing substudy, and the change in sensed amplitude of 0.57 mV did not meet the protocol definition for failed SA. Of the 146 subjects, 145 (99%) passed the RV sensing endpoint (95% LCL 96.79% > performance goal 85%) (Figure 3B). SA was normally distributed (median 0; 80% subjects between –2.1 and 2.27 mV) (Figure 3B). One patient had a decrease in R wave of –13.23 mV classified as a failure, but the patient felt clinically acceptable and was monitored with a Latitude system with no adverse events. Subanalysis of RV lead measurements by device type showed no difference between CRT-Ds and ICDs (Supplemental Table 4).

Quadripolar LV lead values

One hundred twenty subjects with paired LV threshold measurements were included in the analysis. LV PCT success rate was 100% (120/120 patients; 95% one-sided LCL 97.53% > performance goal 87%) (Figure 3C). Changes in LV PCT were normally distributed (median 0; 80% subjects between –0.23 and 0.27 V) (Figure 3C). Median percent change from prescan to 1 month was 0 V (range –1.27 to 0.77 V; interquartile range –0.13 to 0.08 V). One subject had an LV PCT change of 0.8 V that did not meet the definition of failure, and no adverse events were reported. One hundred eighteen subjects had paired LV sensing measurements with a success rate of 98% (116/118) (95% LCL 94.76% > performance goal 85%) (Figure 3D). Distribution of changes in LV SA is shown in Figure 3D. Values were normally distributed (median 0; 80% subjects between 3.40 and 2.87 mV). Median SA change was 0 mV (range –14.97 to 7.13 mV; interquartile range –1.13 to 0.83 mV). Of the 2 patients who failed the LV sensing endpoint, 1 had an SA change of 14.97 mV. No revision was made to the lead, and the patient was provided with the Latitude remote monitoring system to allow for closer follow-up. No further action was taken, and no adverse events were reported. The second patient had an SA change of 7.63 mV with varying LV amplitude measurements postimplant, but no action was necessary. No adverse events were reported. In no instance did MRI result in an unacceptable increase in LV threshold compared to baseline that resulted in the need to change the programmed LV pacing vector irrespective of the initial programmed pacing vector. Supplemental Table 5 lists programmed LV vectors according to LV pacing cathode and shows no significant difference in terms of PCT, SA, or impedance parameters.

Medically necessary scans

Over the course of the study, 7 subjects needed a medically indicated MRI (2 abdominal, 3 cranial, 2 cardiac scans). The protocol requested clinical sites to follow similar instructions per study-required MRI (programming the device to MRI Protection Mode). Lead measurements were taken before and after medically necessary scans. No actions were taken as a result of these lead measurements, and no adverse events related to scanning were observed.

VF episode detection results

Forty-four subjects were enrolled, 24 underwent an induction that successfully induced VF, and 1 subject had a treated spontaneous VF episode several months post-VF induction. Thirty-two VF episodes were observed in 25 subjects (all 5 subjects with multiple VF episodes had spontaneous termination during first induction with additional successful VF

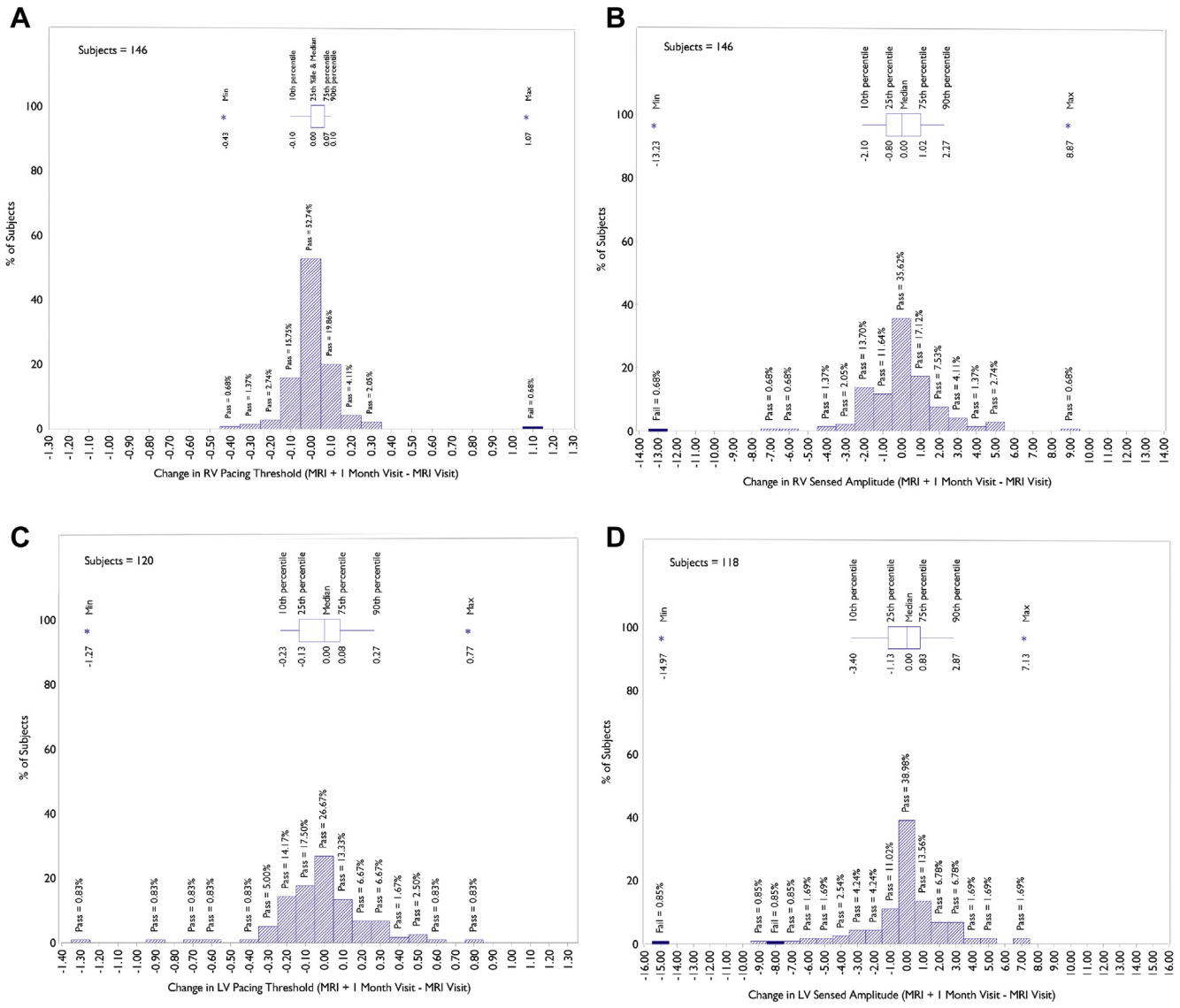

Figure 3 Changes in pacing threshold and sensing parameters between magnetic resonance imaging (MRI) and 1-month post-MRI visit. **A:** Changes in right ventricular (RV) threshold. **B:** Changes in RV sensing. **C:** Changes in left ventricular (LV) threshold. **D:** Changes in LV sensing amplitude. MRI = magnetic resonance imaging.

inductions). All device-detected VF episodes (induced or spontaneous) and all device-detected episodes of nonsustained VF were adjudicated by the ECG core laboratory to be VF, and all were adjudicated for undersensing and detection delay. Supplemental Table 6 summarizes the confirmed VF episode adjudications. For subjects with multiple VF episodes, the episode with the longest detection delay is presented. Therapy was successfully delivered in 100% of subjects, thus confirming the ability to sense and detect VF post-MRI. Expected VF detection time was 2.8 ± 0.2 seconds, and actual detection time was 3.0 ± 0.3 seconds with expected delay of 0.2 ± 0.2 second (range 0.0–0.6 second) (Supplementary Table 7). No subject experienced a clinically meaningful delay in detection (delay >5 seconds) or associated syncope.

Discussion

The ENABLE MRI Study demonstrated the safety and effectiveness of predominantly CRT-D systems after a 1.5-T MRI scan.

1. MRI scan-related complication-free rate through 31 days postscan was 100%, thus demonstrating the effectiveness of the ImageReady MR-Conditional Defibrillation System with stable RV and LV thresholds and sensing.
2. The VF substudy demonstrated the continued ability to sense and detect VF post-MRI.
3. In CRT-Ds with quadripolar LV leads, scanning was safe with no significant change in LV PCT or SA or requirement to change programmed LV pacing vectors, thus suggesting that MRI scanning can be performed without

the need to perform vector reprogramming and without negative impact on the delivery of cardiac resynchronization.

Comparison with previous studies

Previous studies demonstrated the safety and efficacy of MRI scanning in patients with both MRI-conditional and nonconditional systems.[2–4,12] Few publications have reported analysis of MRI in patients with CS LV leads; most evaluated only bipolar LV leads using nonthoracic MRIs. To the best of our knowledge, this is the first study to prospectively evaluate a predominantly CRT-D population (83% of subjects) using CS LV quadripolar leads. Nazarian et al[12] performed a prospective, nonrandomized study assessing 1.5-T MRI safety in 1509 patients with a non–MRI-conditional pacemaker (58%) or ICD (42%) undergoing 2103 clinically necessary thoracic and nonthoracic MRI examinations (pacing mode changed to asynchronous for pacing-dependent patients and demand mode for other patients with tachyarrhythmia functions disabled). Adverse events and changes in lead and generator function and interaction with surrounding tissue (device parameters) were assessed, with no long-term clinically significant adverse events reported. Increases in ventricular capture threshold observed in a small percentage of patients (4%) were not clinically significant and did not require device revision/reprogramming.

The MRI Ready Study, a recent prospective, multicenter study, confirmed the safety and efficacy of MRI scanning in 220 patients with an Ellipse VR ICD (St Jude [Abbott], St Paul, MN) undergoing 1.5-T MRI.[4,12] As in the present study, there were no significant changes in lead capture thresholds and RV sensing 1 month post-MRI. Sheldon et al[6] evaluated 42 MRI scans in 40 patients with CS LV leads. All but 1 patient had bipolar leads; the 1 patient received a St. Jude Quartet quadripolar lead with MRI scan 7 days postimplant. Most patients underwent MRI of the head/neck/spine area, and only 2 patients (5%) underwent a chest MRI. No changes in CS LV lead function were observed pre- and post-MRI. A subset of 13 patients (31%) had evaluation of cardiac biomarkers pre- and post-MRI, with no significant change observed. Whether the single patient with a quadripolar lead or those who had undergone chest MRI were included in this subset was not stated. The recent ProMRI PROVEN study enrolled 194 patients with ICDs or CRTs in Australia, Canada, and Europe.[5] One hundred forty-six patients received study-specific head and lower lumbar MRI scans, including 27 CRT-Ds and 4 CRT-Ps (all incorporating bipolar LV leads). Although the study achieved a 100% MRI-related serious adverse device effect-free rate, there were 3 reports of warming and/or mild pain (1 CRT-P, 2 ICDs) as well as vibration and paresthesia at the device site (1 ICD) during the scan. No adverse effects were observed with the bipolar lead. Although there was little to no change in PCT or SA, the study was underpowered to achieve statistically significant findings, and no patients underwent MRI of the thoracic area.

The current study confirms the findings of the MRI Ready and ProMRI PROVEN studies with no significant change in RV sensing or thresholds post-MRI and importantly extends these findings to CRT-D recipients undergoing scans including the thoracic area. It is the first study to show that MRI scanning has no deleterious effects on LV quadripolar leads, with no patients requiring reprogramming of LV lead vectors. The current study also confirms that VF detection and therapy delivery are not adversely affected by MRI scanning.

The ENABLE MRI Study had a protocol-defined safety endpoint of MRI scan-related complication-free rate to specifically focus on device-related adverse events that occur during the scan itself. The single UADE in this study, in a patient who experienced asystole while in the MR scanner room (zone 4), was not included in the complication-free rate because the event occurred before the scan was initiated. However, its occurrence highlights the importance of patient screening and the need for continued monitoring of patients while they are placed in MRI Protection Mode before, during, and immediately after the MRI scan until reprogramming back to normal device function is completed.

Clinical implications

The current study demonstrated no instance in which MRI resulted in a significant clinical change in LV lead parameters. Likewise, no patients needed LV lead reprogramming with a different pacing vector. This is important, as the LV stimulation site may affect CRT efficacy with avoidance of apical stimulation sites.[11] In the current study, 62% of patients had the LV pacing cathode not programmed from the distal pole, and no cases required programming with a different vector. These results are encouraging, suggesting that 1.5-T MRI can be undertaken without the need for LV lead reprogramming, thus ensuring optimal resynchronization and not adversely affecting battery longevity.

Study limitations

Patients with abandoned leads, lead adapters/extenders, and metallic objects representing an MRI contraindication, and patients with significant bradycardia/AV block were excluded, so we cannot generalize the safety results to these patient groups. Of the 230 implanted patients, 65 (28%) did not undergo scanning and were excluded in the safety and effectiveness results, although baseline demographics did not differ between the scan and no-scan groups. The current study did not evaluate MRI image quality, as this was not a prespecified endpoint of the study. Although there did not seem to be any adverse effect of MRI on LV quadripolar lead programming, the study did not assess CRT response objectively in terms of symptomatic status or remodeling; therefore, we cannot assess the effect of MRI scanning on CRT efficacy although there is no reason to conclude that it would be associated with adverse effects.

Conclusion

The ENABLE MRI Study is the first evaluation of predominantly CRT-Ds with quadripolar LV leads undergoing 1.5-T scans. The study demonstrated scanning was safe, with no significant change in LV PCT or SA, programmed vectors, and VF treatment, suggesting that MRI in patients having a device with quadripolar leads can be performed without a negative impact on CRT delivery.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2020.08.020.

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