Preclinical evaluation of implantable cardioverter-defibrillator developed for magnetic resonance imaging use

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BACKGROUND Many patients with an implantable cardioverter-defibrillator (ICD) have indications for magnetic resonance imaging (MRI). However, MRI is generally contraindicated in ICD patients because of potential risks from hazardous interactions between the MRI and ICD system.

OBJECTIVE The purpose of this study was to use preclinical computer modeling, animal studies, and bench and scanner testing to demonstrate the safety of an ICD system developed for 1.5-T whole-body MRI.

METHODS MRI hazards were assessed and mitigated using multiple approaches: design decisions to increase safety and reliability, modeling and simulation to quantify clinical MRI exposure levels, animal studies to quantify the physiologic effects of MRI exposure, and bench testing to evaluate safety margin.

RESULTS Modeling estimated the incidence of a chronic change in pacing capture threshold >0.5V and 1.0V to be less than 1 in 160,000 and less than 1 in 1,000,000 cases, respectively. Modeling also estimated the incidence of unintended cardiac stimulation to occur in less than 1 in 1,000,000 cases. Animal studies demonstrated no delay in ventricular fibrillation detection and no reduction in ventricular fibrillation amplitude at clinical MRI exposure levels, even with multiple exposures. Bench and scanner testing demonstrated performance and safety against all other MRI-induced hazards.

CONCLUSION A preclinical strategy that includes comprehensive computer modeling, animal studies, and bench and scanner testing predicts that an ICD system developed for the magnetic resonance environment is safe and poses very low risks when exposed to 1.5-T normal operating mode whole-body MRI.

KEYWORDS Hazards; Lead electrode heating; Defibrillator; Implantable cardioverter-defibrillator; Magnetic resonance imaging; Ventricular fibrillation detection

ABBREVIATIONS **CIED** = cardiac implantable electronic device; **DR** = dual-chamber (device); **ICD** = implantable cardioverter-defibrillator; **MR** = magnetic resonance; **MRI** = magnetic resonance imaging; **PCT** = pacing capture threshold; **RF** = radiofrequency; **RV** = right ventricle; **UCS** = unintended cardiac stimulation; **VF** = ventricular fibrillation; **VR** = single-chamber (device)

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Introduction

In recent years, magnetic resonance imaging (MRI) has become the fastest growing technique in diagnostic imaging,[1] and it is the modality of choice for many clinical indications.[2] However, MRI is contraindicated in certain populations because of potential adverse interactions with foreign bodies implanted in patients. One such common contraindication is cardiac implantable electronic devices (CIEDs), including both pacemakers and implantable cardioverter-defibrillators (ICDs). The overlapping demographic resulting from expanding clinical indications for both CIEDs and MRI make safe access to MRI an increasingly common concern. It is estimated that up to 75% of CIED patients are expected to develop an indication for MRI over the life of their device.[3]

This growing interest in MRI compatibility has fostered advancements in design and testing to allow safe access to MRI for patients implanted with select pacemakers under carefully monitored conditions.[4,5] These advancements

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Table 1 Potential MRI hazards for cardiac implantable electronic devices

MRI hazard/clinical impact	Static	Gradient	Radiofrequency energy
Force and torque/patient discomfort, dislodgment	•		
Vibration/patient discomfort, device damage	•	•	
Device interactions/therapy delivery, device reset and/or damage	•	•	•
Device case heating/patient discomfort, tissue necrosis		•	•
Unintended cardiac stimulation/arrhythmia induction, asystole		•	•
Lead electrode heating/therapy delivery, sensing			•

MRI = magnetic resonance imaging.

mitigate the risk of potential adverse interactions between the pacemaker system and MR fields (Table 1). However, MRI is generally contraindicated for ICD patients because of limited safety evidence.[6] ICD patients present additional MR safety concerns compared to pacemaker patients because ICD patients have a history of ventricular arrhythmias and the devices have additional features for arrhythmia detection and treatment. Given the number of variables that impact the safety of MRI scanning in ICD patients (eg, scanner, scan sequence, patient, patient position, lead), a practical clinical trial that leads to valid meaningful conclusions is not feasible. Thus, quantifying and assessing patient risks to minimize these hazards requires a more comprehensive approach.

To address safety concerns and patient need for MRI, an MR conditionally safe ICD system was developed specifically for the purpose of allowing patient access to whole-body MRI under monitored conditions. Development included extensive preclinical testing to ensure patient safety and creation of a programming mode for operation in the MRI environment. The development and preclinical testing, including computer modeling and simulation, animal studies, as well as bench and scanner testing, are presented in this study.

Methods

Preclinical mitigation of MRI hazards included both design decisions during development and experiments during evaluation of the Evera MRI SureScan ICD system (Medtronic Inc, Minneapolis, MN) for whole-body MR scanning at 1.5 T under normal operating mode conditions (maximum whole-body specific absorption rate value of 2 W/kg) and maximum gradient slew rate of 200 T/m/s per axis. The Evera MRI SureScan ICD system is composed of an Evera MRI dual-chamber (DR) or single-chamber (VR) SureScan ICD, Sprint Quattro model 6935M (single-coil) or 6947M (dual-coil) DF-4 right ventricular (RV) defibrillation leads, and any SureScan atrial lead.

To reduce MRI interactions with the ICD system, specific changes were made in the design and materials used in this device. Ferromagnetic content was minimized to reduce force and torque. A hall sensor, rather than a mechanical reed switch, was used for magnet mode to achieve predictable behavior when exposed to magnetic fields.[7] Filters were added to prevent gradient and radiofrequency (RF) energy from coupling onto communication antennas and to reduce tissue heating near the device. Protection circuitry was used to prevent incidental charging of the battery and device damage. No design changes were made to the leads; the 6935M and 6947M leads were identical to the commercially available models originally approved for non-MR use.

For patient safety during MRI, a programming mode called SureScan was developed. In SureScan mode, the device is programmed to a nonsensing mode (asynchronous or disabled pacing) to avoid false detection of electromagnetic noise and potential inappropriate inhibition of bradycardia pacing or competitive pacing . In addition, SureScan mode disables tachyarrhythmia detection to prevent inappropriate antitachycardia pacing or shocks while the patient is in the MRI scanner. Inadvertent tachyarrhythmia detection due to oversensing of electromagnetic noise can result in attempts to charge the defibrillation capacitor and in battery depletion or permanent deactivation of defibrillation therapy.

The preclinical testing and evaluation consisted of 3 major parts: (1) electromagnetic computer modeling and simulations to predict clinically relevant MRI scan conditions, (2) *in vivo* animal studies to measure physiologic response to MRI-induced effects, and (3) bench and scanner testing to confirm system performance per specifications under MRI conditions. Computer modeling was combined with animal study results to quantify the probability of a clinically relevant physiologic effect. Simulation and bench testing exercise the ICD system with regard to precisely controlled clinical and extreme exposure levels. Except for the hazards of force, torque, and vibration, scanner testing is only used to supplement other testing with possible combined field interactions, as the exact RF and gradient exposure levels cannot be controlled. A summary of the approaches used is given in Table 2.

Table 2 MRI hazard evaluation methods

MRI hazard	Bench and scanner testing	Modeling and simulation	Animal studies
Force and torque	•		
Vibration	•		
Device interactions	•	•	
Device case heating	•	•	
Unintended cardiac stimulation	•	•	•
Lead electrode heating	•	•	•

MRI = magnetic resonance imaging.