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LETTER TO THE EDI

MR Imaging in Pat With Pacemakers and O Devices

Engineering the Future

The rapid proliferation of diagnostic and therapeutic modalities using a spectrum of materials and energy sources has led to the potential for interactions that limit or contraindicate the use of magnetic resonance imaging (MRI). This convergence of technologies in patient care due to the frequent use of MRI procedures requires biomedical implant developers to engineer and prospectively study mechanisms to protect against unwanted interactions. The design of a cardiac pacemaker with special attention to the MRI environment represents a paradigm shift in device engineering.

Initial studies of pacemaker/MRI interactions occurred through in vitro experimentation, retrospective case reports, and series of patients with pacemakers accidentally or intentionally placed in the MRI environment (1). Subsequently, prospective studies of carefully monitored patients with pacemakers examined using MRIs under well-defined conditions yielded variable results, as electromagnetic energy conduction can potentially cause tissue damage at the lead tip/endocardial interface, damage to the pulse generator and leads affecting sensing and pacing threshold and impedances, inappropriate pacing acceleration or inhibition, battery depletion, and other issues (1).

Challenges regarding the risks of performing MRI examinations versus the potential benefits to individual patients in situations in which an MRI was essential to patient management (1,2) have led to the first wave of engineering of prospectively designed pacing systems acceptable for use under specific MRI and device conditions (3,4). A "magnetic resonance [MR]-conditional" item is defined as posing no known hazards in a specified MRI environment with specified conditions of use; an "MR-safe" item as posing no known hazards in all MRI environments; and an "MR-unsafe" item as posing hazards in all MRI environments (5).

Currently, there is only 1 published prospective, randomized multicenter study assessing the efficacy and safety of a pacing system engineered to be MR conditional (3). Pulse generator design changes included: 1) reducing ferromagnetic content to minimize magnetic field interactions and to avoid damage or malfunction of components; 2) shielding to minimize the effect of the electromagnetic environments; and 3) changing the reed switch to a Hall sensor, which allows for predictable behavior in a magnetic field. The lead wire winding pattern was designed to minimize potential heating of the pacing system and cardiac tissue due to conduction of electrical impulses from time-varying magnetic fields and radiofrequency energy from the MR scanner to the pacing lead. Dedicated programming modes include

Table 1. Study Factors for the MR-Conditional Pacemaker Available in the United States (Revo MRI SureScan Pacing System [Medtronic, Inc., Minneapolis, Minnesota]) (3)

MR system	Horizontal, cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5-T must be used.
Gradient magnetic fields	Gradient systems with maximum gradient slew rate performance per axis of ≤200-T/m/s must be used.
RF energy/SAR	Scanner in normal operating mode: Whole body–averaged SAR as reported by the MRI equipment of ≤2.0 W/kg. The head SAR must be <3.2 W/kg.
Patient screening	Patients and their implanted systems screened to meet the following requirements: The implanted system consisted solely of a SureScan device and SureScan leads. Any other combination may result in a hazard to the patient during MRI scans. No previously implanted (active or abandoned) medical devices, leads, lead extenders, or lead adaptors. No broken leads or leads with intermittent electrical contact as confirmed by using lead impedance history. A SureScan pacing system implanted for a minimum of 6 weeks. A SureScan pacing system implanted in the left or right pectoral region. Pacing capture threshold values ≤2.0 V at a pulse width of 0.4 ms. A lead impedance value ≥200 Ω and ≤1,500 Ω. No diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose devices were programmed to an asynchronous pacing mode when MRI SureScan is on.
Patient positioning	The patient positioned within the bore such that the isocenter (center of the MRI bore) is superior to the C1 vertebra or inferior to the T12 vertebra.
Patient monitoring	Proper patient monitoring during the MRI scan. The methods included visual and verbal contact with the patient, electrocardiography, and pulse oximetry (or plethysmography).
Pacemaker staff	A healthcare professional with completed cardiology SureScan training present during the programming of the SureScan feature.
Imaging staff	A healthcare professional with completed radiology SureScan training present during the MRI scan.
Results	Patients with the MR-conditional pacemaker underwent MRI (N = 226). Through 1-month follow-up compared with controls: No reported arrhythmias (asystole, sustained ventricular arrhythmias, or unexpected changes in heart rate), electrical reset, inhibition of generator output, or sensations (related to magnetic field interactions or pain). No significant changes in pacing parameters (sensing, threshold, or impedance change) compared with controls.

MR = magnetic resonance; MRI = magnetic resonance imaging; RF = radiofrequency; SAR = specific absorption rate.

asynchronous (5.0 V/1.0 ms) pacing and nonstimulation choices. Labeling to identify the device and components as MR conditional include radio-opaque markings on the pulse generator, leads with a unique radio-opaque indicator, and identification cards with an MR-conditional icon and information. Study conditions and results are listed in Table 1. Importantly, no significant complications were observed in this study. Further post-marketing data will help define potential issues with application to larger groups of patient in other clinical settings.

Three medical device companies (Biotronik, Berlin, Germany; Medtronic, Inc., Minneapolis, Minnesota; and St. Jude Medical, St. Paul, Minnesota) have MR-conditional cardiac pacemakers available in Europe and other countries. In the United States, the U.S. Food and Drug Administration approved the Revo MRI SureScan Pacing System (Medtronic, Inc.). Because the leads and pulse generator technology were specifically designed for use in 1 integrated system, these systems are not indicated for generator changes using pre-existing leads or situations in which abandoned leads are still present in the patient. Currently, in the United States, the Medtronic, Inc. system has scan-positioning limitations (landmark isocenter of radiofrequency coil superior to C1 or inferior to T12), whereas in Europe, MR-conditional pacemaker isocenter conditions include: Medtronic (no scan exclusion zone), St. Jude Medical (contraindication to use of transmit radiofrequency coil directly over the pacing system) and Biotronik (scan exclusion zone with the maximum allowed positioning mark for the isocenter starting from the foot at the hip level and the maximum allowed positioning mark for the isocenter from the top of the skull at the level of the eyes). Because there are no specific guidelines regarding scanning beyond the specified limitations of an individual MR-conditional device, reliance on the current literature and the guidance of institutional review bodies regarding the risks and benefits in these situations are important considerations (1,2).

The spectrum of electronically activated biomedical devices with potential MRI interactions has significantly increased and includes implantable cardioverter-defibrillators, resynchronization devices, loop memory recorders, implantable physiological measurement devices, and neuromodulation devices. Similar design, engineering, and prospective testing will be required for these devices relative to use in patients undergoing MRI procedures.

The current MR-conditional pacemakers provide an important step in device engineering, allowing patients to have greater access to what is considered to be one of the most important noninvasive diagnostic imaging procedures: the MRI. Future questions relate to how to safely and cost-effectively engineer, evaluate, and implement new MR-conditional systems (Table 2). A continued multidisciplinary approach directed toward understanding the interface of medical devices, diagnostic imaging studies, therapeutic procedures, and environmental energy exposures is required to prevent or minimize adverse interactions related to the convergence of these technologies.

Table 2. Future Goals for Development and Evaluation of MR-Conditional Cardiac Devices

Development of:
Cardiac devices and configurations in addition to single- and dual-chamber pacemakers for MR-conditional use.
MR scanner technologies and imaging sequences to further prevent interactions with devices.
Alternative imaging modalities for indications in which MRI is currently the gold standard.
Educational modules on the specific conditions for each device as they are approved.
Multidisciplinary algorithms for the MRI facility for safety and efficiency of imaging patients with cardiac and other devices.
Algorithms for assessing acute to subacute MRI needs before device placement if MRI may limit the ability to perform these studies after device placement.
Research evaluation of:
Use of MR-conditional cardiac devices with other clinically relevant static magnetic field strengths (e.g., 3-T MR systems).
Further assessment of isocenter limitations related to chest/cardiac imaging safety issues and MRI artifacts.
MR-conditional device platforms versus standard device platforms, assessing:
Utility of MR-conditional platforms in specific situations or patient populations versus use as standard cardiac pacemaker platforms.
Cost-effectiveness of MR-conditional platforms versus standard cardiac pacemaker platforms.
Use of MR-conditional cardiac devices with interventional and cardiac electrophysiology laboratory MRI real-time imaging systems for procedural guidance.

Abbreviations as in Table 1.

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