“MR-Conditional” Pacemakers: The Radiologist’s Role in Multidisciplinary Management

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OBJECTIVE. The recent approval of an “MR-conditional” pacemaker system by the U.S. Food and Drug Administration allows patients with that pacemaker system to undergo MRI examinations within specific conditions. These examinations must be attended by radiology health care professionals with training for the use of the pacemaker system.

CONCLUSION. Radiologists should be knowledgeable of the specific limitations with regard to patient isocenter and coil positioning within the required 1.5-T MR system and the importance that the pacer be programmed before and after scanning.

Approximately 50–75% of the more than 1.5 million patients with implanted cardiac devices may have indications for MRI during the course of the use of these devices [1]. At least 15 carefully planned and monitored trials that included 1419 participant encounters have successfully completed MRI examinations of patients since 2007 with cardiac pacemakers [2]. There have been 17 deaths apparently associated with unmonitored MRI examinations of such patients [2, 3]. Perhaps related to these risks, one survey showed that 97% of radiologists decline to perform MRI examinations of patients with cardiac devices [4].

Recently, the Medtronic EnRhythm MRI SureScan Pacing System Trial resulted in no MRI-related arrhythmias, pacemaker inhibition or output failures, electrical resets, or other pacemaker malfunctions during or after scanning at 1.5 T [5, 6].

Three medical device companies (Biotronik, Berlin, Germany; Medtronic, Inc., Minneapolis, MN; St. Jude Medical, St. Paul, MN) now have MR conditional cardiac pacemakers available and approved for use in Europe [7, 8]. Note that the term, “MR conditional” is used to describe an item that has been shown to pose no known hazards in a specified MR environment with specified conditions of use. The field conditions that define the MR environment include static magnetic field strength, spatial gradient magnetic field, time rate of change of the magnetic field (expressed as dB / dt), radiofrequency fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system) may be required [9].

As a result of the success of the Revo MRI SureScan Pacing System (Medtronic) trial, on February 8, 2011, the U.S. Food and Drug Administration approved the Revo MRI Pacemaker System with 5086 MRI CapSureFix MRI Pacing Leads (Medtronic) and the SureScan Software (Medtronic) as “MR conditional” [10]. Notably, the Revo MRI SureScan System was specifically designed to maximally eliminate ferromagnetic content and mechanical force effects; maximize generator electrical circuitry magnetic and radiofrequency energy shielding; limit the transference of radiofrequency energy into heat or electrical stimulation at the leads; and offer battery-programming modes to minimize device malfunction in the MRI environment [5, 6].

With the approval of the Revo and other MR-conditional cardiac pacemakers likely to follow, radiology health care professionals will be required to participate in the care and scanning of patients with these devices. The first task is to consult with the requesting physician and pacemaker patient to ensure that there is no appropriate diagnostic alternative to MRI. On agreeing that MRI is required, radiography can help to confirm that the implanted pacemaker system is labeled for MRI (Fig. 1); that the pulse generator is properly implanted over the right or left...
The patient’s cardiologist responsible for the MR-conditional pacemaker must then confirm the pacemaker history and pacemaker system model using the appropriate programmer. Next, the pacemaker will be examined to verify appropriate thresholds of ≤ 2.0 V at a pulse width of 0.4 msec without diaphragmatic pacing at 5.0 V and 1.0 ms and impedance of between 200 Ω and 1500 Ω [11]. The patient is then scheduled to undergo scanning at an MRI facility prepared to properly manage the MR-conditional pacemaker. Before the patient enters the MR system, a health care professional with cardiology Revo MRI SureScan training will reexamine the pacemaker and if the specifications described are achieved, the pacemaker is set to the SureScan “on” mode [11]. A health care professional with radiology SureScan training must be present to supervise the MRI procedure [11].

The patient is prepared for the MRI procedure, which includes utilizing appropriate monitoring techniques (e.g., MR-conditional monitors may include pulse oximetry, ECG, and other appropriate means of performing physiologic monitoring) before the patient enters the 1.5-T MR system. For MRI of the brain, head, or neck, the supine patient enters the scanner head first, with the MR system’s isocenter located superior to the C1 level. For imaging of the lower thoracic and lumbar spine, pelvis, and lower extremity, the patient enters feet first with the magnet isocenter positioned superior to the T12 vertebra. Importantly, the body radiofrequency coil should not be positioned over the cardiac pacing system [11].

These MR-conditional procedures must be performed only at 1.5 T. The maximum gradient slew rate should be 200 T/m/s per axis or less with the scanner in the so-called “normal operating mode”; the normal operating mode is defined as the mode of operation of the MR system in which none of the outputs has a value that causes physiologic stress to the patient. The whole-body–averaged SAR reported by the MR system must be ≤ 2.0 W/kg, with head SAR at < 3.2 W/kg [11].

On completion of the MRI examination, the pacemaker professional resets the pulse generator to the SureScan “off” mode and reexamines the pacemaker to confirm normal function. The stipulations stated in the labeling for this cardiac pacing system with regard to the landmark sites essentially limit MRI examinations of these patients to anatomic areas that include the brain, skull base, upper neck and cervical spine, thoracolumbar spine, mid and lower abdomen, pelvis, and lower extremities. The hand, wrist, and elbow may be imaged with the arm held over the head. In addition, magnetic susceptibility artifacts are expected in proximity to this cardiac pacing system.

Although MR-conditional pacemakers are designed to better withstand static and time-varying magnetic fields as well as radiofrequency radiation, there are risks associated with entry into the MR system to patients who have not had their devices adjusted for the MRI environment. It is very possible that a number of patients and physicians will assume that such devices are acceptable for routine MRI procedures. Indeed, public news and even medical journals may add to this illusion. For example, in the Medical News and Perspectives section of a recent issue of JAMA, an article titled “First MRI-Safe Pacemaker Receives Conditional Approval From FDA” [12] was presented. The text of this article appropriately describes the basis for the MR-conditional approval of this device but goes on to state that “…that the MRI-safe pacemaker will not be appropriate for every patient being considered for a pacemaker…” [12]. Unfortunately, alongside the JAMA article [12] is a stock photograph of a patient with the apparent pacemaker level at magnet isocenter covered by an array body radiofrequency coil.

It is reasonable for all MRI providers to adjust their policies and procedures to either appropriately scan or decline to scan patients with MR-conditional pacemakers. MRI technologists and facility schedulers should be advised that such patients may have requests for MRI examinations and that appointments for such examinations require prior notification of and approval by a knowledgeable radiologist insofar as the necessary preparations must be in place to properly handle these patients. The device numbers and configuration, as well as the absence of abandoned leads will need to be confirmed. Health care professionals representing cardiology and radiology who have successfully undergone training for the Revo MRI SureScan System will be required to attend the MRI procedure to ensure proper device characteristics and to set the device to scanning mode “on” before and “off” on completion of the MRI examination. The MRI examination should be scheduled only for a 1.5-T cylindrical MR system. MR-conditional pacemakers have not been clinically tested at higher or lower field strengths or with nonhorizontal magnet configurations.

The importance of appropriate MR-conditional pacemaker management cannot be overstated. During the period of time that the pulse generator is set to the scanning mode “on,” patients with a greater degree of pacemaker dependence may present a greater risk of adverse outcome in the event of device malfunction or failure to reset the scanning mode to “off.” It is interesting that of the published 1419 pacemaker participant MRI encounters, only 26 participants were...
MRI of Patients With MR-Conditional Pacemakers

Pacemaker dependency was not recorded with the Medtronic EnRhythm Revo pacemaker study [6], 16 of the 258 participants (6%) had no ventricular intrinsic rhythm before scanning [5, 6]. There are no specific recommendations regarding scanning procedures for pacemaker-dependent patients with MR-conditional devices. Nondependent patients generally have their pulse generators set to the “OOO” (sensing) mode, whereas pacemaker-dependent patients typically have their pulse generators set to a “DOO” or “VOO” (asynchronous pacing, no sense, no inhibitions) asynchronous mode.

The definition of “pacemaker dependence” is challenging because predicting the reliability of an underlying rhythm in a patient with a pacemaker is unknown; therefore, careful monitoring must occur while the patient’s pacemaker is programmed in an OOO mode. Additionally, pacemaker-dependent patients whose pacemakers are inadvertently left in asynchronous modes are at a greater risk for serious complications, including ventricular arrhythmias and ventricular fibrillation [11], due to potential R-on-T phenomenon. Reprogramming should occur immediately after scanning while the patient is still on a cardiac monitor.

The introduction of MR-conditional cardiac devices enables the vital diagnostic capabilities provided by MRI to be available to a new group of previously denied patients. The safe use of this new device technology will require conscientious system-based care delivered by requesting physicians, cardiologists, MRI managers, MRI technologists, and radiologists.

References
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