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RE: Guidelines for MRI in Patients with Cardiac Pacemakers and/or Implantable Cardioverter-Defibrillators

From: MRI Safety Pacemaker Subcommittee - Karl Vigen, PhD (chair); Aaron Field, MD, PhD; Kurt Hoffmayer, MD; Frank Korosec, PhD; Tom McKinlay, RT; Scott Reeder, MD, PhD; Meredith Welty, RT

Background: Historically, MRI of patients with cardiac pacemakers or implanted cardioverter-defibrillator (ICD) devices has been strictly contraindicated. With the increasing prevalence of implantable devices and the increasing utility and availability of MRI, there are many occasions where there is a great medical need to perform MRI in patients with an implanted cardiac device. As a result, two developments have led to the development of these guidelines for scanning patients with cardiac pacemakers/ICDs.

First, there are now several pacemakers that are FDA approved for use with MRI (MRI conditional) when used according to specific guidelines. Second, there is a substantial and growing body of evidence that patients with many devices not FDA-approved for MRI can be scanned safely under certain conditions. The purpose of this document is to outline specific guidelines and circumstances in which patients can be scanned if they have a pacemaker or ICD.

Consideration should always be given to the availability of an alternative diagnostic method, such as CT, ultrasound, or nuclear scintigraphy, even when the patient has a device approved by the FDA for MRI. However, for patients with an FDA-approved device, and when MRI is considered to the best study to answer the clinical question, it is appropriate to perform the MRI exam. MRI can be performed safely so long as the manufacturer-specified scanning guidelines are followed. There are three approved pacemakers on the market in the United States (Revo/Advisa, Medtronic; Entovis, Biotronik). Devices from other manufacturers are expected in the near future. Guidelines for scanning patients with approved devices are detailed below. Informed consent is not required for approved devices. If an approved device must be scanned with parameters that fall outside manufacturer guidelines, it will be treated as if it is a non-approved device.

MRI remains a relative contraindication in patients with devices that have not been approved by the FDA for MRI, and these patients should only be scanned as a measure of last resort, when all other avenues have been exhausted, including invasive diagnostic procedures such as catheter-based angiography. Although there is a large body of evidence suggesting that scanning patients with non-approved devices can be performed safely, the risks are not well understood. Scanning of patients with non-approved devices as a matter of convenience or to avoid radiation from other imaging modalities is not acceptable. The decision to perform an MRI in a patient with a non-approved device requires a discussion between the patient’s attending physician and the attending radiologist responsible for the imaging study. Criteria and guidelines for scanning patients with non-approved devices are detailed below. If a patient does not meet inclusion criteria, the MRI cannot be obtained. Informed consent is mandatory when scanning patients with non-approved devices. A dedicated consent form has been developed for scanning these patients, outlining potential risks specific to MRI scanning with a non-approved device.

A powerscribe template has been developed to document important information that details that the patient was scanned according to department guidelines. It is important to document this information for safety reasons (should the patient return with problems possibly related to MRI scanning), as well as billing reasons since some insurance does not reimburse for non-approved devices, but will for approved devices.

Scanning of patients with any device (approved or non-approved) must be performed with an electrophysiology device nurse present for the duration of the exam. When scanning patients with non-approved devices, an ACLS certified cardiologist must be near the MRI scanner (i.e. within 2 minutes). A physician need not be present when scanning a patient with an approved device.

Finally, no subjects with either approved or non-approved pacemakers will be imaged as part of any MRI research protocol, unless the research protocol specifically addresses all safety concerns within the IRB protocol itself.
Procedure for Scanning Patients with Approved Pacemaker Devices:

Revo™ & Advisa™ MRI Pacing Systems
Engineered with SureScan® Technology

CHECKLIST FOR RADIOLOGY

MRI Procedure Requirements (Initial when completed/confirmed)

1. Patient pre-screening requirements
   - Only patients with a complete Revo or Advisa MRI SureScan Pacing System (consisting of a Revo/Advisa MRI SureScan IPG and two CapSureFix MRI™ SureScan leads) can undergo an MRI procedure. Check at least ONE below:
     1. Use the patient ID card to identify the device and leads implanted.
     2. Perform a screening X-Ray (mandatory if not UW-implanted).
     3. Call Medtronic at 1 (877) MRI-7677 to verify the patient’s pacing system.
     4. Check patient chart to verify complete Revo/Advisa MRI system implanted.
   - Confirm that the patient does not have any other previously implanted (active or abandoned) medical devices, leads, lead extenders, or lead adaptors.

2. Pre-scan pacemaker programming requirements
   - Cardiology personnel must be notified for SureScan programming and clearance.
   - Confirm SureScan is programmed On prior to the MRI procedure (see sample device programming on back).

3. MRI procedure protocols
   - A Radiology MRI nurse must screen the patient; in addition, at the present time, a MRI physicist must be present during the MRI examination.
   - Horizontal cylindrical bore magnet MRI system of 1.5 Tesla must be used (UWMR2, UWMR3, or UWMR4 only).
     (Only gradient systems with maximum gradient slew rate performance per axis of ≤ 200 T/m per second (7/T/m/s) are currently used at UW-Madison.)
   - Whole body averaged SAR must be ≤ 2W/kg, head averaged SAR < 3.2W/kg.
     Scanner must be in “Normal Operating Mode”.
     (Isocenter positioning restrictions were removed December 2013 by the FDA.)
   - During the MRI procedure, patient must be continuously monitored, including the following methods: visual and verbal contact with the patient, and pulse oximetry or electrocardiography. An external defibrillator must be available nearby during the MRI procedure.

4. Post-scan pacemaker programming requirements
   - Cardiology personnel (EP nurse or Cardiology fellow) notified to program patient’s device back to previous settings.
   - Initial when Cardiology completes device reprogramming.

For complete MRI Conditions for Use, operating and programming guidelines and restrictions, refer to the SureScan Pacing System Reference Manual, call 1 (877) MRI-7677, or visit www.medtronic.com/MRI.
Guidelines for Scanning Patients with Non-FDA Approved Pacemaker Devices:

1. Pacemaker or ICD must be manufactured 1998 or later (PM), or 2000 or later (ICD).
   a. Screening is performed by Device Clinic Nurse Electrophysiology (EP) fellow or EP attending.
   b. Pacer-dependent patients (both PM and ICD) are not eligible.
   c. Epicardial pacing systems are not eligible.
   d. Patients with a coronary sinus lead are not eligible.
   e. Patients with abandoned leads are not eligible (this can be confirmed by review of operative report and chest radiography or chest CT).
   f. Avoid patients < 6 weeks post-implant, or with suboptimal pacing parameters (as determined by the electrophysiologist).

2. Risk-Benefit relationship must be discussed, in-person or via phone-call, between the attending faculty radiologist and the referring physician.
   a. Alternative imaging modalities (e.g. CT, US) must be considered.
   b. Care should be taken that the referring physician is not pursuing alternatives such as explanting the pacemaker, or replacing with an MRI-compatible model; such procedures likely have higher risk.
   c. Imaging of patients with non-FDA approved devices is only available weekdays (8am-4pm) at the Clinical Science Center of UWHC, due to staff availability.
   d. The decision regarding whether MRI will be performed must be made by a Radiology faculty member only (i.e. no residents or fellows).
   e. A discussion (including informed consent) must occur between the patient or designated health care proxy, and the EP fellow or attending, and Radiology fellow or attending.

3. If an MRI procedure is deemed absolutely necessary, the MRI scan must be performed as follows:
   a. MRI on a 1.5T MRI system; Clinical Science Center only.
   b. MRI system set to “Normal Operating Mode” for dB/dt and SAR (<2.0 W/kg body, <3.2 W/kg head).
   c. Record baseline device settings.
   d. Set pacing device to appropriate setting:
      i. Non-pacing dependent ICD: DDI or VVI
      ii. Non-pacing dependent PM: DDI or VVI
   e. The following personnel must be present, including at least one ACLS-trained staff member.
      i. Radiology Nurse.
      ii. Clinical MRI Physicist.
      iii. A Device Clinic Nurse and an EP fellow or EP attending (i.e. must be ACLS trained and familiar with device reprogramming) must be present for the duration of the scan. The EP fellow or attending may cover for the Device Clinic Nurse if one is not available.
      iv. Attending cardiologist and radiologist must be aware and in close proximity.
   f. The patient’s blood pressure, ECG, and pulse-oximetry will be monitored throughout the study.

4. Following the MRI scan, pacemaker must be reset to pre-MRI settings, and interrogated for any sensing or other parameter changes.
   a. If changes occur, follow-up in device clinic within 1 week, at 3 mos and at 6 mos.

5. If no changes, follow-up in device clinic at 1 month (all patients).
Appendix:

The Use of Conventional Pacemakers and ICDs in the MRI Environment – UW-Madison Review 2013

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In recent years, the rate at which cardiac devices such as pacemakers (PM) and implantable cardioverter-defibrillators (ICDs) are being implanted into patients has continued to increase. Patients with these devices will often need an imaging study at some point in their lives, and MRI has traditionally been strictly contraindicated due to the potential for device malfunction and lead heating due to exposure to the magnetic field gradients and RF fields used in MRI. To address the issue, device companies have begun to introduce MRI-compatible pacemakers. Two pacemakers from Medtronic are currently FDA-approved, with several more approved in Europe; and pacemakers from other manufacturers are now in the approval process. However, patients implanted with traditional pacemakers and ICDs may develop conditions that require MRI scans. Removal of the device and leads, and possible replacement with MRI-compatible devices is often contemplated, but the required surgery and lead extraction carries its own risks. As an alternative, many investigators have looked at the effects of MRI imaging on conventional pacemakers and ICDs.

Possible effects of the MRI system on pacemakers and ICD’s is summarized in a recent review by Shinbane et al. (1). Primarily, these effects include magnetic force on the device itself, or on the magnetically-activated reed switch; malfunction due to RF interference with electronic components of the device; and the induction of current in the device leads, which could lead to heating at the implanted lead tips. This last effect, in addition to tissue destruction, could cause adverse effects on measured lead impedance, sensing, and pacing capture thresholds. An accurate estimate of the rate of adverse events can be difficult to obtain; one review attributed 17 deaths worldwide after inadvertent MRI imaging of cardiac devices without patient monitoring and none with appropriate patient monitoring (2), but no sources were cited and subsequent discussion by Kanal and Gimbel questioned what role MRI actually played in the events (3) compared with other disease-related causes. Specific studies in the literature reporting adverse events are difficult to find. One case study reported reversible asystole during head imaging at 3T (4); another reported inappropriate sensing malfunction of an ICD (which inappropriately was not disabled) and increased pacing threshold (5).

Despite the risk of adverse events, for patients that require an MRI scan, a scan following the proper precautions is likely to be safer than alternatives such as removing or replacing a non-MRI compatible device. As noted by Russo (6), the REPLACE study documented a six-month major complication rate in patients undergoing pacemaker or ICD replacement of 4% for those requiring only a device replacement and 15% for those requiring the replacement of a lead as well (7); the FDA MAUDE database reported 105 events from lead extractions between 2007-2008; and other studies have reported a 0.4% to 2% rate of major complications after lead extractions.

The review by Shinbane et al. (1) compiled data from studies documenting MRI scans performed in patients with implanted, non-MRI compatible-labeled devices, published up to 2011. In 37 studies, ranging from case reports of a single patient being scanned, to large prospective trials with up to 171 scans, a total of 832 (723 PM, 109 ICD) patients with either pacemakers or ICD’s were reported to have undergone a total of 1098 MRI sessions. No serious adverse events appeared to have occurred, although changes in certain pacing...
parameters (i.e. small changes in pacing capture threshold, lead impedance, reprogramming of device) occurred in a number of patients. Seven studies published since then, including a significant trial from the Hopkins group (8), include 768 (PM 502, ICD 266) patients with 972 MRI examinations, with no apparent serious adverse events (8-14).

A large multicenter, prospective clinical trial called MagnaSafe (6) was begun in 2009, with the goal of enrolling 1500 patients with either programmable pacemakers or ICD’s for non-thoracic MRI. Preliminary results from 19 sites (15) included imaging 881 patients with pacemakers and 308 with ICDs for a total of 1189 imaging examinations. Significantly, "no deaths, device failures, generator/lead replacements, ventricular arrhythmias, or losses of capture during non-thoracic MRI at 1.5T" were demonstrated. (Similar to previous studies, potentially clinically-relevant effects such as changes in battery voltage, pacing threshold, and small R-wave amplitude changes were seen in 11% of pacemaker and 26% of ICD cases.)

In all, in 45 published studies found, a total of 2789 patients (2106 PM, 683 ICD) underwent 3259 MRI studies. Most cases seemed to be strictly monitored with ACLS-trained personnel present, with an electrophysiologist available to reprogram the device if necessary. Other than occasional small changes to some detected pacing parameters (lead impedance, pacing thresholds, etc.), which did not seem to concern most study authors who mentioned them (i.e. did not lead to device or lead replacement); battery drainage and/or inaccurate event detection in a few ICD cases; and a few power-on-reset pacing inhibition that could be fixed by reprogramming after the scan, there seemed to be no serious adverse events reported in these studies.

For imaging patients with implanted devices (pacemakers and ICDs), each study typically defines its own inclusion criteria and study workflow. Most studies follow some variation of the following steps.

- Determination of the risk/benefit ratio; and appropriateness of other non-MRI imaging modalities.
- Discussion with patient, and likely informed consent obtained.
- Scanning at 1.5T only, with lowest reasonable SAR (i.e. <2.0 W/kg).
- Presence of adequate support staff, including ACLS-trained staff, backup pacing if needed, and an electrophysiologist available for device reprogramming.
- Programming of the pacemaker to a state suitable for the patient during the MRI exam (i.e. asynchronous pacing mode for pacemaker-dependent patients).
- Monitoring the patient throughout the scan.
- Interrogation and, if necessary, reprogramming of the device following the MRI exam.
- Follow-up, for example, at 3- or 6-months to determine device status.

Two widely-used protocols are reproduced in Figures 1 and 2. The protocol reproduced in Figure 1 is from the group at Johns Hopkins University (8,16); the one in Figure 2 is from the MagnaSafe trial. In both protocols, patients with ICDs who are pacemaker dependent are excluded (it seems since most if not all ICDs do not have an asynchronous mode); otherwise, ICD patients who are not pacemaker dependent, and both types of pacemaker patients are included. Also, the Hopkins protocol excludes patients whose device was implanted before 1998 (pacemakers) or 2000 (ICDs), as the devices produced after these dates are regarded to be more EM resistant.
References:

Figure 1: Johns Hopkins protocol for MRI of patients with pacemakers and ICDs; from Nazarian et al. (8).
Figure 2: Protocol for MRI of a patient enrolled in the MagnaSafe study; reproduced from Russo (6).