MRI in Patients with Cardiac Pacemakers

What You Need to Know

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Disclosures

• Materials for this presentation were provided by Medtronic
• Consultant for Boston Scientific
MRI: Three Powerful Fields

- Static Field
- Gradient Field
- RF Field
Multiple Potential Interactions

Static

Gradient

RF

Case Heating

Force & Torque

Vibration

Device Interactions

Lead Heating

Stimulation
Unpredictable Device Behavior

Unexpected asystole during 3T magnetic resonance imaging of a pacemaker-dependent patient with a ‘modern’ pacemaker

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Europace vol. 11
no. 9 Sept 2009 pp
1241-1242
doi:10.1093/europace/eupp162
Lead Tip Heating

- PCT is lowest at implant
- Healing produces scar
- Increased distance increases PCT

- Significant heating causes tissue damage
- Increased scar volume increases PCT
Stimulation Clinical Impact

MRI Gradient Induced – High Rate Pacing

The MRI scanner is pacing the heart
Hazards and Risks are Real

A 2-second pause was noted…

…diminished battery voltage was noted immediately after MRI…

Significant changes were reported in 9.4% of leads… 1.9% required a change in programmed output.

…increased capture threshold was noted post MRI.

Nazarian S. Heart Rhythm, Vol 6, No 1, January 2009
From 1995-2005 there were only 389 reports of MR safety incidents to FDA’s Manufacturer and User Facility Device Experience database
- 9 deaths (mostly pacemakers and insulin pumps)
Clear FDA Position

"…the removal of the warnings and contraindications for MRI use with pacemaker or ICD patients will require thorough characterization of the array of safety concerns. This may necessitate bench and animal studies designed to elucidate the underlying mechanisms associated with the potential risks so that they may be better understood and avoided. Device modification may be necessary to mitigate particular concerns, which could result in model-specific MRI recommendations."

Faris OP and Shein MJ, PACE April 2005
Unexpected programming changes, inhibition of pacemaker output, failure to pace, transient asynchronous pacing, rapid cardiac pacing, the induction of ventricular fibrillation, heating of the tissue adjacent to the pacing or ICD system, early battery depletion, and outright device failure requiring replacement may all occur during MRI of patients with pacemakers or ICDs.

ACR Guidance Document 2007

Patients who have a pacemaker or ICD should not undergo an MR study if an alternative diagnostic test is available, and MR imaging should only be considered in cases in which the potential benefit to the patient clearly outweighs the risks to the patient.

AHA Scientific Statement 2007
Growing Need for Pacemaker Patients

Overlapping Demographics

• > 65y 2x as likely to require MRI*

• 80% pacemaker patients > 65y
Prevalence of Common Comorbidities

Common Comorbidities, many of which rely on MRI, increase rapidly over age 65.
HANDS ON

How to perform magnetic resonance imaging on patients with implantable cardiac arrhythmia devices

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Introduction
Magnetic resonance imaging (MRI) offers unrivaled soft tissue resolution and multiplanar imaging capabilities. Cardiac MRI is capable of accurate characterization of cardiac function and is uniquely capable of identifying scar fibrosis and fat deposition, thus making it an ideal imaging modality for the evaluation of patients presenting with arrhythmia. In addition, the absence of x-ray radiation makes MRI suitable for follow-up of chronic disease and for imaging in young patients and women of childbearing age. Due to the ever expanding indications for implantation of permanent pacemakers and implantable cardioverter-defibrillators (ICDs), advancing severity of disease and age of the population, and advances in device technology, the number of patients with implantable cardiac devices will continue to increase. It has been estimated that each patient with a pacemaker or ICD strength, the ferromagnetic properties of the device, the implant distance from the magnet bore, and the stability of the implant. In our in vitro analysis of modern permanent pacemakers (manufactured after 1996) and ICDs (manufactured after 2000), we found that the maximal force acting upon devices was less than 100 g in a 1.5-T MRI scanner. This amount of force is unlikely to dislodge a chronic device that is anchored to the surrounding tissue. However, this observation led to our adaptation of a 6-week waiting period prior to MRI after device implantation.

Current induction. The radiofrequency and pulsed gradient magnetic fields in the MRI environment may induce electrical currents in leads within the field. Lead length (vs radiofrequency wavelength) and conformations such as loops favor improved transition of energy to the implanted device. This may result in increased lead temperatures and the potential for lead failures. Longer leads are likely to be more susceptible to such an effect. The radiofrequency electromagnetic field in the MRI environment may result in increased lead temperatures.
SUBJECT: Final Decision Memorandum of Magnetic Resonance Imaging

DATE: February 24, 2011

I. Final Decision:

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is not adequate to conclude that the use of magnetic resonance imaging (MRI) improves health outcomes for Medicare beneficiaries with implanted permanent pacemakers (PMs) or implantable cardioverter defibrillators (ICDs), and thus we determine that it is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act). Therefore, subject to one exception, we will retain the current general contraindications at Chapter 1, Section 220.2.C.1 in the NCD Manual.

CMS believes that the evidence is promising although not yet convincing that MRI will improve patient health outcomes if certain safeguards are in place to ensure that the exposure of the device to an MRI environment adversely affects neither the interpretation of the MRI result nor the proper functioning of the implanted device itself. We believe that specific precautions (listed below) could maximize benefits of MRI exposure for beneficiaries enrolled in clinical studies designed to assess the utility and safety of MRI exposure. Therefore, CMS determines that MRI will be covered by Medicare when studied in a clinical study under § 1862(a)(1)(E) (consistent with § 1142 of the Act) if the study meets the criteria in each of the three paragraphs below.
Designed for Use in MRI

- Revo MRI SureScan Pacing System
  - Revo MRI Pacemaker
  - 5086 MRI CapSureFix MRI™ Pacing Lead
  - SureScan Software

- MR Conditional
The language in section 220.2.C.1 of the NCD Manual removed the contraindication for Medicare coverage of MRI in beneficiaries with implanted PMs when the PMs are used according to the FDA-approved labeling for use in an MRI environment.
MR Conditional Labeling

ASTM Standard F2503* Defines Three Terms:

- **MR Safe**
- **MR Unsafe**
- **MR Conditional**

*ASTM standard F2503: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*
Key Conditions of Use – Radiology

- Static magnetic field 1.5 T
- Maximum gradient slew rate ≤ 200 T/m/s
- Whole body SAR ≤ 2.0 W/kg; head SAR < 3.2 W/kg
- Isocenter (center of bore) superior to C1 or inferior to T12
- Patient monitoring
“Patients with a history of potential ferromagnetic or metallic foreign object undergo further investigation...

...patient medical records

...radiographic studies

...access to written documentation”
Positive System ID: Patient Medical Records

Medical Records
• Confirms implant status

Sample Patient ID
• Provides confirmation of system’s labeling
• Directs user to website for detailed labeling
Positive System ID: Radiographic Studies

X-rays identify the system via unique radiopaque MRI symbol.
**Positive System ID:**

**Written Documentation**

Programmer Printout

- Provides confirmation that the system is MR Conditional, model number and Cardiology pre-MR checklist

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**Device Information**

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<th>Device</th>
<th>Manufacturer</th>
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MRI SureScan Parameters

The following device clinic information has been confirmed:
- System has been implanted for more than 6 weeks
- Device was implanted in the pectoral region
- No additional active implantable devices are present
- Leads are Medtronic MRI labeled
- Leads are electrically intact
- Abandoned or additional leads or wires are not present
- No lead extenders or adapters are present
- Capture thresholds do not exceed 2.00 V at 0.40 ms

Continuous monitoring of the patient during MRI scan is required.
Observe the restrictions on landmark, SAR, and the use of local coils as described in the manual.

Note: See manual for detailed information.
Patient Monitoring

• Proper patient monitoring must be provided during the MRI scan.
  – visual and verbal contact with the patient
  – electrocardiography
  – pulse oximetry (plethysmography)

• Preparation for patient rescue – An external defibrillator must be available nearby during the MRI scan.
YNHH Pacemaker MRI Checklist

Radiologist:
I am Revo trained.
MRI is medically indicated.
Chest X-ray has been cleared by Revo Trained Radiologist.

_____________________________________________________________Print:
Signature/Date/Time

Cardiology Device Nurse
Pre Scan:
I am Revo trained.
Revo System is verified.
Sure Scan Mode turned on.

_____________________________________________________________Print:
Signature/Date/Time

Procedure Nurse:
External defibrillator nearby.
Monitor ready; pulse ox and EKG connected with proper readout.
I am Revo trained
Peripheral IV placed
MRI safe stretcher in scanning room

_____________________________________________________________Print:
Signature/Date/Time

Technologist:
I am Revo trained.
I am on a 1.5 Magnet.
Pt. is completely monitored (ECG, BP, O2 Sat).
No C1-T12 centering.
Sar < 3.2 w/kg for head < 2w/kg whole body.

_____________________________________________________________Print:
Signature/Date/Time

Cardiology Device Nurse:
Post Scan:
Sure Scan reset to previous settings. ____________________________Signature