MRI Exams in Patients with Non-MR Conditional Pacemakers and with MR Conditional Pacemakers

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www.MRI safety.com
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- Advanced Bionics
- Abbott Laboratories
- Bard
- B. Braun
- Ethicon
- SuperDimension
- Teleflex
- Medtronic Orthopedics
- Smith & Nephew
FACTORS RESPONSIBLE FOR MRI INCIDENTS AND ACCIDENTS

• Missile effect
• Incorrect, outdated, lack of screening
• Implants and devices
• Outdated or inappropriate policies
Implants and Devices

• Magnetic field interactions
• MRI-related heating
• Induced currents
• Operational/functional disturbances, damage
• Artifacts
Each Factor May Impact a Patient with Cardiac Pacemaker Undergoing MRI
Terminology: Implants and Devices

• Developed by ASTM International

• In 2005, adopted and applied by the FDA

ASTM International Designation: F 2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

MR Labeling Information for Implants and Devices: Explanation of Terminology

The magnetic resonance (MR) environment may pose risks or problems to patients with certain implants and other medical devices. Therefore, the goal of this editorial is to present background information about the terms used for MR labeling of implants and other medical devices, to de-

Radiology 2009; 253:26-30

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Implants and Devices: Terminology

• **MR Safe** – no hazards in all MRI environments

• **MR Conditional** – no hazards in specified MRI environment, MRI labeling info typically found in the *Instructions for Use*

• **MR Unsafe** – hazards in all MRI environments

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Electronically-Activated Implants

MR Conditional labeling (U.S. and Europe) exists for:

- Bone Fusion Stimulator
- Programmable Infusion Pumps
- Cochlear Implants
- Neurostimulation Systems
- Cardiac Pacemakers/ICD
Electronically-Activated Implants

MRI Conditions and Device Requirements Include:
• Static Magnetic Field Strength (1.5-T, 3-T)
• Frequency for RF (64-MHz, 128-MHz)
• Type of Transmit RF Coil
• Acceptable SAR Level
• Other MRI Conditions
• Implant Configuration or Placement Scenario (i.e., patient positioning relative to transmit RF coil)
• Special Programming
Cardiac Pacemakers

Possible MRI Issues

- Movement or vibration of pulse generator
- Excessive lead heating
- Temporary or permanent functional changes
- EMI causing interference and/or arrhythmias
The presence of an implanted pacemaker is widely regarded as an absolute contraindication to magnetic resonance (MR) imaging; however, this viewpoint is based largely on safety concerns in the 1982–1996 period. Since 1996, changes in pacemaker electronics including decreased ferromagnetic content, increased sophistication of the circuitry, and onboard computer capabilities suggest that the absolute contraindication of MR imaging for pacemaker patients should be reconsidered. In addition, there are now data from prospective trials of 232 patients with demand pacemakers who underwent MR imaging at
MRI and Non-MR Conditional Cardiac Pacemakers

• There is considerable evidence in the peer-reviewed literature, from *in vitro* and clinical reports, that it is safe to perform MRI exams under highly specific conditions.
In Vitro Studies

Non-MR Conditional Cardiac Pacemakers

Shellock FG, O'Neil M, Ivans V, Kelly D, O'Connor M, Toay L, Crues JV. Cardiac pacemakers and implantable cardioverter defibrillators are unaffected by operation of an extremity MR imaging system. AJR Am J Roentgenol. 1999 Jan;172:165-70.


Clinical Studies

Non-MR Conditional Cardiac Pacemakers

Safe MRI Exams at 0.5-T

- 51 patients
- Pacemaker pre and post MRI
- Monitoring with cardiologist, ECG, pulse oxymetry, capnography
- No pacing dysfunction/arrhythmias, or reprogramming

Safe MRI Exams at 1.5-T

- 54 patients
- 62 studies: cardiac, general exams (SAR 0.08 – 2.0 W/kg)
- No exclusions; No special programming prior to MRI
- Devices interrogated before and after MRI
- Patients continuously monitored during MRI
- No adverse events occurred; No studies interrupted
- 40 (37%) leads had changes
- 2 (1.9%) leads required a change in output
- None were significant

Martin, Coman, Shellock et al (JACC 2004;43:1315–24)
Non-MR Conditional Cardiac Pacemakers

Safe MRI Exams at 1.5-T

- 115 exams – (non thoracic, one vendor)
- No pacer dependent patients
- Pre and post exam interrogation
- Monitoring with cardiologist, ECG, pulse oxymetry, capnography
- No pacing dysfunction/arrhythmias, reprogramming
- Small increase in pacing capture threshold, but not clinically significant at 0, 3 month f/u

Sommer et al. Circulation; 2006 114(12) 1285-92
Non-MR Conditional Cardiac Pacemakers

Safe MRI Exams at 1.5-T

- 438 pts (pacemakers and ICDs), 555 MRI exams
- Blood pressure, electrocardiography, oximetry, and symptoms were monitored by a nurse with experience in cardiac life support and device programming who had immediate backup from an electrophysiologist.

“With appropriate precautions, MRI can be done safely in patients with selected cardiac devices. Because changes in device variables and programming may occur, electrophysiologic monitoring during MRI is essential.”

Non-MR Conditional Cardiac Pacemakers

Safe MRI Exams at 1.5-T

- 109 pts (pacemakers and ICDs), 125 MRI exams
- Control group of 50 pts, no MRI

“MRI in patients with cardiac devices resulted in no device or lead failures. A small number of clinically relevant changes in device parameter measurements were noted. However, these changes were similar to those in a control group of patients who did not undergo MRI.”

Cohen et al. Am J Cardiol 2012 Aug 23. [Epub ahead of print]
Guidelines for MRI in Patients with Non-MR Conditional Pacemakers

- Establish risk:benefit, obtain consent
- Cardiologist/EP specialist
- Programmer, interrogate pre and post
- ACLS certified personnel and equipment
- Certain MR procedures (e.g., head/brain)
- Specific MRI conditions, limit RF
- Monitor patient during MRI (ECG, 0₂ sat, BP)
- Be prepared to intervene

Martin et al., Roquin et al., Loewy et al., ACC/AHA (2007)
### MR in Patients with Pacemakers and ICDs: Defining the Issues

Jerold S. Shinbane, MD, FACC, Patrick M. Colletti, MD, and Frank G. Shellock, PhD, FACC

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<th>Table 3. Considerations for patients with pacemakers and ICDs</th>
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<td><strong>Indication</strong></td>
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<td><strong>Post MR</strong></td>
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Non-MR Conditional Cardiac Pacemakers

• Essentially “off-label” use
• “Team effort” is required
• Specially-trained healthcare professionals
• Specific conditions and guidelines required
• Monitoring, be prepared for emergencies

"If you start to feel dizzy or weak, get outside immediately! Your new pacemaker is solar powered."
Non-MR Conditional Cardiac Pacemakers

Issues

• All MRI and pacemaker interactions have not been fully characterized

• Risk/Benefit appears to be acceptable for strong clinical indications for MRI
Non-MR Conditional Cardiac Pacemakers

The reality is most MRI facilities do not have the medical and technical expertise to follow the procedures and conditions necessary to safely perform MRI exams on patients with cardiac pacemakers.
MR Conditional - Cardiac Devices

Magnetic resonance imaging in patients with cardiac pacemakers: era of “MR Conditional” designs

Jerold S Shinbane¹, Patrick M Colletti² and Frank G Shellock²

Recent innovations in the development of magnetic resonance imaging conditional pacemakers and implantable cardioverter-defibrillators

S. Suave Lobodzinski
Department of Electrical and Biomedical Engineering, California State University Long Beach, CA, USA
MR Conditional Cardiac Pacemakers

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

Patrick M. Colletti1,2
Jerold S. Shinbane3
Frank G. Shellock4

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.

MR Conditional Pacemakers

• Now available for patients needing MRI exams
• Specially-trained healthcare professionals
• Specific conditions and guidelines required
• Only one (Medtronic) available in the U.S., with scan limitations

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Table 1. Availability of approved magnetic resonance imaging conditional devices.

<table>
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<tr>
<th>Device</th>
<th>Type</th>
<th>Availability date</th>
<th>Region</th>
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<tr>
<td>EnRhythm MRI SureScan (Medtronic, Inc.)</td>
<td>Pacemaker</td>
<td>2008</td>
<td>Europe</td>
</tr>
<tr>
<td>Accent MRI (St. Jude Medical Inc.)</td>
<td>Pacemaker</td>
<td>2010</td>
<td>Europe</td>
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<tr>
<td>ProMRI (Biotronik)</td>
<td>Pacemaker</td>
<td>2010</td>
<td>Europe</td>
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<tr>
<td>Ensura MRI SureScan (Medtronic, Inc.)</td>
<td>Pacemaker</td>
<td>2010</td>
<td>Europe</td>
</tr>
<tr>
<td>Advisa DR MRI SureScan (Medtronic, Inc.)</td>
<td>Pacemaker</td>
<td>2010</td>
<td>Europe</td>
</tr>
<tr>
<td><strong>Revo MRI SureScan Pacemaker System (Medtronic, Inc.)</strong></td>
<td>Pacemaker</td>
<td>2011</td>
<td>USA</td>
</tr>
<tr>
<td>Lumax 740 series Device (Biotronik)</td>
<td>ICD</td>
<td>2011</td>
<td>Europe</td>
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</table>
MR Conditional Pacemaker – U.S.

Revo MRI™ Pacing System – Conditions for Use

A complete SureScan® pacing system including a Revo MRI SureScan IPG and two SureScan leads is required for use in the MRI environment. Any other combination may result in a hazard to the patient during an MRI scan. The SureScan feature must be programmed to On prior to scanning a patient according to the specified conditions for use.

Cardiology requirements:

- Patients and their implanted systems must be screened to meet the following requirements:
  - 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 lead impedance history
  - A SureScan pacing system that has been implanted for a minimum of 6 weeks
  - A SureScan pacing system implanted in the left or right pectoral region
  - Pacing capture thresholds of ≤ 2.0 volts (V) at a pulse width of 0.4 milliseconds (ms)
  - A lead impedance value of ≥ 200 ohms (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 device will be programmed to an asynchronous pacing mode when the MRI SureScan is on

Radiology requirements:

- The scanner must be operated in Normal Operating mode:
  - The whole-body–averaged specific absorption rate (SAR) must be ≤ 2.0 watts per kilogram (W/kg)
  - The head SAR must be < 3.2 W/kg
  - The patient must be 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

- Proper patient monitoring must be provided during the MRI scan. The methods include visual and verbal contact with the patient, electrocardiography, and pulse oximetry (plethysmography).

Training requirements:

- A health professional who has completed cardiology SureScan training must be present during the programming of the SureScan feature
- A health professional who has completed radiology SureScan training must be present during the MRI scan
MRI and MR Conditional Pacemakers

General Limitations

- Cardiac devices available for “new” patients only (must remove both old PG and leads entirely if replacing with MR conditional device, with new PG and leads)

- Patients must wait for 6 weeks prior to MRI

- Restrictions regarding MRI procedures, scanning over the thorax and SAR levels (this may change)

- MR conditional cardiac devices still require special screening and training personnel, monitoring, etc.
MRI Safety Resource

www.MRIssafety.com

• MRI safety information
• “The List” – information for thousands of objects
• Search engine
• Email address