MR Conditional Pacemakers: What to do?

Anshuman Panda, Ph.D.

AAPM 56th Annual Meeting
Austin, TX
July 24, 2014

No conflict of interest to declare

Outline

• MR-conditional pacemakers
  • Pacemaker MRI safety
  • FDA approved devices
• Scan guidelines
  • ACR 2013 white paper
  • How we do it
    • Mayo Arizona guidelines
• Look ahead
  • Role of Medical Physicist?
  • Role of AAPM?

Pacemaker MRI: Safety Concerns

• Static magnetic field
  • Mechanical forces exerted are usually negligible at 1.5 T
    • Exception: older devices pre-1998
  • Magnetic sensor activation and unpredictable reed-switch behavior
    • Causing the device to revert to asynchronous pacing
  • Magnetohydrodynamic effect
    • Simulate life-threatening arrhythmias and produce other electrocardiographic changes
Pacemaker MRI: Safety Concerns

- **Gradient magnetic fields**
  - Capable of producing gradient magnetic fields of 20–100 mT/m or higher at 1.5 T
    - Repeatedly and rapidly turned on and off
  - Can induce electrical currents in pacemaker lead
    - Cause oversensing or undersensing
    - Life-threatening arrhythmias

Pacemaker MRI: Safety Concerns

- **Radiofrequency energy: Pacemaker**
  - Pacing at multiples of the radiofrequency pulse and associated rapid ventricular pacing
  - Pacemaker leads can act as “antennae” producing heat and electrical by concentrating RF energy
    - Damage to the pulse generator circuitry
    - Pacemaker reset
    - Battery depletion

Pacemaker MRI: Safety Concerns

- **Radiofrequency energy: Lead Wires**
  - Produce heat and electrical currents
  - Cause pacemaker reset
  - Cause tissue destruction at the lead tip, myocardial stimulation
  - Damage to the pulse generator circuitry and battery/battery depletion
  - Adverse effects on sensing, pacing thresholds, and lead impedances
  - Abandoned or fractured leads are more prone to tip heating
Which of the following is a primary concern during MR scanning of a pacemaker:

1. Heating at the lead tip and at the lead tissue interface
2. Force and torque on devices
3. Change of programming with potential damage to the pacemaker circuitry
4. Asynchronous pacing or pacing at multiples of the radiofrequency pulse
5. All of the above

Journal of Mag Res Imag. 2013:37 501-503
MR Conditional Pacemaker: Development Timeline

- **2008:** MRI-conditional pacemakers introduced
- **2011:** FDA approved the first MR-conditional pacemaker - Medtronic Revo
  - Both lead and pulse generator have to be MR conditional
- **2013:** Second Generation Medtronic (Advisa) MR-conditional pacemaker gets FDA approval
- **2014:** Biotronik single chamber and dual chamber pacemaker gets FDA approval

MR Conditional Pacemakers: FDA-approved

- **Medtronic**
  - Revo MRI SureScan – Approved 2011
  - Advisa MRI SureScan – Approved 2013 (Both dual chamber only)
  - Leads: CapSure Sense and CapSureFix MRI

- **Biotronik**
  - Entovis ProMRI single chamber and dual chamber – Approved 2014
  - Leads: Setrox SS3/SS6

Pacemaker Design Changes: Pulse Generator

- **Pulse generator shielding**
  - Minimize effect of the electromagnetic environments

- **Reducing ferromagnetic content**
  - Avoid damage or malfunction of components
  - Reduce magnetic attraction and susceptibility artifacts

- **Reed switch changes to a solid-state Hall sensor**
  - Allows for predictable behavior in a magnetic field

- **Radio-opaque markings**
  - Identify the device and components as MR conditional

- **Dedicated programming modes - asynchronous pacing**
  - Prevent inappropriate pacemaker inhibition
  - Prevent competing rhythms
Radio-Opaque Markings

- Visual confirmation through radiograph
  - MR-conditional pulse generator - emblem
  - MR-conditional leads - wavy pattern

Radio-Opaque Markings: Medtronic

- Gen 1: Revo/EnRhythm
  1. Marker identifying the device as MR conditional
  2. Medtronic identifier
  3. Device specific identifier

- Gen 2: Advisa/Ensura
  1. Marker identifying the device as MR conditional
  2. Medtronic identifier
  3. Device specific identifier

Pacemaker Design Changes: Lead Wire

- Design: Higher inductance and reduce lead tip heating
  - Minimize resonant frequency conduction
    - Changing the winding pattern
    - Modifications in lead geometry of the filaments

- Insulation: Filter circuitry
  - Prevent damage to internal power supply
  - Limit transfer of certain frequencies and dissipate energy

- Identification: Radio-opaque indicator*

Radio-Opaque Markings:

Medtronic

• Gen 1: Revo/EnRhythm
  1. Marker identifying the device as MR conditional
  2. Medtronic identifier
  3. Device specific identifier

• Gen 2: Advisa/Ensura
  1. Marker identifying the device as MR conditional
  2. Medtronic identifier
  3. Device specific identifier
Radio-Opaque Markings: Biotronik

- Entovis Single/Dual Chamber
  1. Radiopaque device maker
  2. Biotronik identifier
  3. Device specific identifier

- No radiopaque markers are present for MR-conditional lead identification

Needs Standardization

MR-Conditional Pacemakers: FDA Restrictions

<table>
<thead>
<tr>
<th>Field</th>
<th>MEDTRONIC</th>
<th>BIOTRONIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scan Zone Restrictions</td>
<td>Whole body</td>
<td>Exclusion zone: between C1 and L5 vertebrae</td>
</tr>
<tr>
<td>Field Strength</td>
<td>Cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5T</td>
<td></td>
</tr>
<tr>
<td>Gradient Slew Rate</td>
<td>≤ 200 T/m/s</td>
<td>≤ 200 T/m/s</td>
</tr>
<tr>
<td>SAR – Head</td>
<td>≤ 2.0 W/kg</td>
<td>≤ 2.0 W/kg</td>
</tr>
<tr>
<td>SAR – Body</td>
<td>≤ 3.2 W/kg</td>
<td>≤ 3.2 W/kg</td>
</tr>
<tr>
<td>Scan Duration</td>
<td>No</td>
<td>Each scan ≤30 min maximum: 10 hours lifetime</td>
</tr>
<tr>
<td>Coils</td>
<td>Transmit/Receive</td>
<td>No additional local Transmit</td>
</tr>
<tr>
<td>Patient positioning</td>
<td>No Lateral Decubitus</td>
<td>Only supine</td>
</tr>
<tr>
<td>Patient height – min</td>
<td>No exclusion</td>
<td>1.4 m</td>
</tr>
<tr>
<td>Patient Monitoring</td>
<td>ECG/Blood Ox/BP</td>
<td>ECG/Blood Ox/BP</td>
</tr>
</tbody>
</table>

*MR-conditional pacemakers: current perspectives*  
Medical Devices: Evidence and Research. 2014:7 115–124

Which of the following static magnetic fields and SAR limitations will meet safe scanning conditions of all FDA approved MR-conditional pacemakers:

- 33% 1. 1.5 T and 2.0 W/kg
- 10% 2. 3.0 T and 2.0 W/kg
- 20% 3. 1.5 T and 4.0 W/kg
- 10% 4. 3.0 T and 4.0 W/kg
- 20% 5. None of the above. All pacemakers are contraindicated for MRI.
Which of the following static magnetic fields and SAR limitations will meet safe scanning conditions of all FDA approved MR-conditional pacemakers:

1. 1.5 T and 2.0 W/kg


### FDA/CEMARK MR-Cleared Pacemakers

<table>
<thead>
<tr>
<th>Pacemaker Model</th>
<th>MEDTRONIC</th>
<th>ST JUDE MED</th>
<th>BIOTRONIK</th>
<th>BOSTON SCI</th>
<th>SORIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Supplier</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Biotronik</td>
<td>Biotronik</td>
</tr>
<tr>
<td>Leads</td>
<td>CapSure™ leads</td>
<td>Tendril™ leads</td>
<td>Safe™ and Silicon™ leads</td>
<td>FINELINE™ leads</td>
<td>BEFLEX™ leads</td>
</tr>
<tr>
<td>MRI machine</td>
<td>Cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5T</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAR – Body</td>
<td>≤ 2.0 W/kg</td>
<td>≤ 3.0 W/kg</td>
<td>≤ 2.0 W/kg</td>
<td>≤ 2.0 W/kg</td>
<td>≤ 2.0 W/kg</td>
</tr>
<tr>
<td>SAR – Head</td>
<td>≤ 3.2 W/kg</td>
<td>≤ 3.2 W/kg</td>
<td>≤ 3.2 W/kg</td>
<td>≤ 3.2 W/kg</td>
<td>≤ 3.2 W/kg</td>
</tr>
<tr>
<td>Gradient Slew Rate</td>
<td>≤ 200 T/m/s</td>
<td>≤ 200 T/m/s</td>
<td>≤ 200 T/m/s</td>
<td>≤ 125 T/m/s</td>
<td>≤ 200 T/m/s</td>
</tr>
<tr>
<td>Max nr of scans</td>
<td>No</td>
<td>No</td>
<td>Each scan:</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Scan zone restrictions</td>
<td>No</td>
<td>No</td>
<td>Exclusion zone between C1 and T12 vertebrae</td>
<td>No</td>
<td>Exclusion zone between C1 and T12 vertebrae</td>
</tr>
<tr>
<td>Patient positioning</td>
<td>No Lateral Decubitus</td>
<td>Supine only</td>
<td>Supine only</td>
<td>Supine only</td>
<td>Supine Only</td>
</tr>
</tbody>
</table>

### MR Conditional Pacemakers: FDA/CEMARK cleared

- Medtronic Advisa® SR MRI(TM) - CEMARK
- Medtronic Ensurra SR MRI(TM) SureScan® - CEMARK
- Medtronic Ensura MRI™ SureScan® - CEMARK
- Boston Scientific ADVATIO(TM) MRI - FDA
- Boston Scientific ITALIO™ MRI - FDA
- Boston Scientific FORMIO(TM) MRI - FDA
- Boston Scientific Entovis SR/DR - FDA
- Biotronik Evita SR/DR - FDA
- Biotronik Estea SR/DR - FDA
- Biotronik St Jude Assurity™™ - FDA
- Biotronik St Jude Endurit™ - FDA
- Biotronik St Jude KORA 100™ - CEMARK

Need for Uniform Baseline Standards
MR-Conditional Pacemaker Scanning: Current Guidelines

- American Heart Association (AHA) - 2007
- American College of Radiology (ACR) - 2013
- Mayo Arizona - How we do it?


- American Heart Association Committee on Diagnostic and Interventional Cardiac Catheterization; American Heart Association Council on Clinical Cardiology; American Heart Association Council on Cardiovascular Radiology and Intervention
- Safety of magnetic resonance imaging in patients with cardiovascular devices: an American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention; endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. Circulation 2007; 116:2878-2891

AHA Guidelines: 2007

- MRI examination of nonpacemaker-dependent patients is discouraged
- Should only be considered in cases in which there is a strong clinical indication and in which the benefits clearly outweigh the risks
- MRI examination of pacemaker-dependent patients should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks
- In every single case the physician should assess the risk-benefit ratio and take the final decision
ACR Guidelines: 2013

- All device hardware should be included in the practitioner's assessment of the patient's suitability for MR scanning
- Coordination with the physician managing the device (cardiologist/electrophysiologist) and a representative from the device manufacturer
- Ensure the entire system (pulse generator and leads) must be labeled “MR Conditional” for a system to in fact be considered MR conditionally safe
- MR Conditional system is only considered safe if all of the MR conditions for safe use are followed
- The presence of abandoned leads from previous nonlabeled systems or "mix-and-match" systems (combined MR Conditional labeled and nonlabeled hardware) renders the system as a whole MR Unsafe or at best "MR unknown"
How we do it? Mayo Arizona Guidelines

Medical Physicist is an integral part of the patient care team

Medical Physicist is responsible for safe MR scan execution and has the authority to stop the exam at any point

Use Checklist

Adopted from Mayo Clinic in Florida, Dr. Pooley
Mayo Arizona Scan Guidelines: Scheduling

• Physics pre-scheduling consultation needed
  • Pacemaker dependent – can’t sustain 30-35 bpm without pacing*
  • Pacemaker outside of right or left pectoral implant (prepectoral or submuscular)
  • Within 6 weeks after implantation
  • MRI scan under sedation
  • Cardiac or thoracic exams
  • Anticipated scan time longer than 30 mins

Pre-MRI Checklist

• Physicist, Pacer RN, Rad RN, and MRI technologist are present
• EP Cardiologist consult completed
• The risks are documented in Pacemaker Checklist
• Cardiologist called and informed - MRI exam to begin
• Code cart availability check
• Pacemaker model reviewed by Pacer RN and Physicist
• Lead Model (device and leads can be different models) reviewed by Pacer RN and Physicist
SAR Reduction Strategies

- Set RF Type to “Low SAR”
- Turn gradient mode to Whisper or Normal Scan mode
- Decrease # of slices (for 2D scans)
- Decrease # of averages
- Eliminate SAT bands and Fat Sat
- Increase TR
- Decrease flip angle
- Gradient echo scans provide less SAR than spin echo
- Spin echo scans provide less SAR than fast (turbo) spin echo
- Reduce echo-train-length for FSE

Post-MRI Checklist

- Radiologist review before exam completion
- EP Cardiologist informed MRI has concluded
- Pacer clinic nurse evaluates patient
  - Pacemaker programming restored
- Checklist completed and signed off
  - MR physicist checklist
  - MR technologist checklist
  - Cardiology nurse checklist
- Safety review for root cause analysis is filed
  - Near misses, adverse outcomes, guideline deviation

MR-Conditional Distribution of Cases: Mayo Arizona

- Medtronic, 3
- Biotronik, 1
- Medronic Advan, 6
- MSK, 4
- Neuro, 6

Total = 10
Future Growth and Challenges

• Pacemaker scanning at 3T
• Relaxation of Exclusion Zone criteria
  • Newest generations have no limitation on the part of the body to be scanned
• Single-chamber pacemakers (Biotronik and St. Jude)
  • Used in permanent atrial fibrillation patients
  • Significant increase in the number of patients with MR-conditional pacemakers
• New Lead design - Reduced lead performance issues
• Devices getting better - Miniaturization

Future Pacemaker

Role of Medical Physicist?

• Ideally available on site to supervise each scan
  • Integral part of the patient care team
  • Maintains safety checklist during scan
  • On the spot protocol modification

• Out-patient imaging centers - assist to develop
  • MR pacemaker policy
  • Patient scan checklist
  • Pacemaker protocol optimization
  • Annual pacemaker protocol review
Role of AAPM?

- Medical physics practice guidelines
  - Annual review of pacemaker protocols
  - Pacemaker safety checklist
  - Advocate for uniform baseline standards for MR-conditional pacemakers

- SAR report guidelines
  - Similar to CT structured dose report
  - Engage DICOM

Acknowledgements

- Judy R. James, Ph.D.
- Heidi A. Edmonson, Ph.D.
- Robert A. Pooley, Ph.D.
- Joel P. Felmlee, Ph.D.
- William Pavlicek, Ph.D.