Disclosures

- Conflicts - none
- MRI is only FDA approved for patients with MR conditional pacemakers and ICDs
- Gadolinium is an off-label use for CMR in USA

Outline

- Scope of the problem
- Types of devices and FDA labeling
- MRI safety concerns
- MRI in patients with CRMD
- Loyola experience
- Patient selection & imaging
- Clinical case presentation
- Challenges for CMR
- Potential clinical applications
MRI in CRMD
Scope of the Problem
- Estimated 60 million MRI are performed worldwide each year
- Increasing implantation of CRMD
- 50-75% probability of a patient with CRMD requiring an MRI scan
- MRI appropriate indications: Neurology, oncology, musculoskeletal & cardiovascular
- Presence of a CRMD is generally considered a contraindication for MRI

Types of CRMD
- Pacemakers with intra-cardiac leads - single chamber or dual chamber
- ICDs with intra-cardiac leads - single chamber or dual chamber
- CRT-D or CRT-P with intra-cardiac leads - RA, RV and coronary sinus leads
- Subcutaneous ICD (no intravenous or intra-cardiac leads)
- Leadless pacemakers

CRMD Safety Labeling
- MR safe - None
- MR conditional - FDA approved for MRI scan that meets certain scan & device conditions – 1.5T vs 3T, full body scan vs exclusion zone in the chest etc.
- MR unsafe - All non-conditional devices (legacy devices)
April 28, 2018

Potential Risks of MRI in CRMD

• 17 MRI-associated death in patients with legacy pacemakers
• Most deaths occurred in elderly with older models, without appropriate programming or supervision
• Risks are associated with interaction between CRMD and 3 essential components of MRI
  - Static magnetic field
  - Gradient magnetic field
  - Radiofrequency energy

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Potential Risks of MRI in CRMD

Static magnetic field
• 1.5T (30,000 x earth’s magnetic field)
• 3T (60,000 x earth’s magnetic field)
• Torque and displacement forces leading to device movement
• Mechanical forces exerted on CRMD are usually negligible at 1.5T
• Magnetic sensor activation (reed-switch)
• Magnetohydrodynamic effect: ECG artifacts

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Potential Risks of MRI in CRMD

Gradient magnetic fields
• Additional time varying magnetic fields generated during scanning
• Measured in mT/m
• Can induce electrical currents in device leads causing oversensing, undersensing or arrhythmias
Potential Risks of MRI in CRMD

Radiofrequency energy
- RF pulses are generated during scanning
- At the end of each pulse, RF energy is released
- Specific absorption rate (SAR): W/kg
- Leads act as antenna which concentrate RF energy, producing heat and electrical current
- Tissue thermal injury at lead tips
- Myocardial stimulation/arrhythmia
- Damage to pulse generator & battery
- Abandoned or fractured leads are more prone to heating

MR-Conditional CRMD

- MRI-condition pacemaker introduced in 2008
- Main modifications introduced in MRI-conditional CRMD

<table>
<thead>
<tr>
<th>Modification</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in ferromagnetic</td>
<td>Reduce magnetic attraction and susceptiability artifacts</td>
</tr>
<tr>
<td>components</td>
<td></td>
</tr>
<tr>
<td>Replacement of reed switch with Hall sensor</td>
<td>Avoid unpredictable reed switch behavior</td>
</tr>
<tr>
<td>Lead coil design and insulation</td>
<td>Minimize lead heating and electrical current induction</td>
</tr>
<tr>
<td>Filter circuitry</td>
<td>Prevent damage to internal power supply</td>
</tr>
<tr>
<td>Dedicated pacemaker programming (MRI mode)</td>
<td>Prevent inappropriate pacemaker inhibition</td>
</tr>
<tr>
<td></td>
<td>Prevent competing rhythms</td>
</tr>
</tbody>
</table>

Safety of MRI in Patients with Cardiac Devices

- 1509 patients, 1.5T; 2103 scans
- Legacy devices: Pacemaker 58%; ICD 42%
- Exclusion
  - Lead implantation <4 wks
  - Epicardial or non-functional leads
  - Subcutaneous ICD
  - ICD without asynchronous pacing
- Pre-scan programming
  - PM dependent (9%): asynchronous mode
  - Others: inhibited pacing mode
  - Tachyarrhythmia functions disabled

Nazarian et al. NEJM 2017;377:2555-64
Safety of MRI in Patients with Cardiac Devices

Nazarian et al. NEJM 2017;377:2555-64

Outcomes: No events in 96% of MRI

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power-on-reset</td>
<td>9 (0.4%)</td>
</tr>
<tr>
<td>Premature termination of MRI (power-on-reset 4; demand pacing inhibition 3; VT 1; image artifact 3)</td>
<td>9 (0.4%)</td>
</tr>
<tr>
<td>Inhibition of necessary pacing</td>
<td>2 (0.1%)</td>
</tr>
<tr>
<td>Battery depletion</td>
<td>1 (0.05%)</td>
</tr>
<tr>
<td>Sensation of pressure/pushing/pulling at generator site or heating within chest</td>
<td>1 (0.05%)</td>
</tr>
<tr>
<td>Sustained arrhythmia attributable to current induction in pacemaker or ICD system leads</td>
<td>0</td>
</tr>
<tr>
<td>Inappropriate delivery of anti-tachycardia pacing or shocks</td>
<td>0</td>
</tr>
<tr>
<td>Significant pacing threshold or sensing changes requiring system revision or changes in programmed sensitivity or pacing output</td>
<td>0</td>
</tr>
<tr>
<td>Generator failure</td>
<td>0</td>
</tr>
</tbody>
</table>

MagnaSafe Registry

- Prospective registry
- Legacy devices
- 1.5T, non-thoracic imaging (75% brain/spine)
- 1000 pacemaker, 500 ICD
- Exclusion criteria
  - Implanted before 2001
  - Abandoned or inactive leads
  - Pacemaker dependent ICD patients
  - Near end of battery life
  - Non-thoracic device location

Russo et al. NEJM 2017;376:755-64

MagnaSafe Registry

Table 1: Primary End Points

<table>
<thead>
<tr>
<th>Event</th>
<th>Pacemaker</th>
<th>ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death during the MRI exam</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Death following repair</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Ventricular arrhythmia</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Inappropriate delivery of anti-tachycardia pacing or shocks</td>
<td>0</td>
<td></td>
</tr>
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<td>Significant pacing threshold or sensing changes requiring system revision or changes in programmed sensitivity or pacing output</td>
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</tbody>
</table>

Russo et al. NEJM 2017;376:755-64
MRI in Subcutaneous ICDs
- MRI-conditional and non-conditional models
- No intravascular leads, larger can size
- No pacing capability

Keller et al. Europace 2015;17:761-66
- 15 patients (Boston Scientific SQRx Model 1010 and Q-TRAK Model 3010)
- 22 MRIs on 1.5T (cardiac, brain, spine)
- ICD function turned off during MRI
- No device malfunction
- Heating in 4 patients (?thermistor probe)

MRI in Leadless Pacemakers
- Implanted via a catheter directly into the RV
- Patients who need single chamber pacing
- MRI-conditional
  - Medtronic Micra 1.5T & 3T
  - St. Jude Nanostim model LSP102 for 1.5T

Loyola Experience
- Cardiac MRI
- More than 120 patients with legacy CRMD
- Clinical indications:
  - Scar mapping in VT
  - ARVC
  - Infiltrative cardiomyopathy
  - Constrictive pericarditis
- Outcomes: No major events - deaths, power-on-reset, generator or lead failure, ICD shock, pacing failure
Patient Selection

- MRI-conditional CRMD
  - Be aware of the specific device and MRI conditions
  - No MRI contraindications
  - EP interrogation and programming of the device before and immediately after MRI

Patient Selection: Legacy CRMD

- CMR is clinically indicated and there are no MRI specific contraindications
- Able to provide informed consent
- Device interrogation record is available and reviewed
- Chest X-ray is available & reviewed for device position and to rule out abandoned leads.
- No device related contraindications as listed below:
  - Temporary pacemakers
  - Retained/abandoned, nonfunctioning leads
  - Patients with older devices (before 2002)
  - Pacemaker or ICD with recalled leads
  - Pacemaker dependent ICD without asynchronous pacing mode
  - Pregnancy

General Principles: MRI in CRMD Patients

- Team personnel: EP & Imaging
- Patient prep
- Pre-scan device interrogation & programming
- Patient monitoring during the scan
- Dedicated imaging protocol
- Post-scan device interrogation and re-programming to original settings
CMR in CRMD: Case Example

- 56 YM
- NICM, VT s/p ICD
- Transferred from OSH for recurrent VT terminated by overdrive pacing
- LHC: non-obstructive CAD
- CMR for VT ablation planning

Cine CMR

CMR – T₂ and LGE

Cardiac Sarcoidosis with active inflammation
Non-caseating granulomas
Cardiac Sarcoidosis

CMR in CRMD: Challenges
1. Safety
2. Artifacts
   a) Cine
   b) Black blood imaging
   c) Perfusion
   d) Late gadolinium enhancement

CMR in CRMD: Cine Artifacts
SSFP
Gradient Echo
CRMD - CMR applications

- CV imaging: several competing noninvasive modalities – echo, TEE, CT, Nuclear
- Routine CMR indications: morphology, function, perfusion, stress, viability
- Unique feature of CMR is tissue characterization
- Clinical value of CMR in CRMD patients
  - Infiltrative cardiomyopathies
  - Cardiac masses
  - Pericardial constriction
  - Scar mapping for VT ablation
  - RV or ARVC evaluation

Conclusion

- MR imaging is safe in selected patient with legacy devices and in all patients with MR-conditional devices
- MRI in patients with legacy CRMD should only be performed in experienced centers with established patient selection, monitoring and imaging protocols
- Imaging artifacts can be a significant issue for CMR
- Further research is needed to develop specific CMR sequences for CRMD patients