MRI in the presence of Cardiac Implantable Electronic Devices

Wayne Patola, RTR RTMR
Clinical Assistant Professor, Faculty of Medicine, UBC
MRI Leader, Providence Health Care, Vancouver
Disclosure

• Employed by GE Health Care, Canada, to provide MRI Applications.
Objectives

1) To review the historic and current reasons for concern regarding the safety of MRI in the presence of Cardiac Implanted Electronic Devices (CIEDs).

2) To review the most recent literature regarding the imaging of patients with these implants.

3) To share the experience obtained at St. Paul’s Hospital and review the potential barriers to more widespread adoption.
CIEDs

• For the purposes of this discussion, CIEDs are defined as any electronic device that is implanted in the patient to assist in the functioning, modulation or monitoring of the cardiac function.

• This includes loop recorders, pacemakers (PM) (single or dual chamber), and implantable cardioverter-defibrillators (ICD) (may be in conjunction with a pacemaker).

• The majority of these currently implanted in the patient population have not been validated as “Safe” or “Conditional” for MRI and are thus considered “Unsafe”.
Aging Population

- As the population ages, there will be more demand for imaging.
- There will also be a higher prevalence of those patients having a CIED in place.
- Rate of CIED implantation is increasing not only due to age, but also due to increase in indications for implantation.
HEALTH PROFILE: CANADA

Canada Population Pyramid

44,414,000

MRI with CIEDs
Wayne Patola, RTR RTMR, Clinical Assistant Professor - UBC
Aging Population

• Currently 2,000,000 people have CIEDs in the USA.
• Currently 200,000 people have CIEDs in Canada.
• 50% - 70% of patients with a pacemaker or ICD will have an indication for MRI during their lifetime.¹
• Within 4 years of implantation, more than 36% of patients with ICDs will require an MRI, yet only 1.4% are actually receiving one.²

MRI vs. Other Imaging

- The current Canadian Association of Radiologists and the American College of Radiology appropriateness guidelines indicate that there are many conditions where MRI is the preferred imaging modality.

- In some cases using an alternate imaging modality will not answer the clinical question, result in inappropriate treatment or will incur the potential for harm to the patient.
  - Radiation from CT.
  - Invasive procedures such as myelography.
  - Poorer visualization of tumor extent (lower sensitivity and specificity).
Replace the Device?

• Replacing an existing CIED with an MRI-compatible one entails some risk to the patient.

• In the REPLACE study\(^1\), generator (PM or ICD) replacement, with or without lead replacement, resulted in up to a 15% rate of major adverse cardiac event.

---

\(^1\) Poole J et al. Complication Rates Associated with Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures: Results from the REPLACE Registry. Circulation. 2010;122(16):1553-156
Potential Risk of Exposing CIED to MRI

- ACR 2013 Guidance Document on MRI Safety Practices list the following potential risks in exposing CIEDs not specifically approved for MRI:
  - Unexpected programming changes
  - Inhibition of generator output
  - Failure to pace/transient asynchronous pacing/rapid cardiac pacing/induction of ventricular fibrillation
  - Heating of tissue adjacent to the pacing or ICD system and especially cardiac tissue near the lead tip
  - Early battery depletion
  - Outright device failure requiring replacement
Historical Mortality

• 10 deaths in the 1980’s that were “poorly characterized” with no ECG records for review.

• From 1992 to 2001 there were 6 deaths, during or following, MRI scanning in Germany. No ECG records were available, and autopsy reports were unrevealing. The authors “guessed” the cause was ventricular fibrillation due to inadequate asynchronous pacing.

• These 6 occurred after exams in private clinics, none in the hospital environment.

• No deaths have been reported with MRI scanning in the past decade.
Risk vs. Benefit

- Given that there is a need for patients with CIEDs to have MRIs, but there is an inherent risk in doing so, and that St. Paul’s Hospital is the cardiac centre for BC, we felt that we should investigate how best to accommodate these patients.

- We reviewed the literature and sought input from sites that had been successfully scanning these patients to determine the safest protocol possible to deliver MRI services to this patient population.
Appropriateness

- Not all referrals for MRIs on patients with CIEDs are accepted.
- The reqs are reviewed by the Radiologists and the referring physician is often contacted to discuss the indication and options available.
- If an alternate imaging procedure is appropriate, the request is changed to that procedure after consultation with the referring physician.
Absolute Contra-indications

• Patients with CIEDs are referred to our Electrophysiology department for pre-MRI assessment.
  • Patients cannot be pacemaker-dependent.
  • Capture thresholds must be within an acceptable range.
  • Generator function must not be degraded (not end of battery life).
• No retained or broken leads or lead extenders (Pre-MRI CXR is obtained).
• Generator must not be placed in the abdomen.
• Scanning over the thorax is not indicated (unless the entire system (generator and lead combination) is classified as “MRI Conditional”)

MRI with CIEDs
Wayne Patola, RTR RTMR, Clinical Assistant Professor - UBC
Abandoned Lead

- 2 ports on generator (small arrows)
- 3 leads present (large arrow)
Abandoned Lead

- Abandoned lead coiled under generator.
Broken Leads
Sources of Potential Complications

- Static magnetic field
- Gradient fields
- RF fields
- Combination of 2 or more of the above
Static Field – Potential Complications

- Torque or movement of the generator or lead tip if composed of ferromagnetic materials.
- Closure of the reed switch resulting in loss of generator function.
- Integrated magnetic sensor activation resulting in unpredictable function (such as power-on reset).
- Changes to ECG waveform.
Static Field - Mitigation

• Scan on 1.5 T or less.
• Wait minimum of 6 weeks post-implantation to allow lead tip to adhere to endocardium through scar tissue formation and generator pocket to heal.
• Advise patient to monitor for discomfort due to torque on the generator and inform techs immediately. Abort exam and follow-up with CXR to confirm placement if severe discomfort experienced.
• Monitor hemodynamic function with ECG, Pulse Oximetry and Non-Invasive Blood Pressure with ALS certified Cardiologist present.
Static Field - Mitigation

• Generally the force experienced by the generator and lead at 1.5T due to the static field is less than the physiologic force normally felt by these in the body.

• In our experience, we have not had any patient report discomfort or had evidence of lead or generator displacement.

• We have had a single instance of “Power-on reset” with an older model of ICD, but the patient had no adverse effect.

• Generator function is assessed pre- and post-MRI by the Electrophysiology dept. and no change in function has been recorded.
Gradient Field – Potential Complications

• Induction of current on lead causing over/under sensing.
• Induction of current on lead causing inappropriate pacing/arrhythmia.
Gradient Field - Mitigation

• Use lowest performance gradient system possible (Whole, not Zoom).
• Avoid rapid gradient sequences such as EPI.
• Use “Normal” mode to reduce system performance.
• Monitor hemodynamic function with ECG, Pulse Oximetry and Non-Invasive Blood Pressure with ALS certified Cardiologist present.
RF Field – Potential Complications

• Heating of lead tip, potentially causing ablation of cardiac tissue.
• Heating of generator casing, potentially causing tissue necrosis.
• Possible induction of current in leads causing inappropriate pacing/arrhythmia.
• Induced current in gating leads causing disruption of ECG monitoring waveform.
RF Field - Mitigation

• Wrap thorax in RF shielding blankets (cover entire CIED system).
• Use local Transmit/Receive coil over area being examined.
• Do not scan over CIED system (no chest/cardiac/T-spine imaging).
• Monitor SAR for each sequence, keeping under 2 W/kg.
  Note: soon this will change to consider B1+rms.
• Use “Normal” or “Low SAR” mode.
• Obtain troponin levels pre- and post-MRI.
• Monitor hemodynamic function with ECG, Pulse Oximetry and Non-Invasive Blood Pressure with ALS certified Cardiologist present.
RF Shielding Blankets

- RF shielding blankets will prohibit RF from affecting implants within the blanket. Creates a Faraday cage around the thorax.
- Not currently an application specifically endorsed by the manufacturer (Accusorb).
- Must be used in the manner described by the manufacturer to be effective (fully wrapped around the patient with no gaps, no folds, labelled side facing out).
- Can improve appearance of ECG waveform if leads encased in blanket.
RF Blankets
RF Blankets
Workflow for CIEDs at St. Paul’s Hospital

- Requisition received by department.
- Documentation of make and model of CIED obtained.
- Manufacturers recommendations attached.
- Radiologist reviews indication and consults with referring physician to determine appropriateness of performing MRI or alternate exam.
- If MRI indicated, protocolled to limit number and type of sequences.
Workflow for CIEDs at St. Paul’s Hospital

• Patient referred to Electrophysiology department for assessment of pacemaker and dependency. If approved, book MRI time slot.
• On date of exam, patient arrives extra 30 min early for CXR, baseline Troponin level and standard MRI screening.
• CXR reviewed with Radiologist to exclude broken/retained leads or additional implants.
• Radiologist or Cardiologist obtains signed informed consent from patient.
Workflow for CIEDs at St. Paul’s Hospital

- Patient is hooked up to monitoring equipment (ECG, BP, Pulse Ox) outside of the MRI magnet room.
- Cardiologist attends during entire procedure. Crash cart is available.
- EP nurse attends, interrogating the CIED and then disabling it.
- Patient is brought into MRI magnet room.
- MRI-safe monitoring equipment (ECG, BP, Pulse Ox) applied.
- Patients torso is wrapped in RF shielding blankets.
- Coil is placed over area of interest (transmit/receive if possible).
Workflow for CIEDs at St. Paul’s Hospital

• Patient is supplied with standard safety equipment (call bell, hearing protection) and informed to alert techs if any cause for concern (discomfort, heart rhythm issues, SOB, etc.)

• Scan is initiated on “Normal” mode and “Whole” gradients.

• SAR is monitored for every sequence and kept below 2 W/kg.

• Verbal communication is maintained between every sequence.

• Cardiologist monitors hemodynamic function throughout exam.
Workflow for CIEDs at St. Paul’s Hospital

- Images checked with Radiologist to confirm exam complete.
- Patient removed from MRI magnet room and hooked up to monitoring equipment outside of magnet room.
- EP nurse attends and re-starts CIED and confirms correct operation and settings.
- Patient is given lab req for Troponin level to be drawn 8 hours post MRI.
- Patient has follow-up exam with EP lab to monitor CIED function.
- Patient is grateful exam was done and sent home with no ill effects!
Magnetic Resonance Imaging in Patients with Implanted Cardiac Devices

Skill Level: Specialized
Heart Rhythm Services Device Clinic Nurses, Electrophysiology (EP) physicians, Radiology physicians, MRI Technologists

Clinical Indication: This guideline applies to the care of individuals with an implanted cardiac device who require magnetic resonance imaging (MRI).

Need to Know:
- It is estimated that up to 75% of patients with an implanted pacemaker will develop an indication for MRI at some point after implantation.
- MRI can cause potential adverse effects to individuals with implanted cardiac devices which include radiofrequency induced heating of the leads, movement or dislocation of the device, current induction, pacing inhibition/dysfunction, asynchronous pacing with the possibility of induction of tachyarrhythmias, transient rest switch activation, changes in capture threshold and loss or changes to programmed data.
- The closer the scanning area to the cardiac device, the higher the risk for adverse effects.
- For patients with conventional implanted cardiac devices (Section A), MRI may only be performed if the radiologist has consulted with the referring physician and determined that: the exam is absolutely necessary to the patient’s well-being and the risks associated with MRI are outweighed by the potential benefits.
- For patients who have MRI compatible cardiac devices (Section B), scanning may be performed because these pacing systems were designed to allow patients to be safely scanned by an MRI machine (also referred to as MRI-conditional device).
- The type of cardiac device and lead system will be confirmed by surgical report and x-ray prior to MRI.
- The radiologist must be present at all times during scanning of both MRI compatible cardiac devices and conventional cardiac devices. It is the physician’s responsibility to monitor the patient’s hemodynamic function and provide intervention as necessary.
- Standard follow-up appointment for all patients with cardiac devices undergoing MRI will be at 6 weeks following MRI unless otherwise indicated by the EP physician.
- Patients will undergo a follow-up appointment at their usual routine device clinic unless otherwise indicated by physician at the time of MRI.
- Although patient MRI’s are infrequent, they will also require referral to EP physician for appropriate assessment and device interrogation. Work load of nurses in the SPH Device clinic may limit the ability to perform device interrogation without prior scheduling approval.
# Providence Health Care

## MR Pacemaker Clinic - For Pre-MRI Assessment

**Appointment Date:**

**Exam Requested:**

**Pre-MRI assessment of implanted device.**

**Relevant History / Reason for Exam (Includes any Medications):**

Patient has implanted device. Please see attached documentation regarding device and indication for MRI.

MRI scheduled for:

**Essential Pre-Examination Information**

**FOR PATIENT SAFETY: EXPLAIN IF "YES," KNOWN IMPLANTED METAL OR DEVICE:**

- **OCCURRING METAL OR DEVICE:**
  - **INTERNAL PACEMAKER:**
    - **NO**
    - **YES**
  - **IMPLANTED HAIR NET:**
    - **NO**
    - **YES**
  - **MAGNETICALLY ATTRACTION METAL:**
    - **NO**
    - **YES**
  - **METAL WORKS OF ENTRANCE:**
    - **NO**
    - **YES**
  - **SMALL METAL OBJECTS:**
    - **NO**
    - **YES**
  - **NEEDLE IN METAL:**
    - **NO**
    - **YES**
  - **HAIRPIN / RIVETS:**
    - **NO**
    - **YES**
  - **VIRBUPUS ACCESSORY:**
    - **NO**
    - **YES**
  - **OTHER:**
    - **NO**
    - **YES**

**Incomplete Requests will be Returned**

**Informed Consent:**

**By Signature:**

**Patient's Name:**

**Date:**

**MR Department:**

**FAX OR MAIL COMPLETED REQUESTION TO MR DEPARTMENT**

**Appointment**

**Prepared by:**

**Document Details:**

- **Form No:** MRIC-0402
- **Printed On:** 8-16-07
MAGNETIC RESONANCE IMAGING
ASSESSMENT AND CHECKLIST
FOR PATIENTS WITH PACEMAKER OR ICD

CLINIC ASSESSMENT
(to be completed by physician at time of consultation)

Date of assessment: ____________________________

MRI site:
☐ X-ray complete or ☐ to be done on day of MRI ☐ 12 lead ECG

No documented: ☐ external leads ☐ lead extender or adapters present ☐ other devices or sounded/retrieved leads

☐ Cardiac device: Pacemaker ☐ ICD

MRI conditional generator: ☐ Yes ☐ No All leads MRI condition: ☐ Yes ☐ No

Model: ____________________________ Date of Implant: ____________________________ Site of Implant: ____________________________

Lead Model: ____________________________ Date of Implant: ____________________________ ☐ Atrial

Lead Model: ____________________________ Date of Implant: ____________________________ ☐ Right Ventricular

Lead Model: ____________________________ Date of Implant: ____________________________ ☐ Left Ventricular

DEVICE TESTING (to be completed by Device Clinic Nurse during clinic assessment)

Parameter dependent: ☐ Yes ☐ No

Atrial threshold Underlying heart rate:

Atrial impedance Current pacing parameters:

R wave: ☐ Pacing capture threshold values stable and below 2V at a pulse width of 0.4 ms

Pacemaker threshold Lead impedance must be 400 to 1000 ohms without change in trend

Pacemaker impedance No pacing related death/magnetic simulation

Battery longevity

EP Physician orders for device settings during MRI:

__________________________

EP Physician comments:

__________________________

EP Physician signature: ____________________________ Printed name:

Device Clinic Nurse signature: ____________________________ Printed name:

Providence
HEALTH CARE

Page 1 of 2
MAGNETIC RESONANCE IMAGING 
ASSESSMENT AND CHECKLIST 
FOR PATIENTS WITH PACEMAKER OR ICD

DAY OF MRI 
(to be completed by Device Clinic nurse prior to scan)

Date: ________________________________

DEVICE TESTING (prior to scan)

- P wave
- Atrial threshold
- Atrial impedance
- R wave
- Ventricular threshold
- Ventricular impedance

☐ Pacing capture threshold values stable and below 2V at a pulse width of 0.4 ms
☐ Lead impedances 400 to 1500 ohms without any change in trend
☐ Both leads functioning normally (as evaluated during device check-up)
☐ No pacing related diaphragmatic stimulation

Device settings (programmed as per EP physician orders):

________________________________________ 

Device Clinic Nurse signature: __________________________ Printed name: __________________________

POST MRI (to be completed by Device Clinic nurse upon completion of MRI)

DEVICE TESTING (Post MRI)

- P wave
- Atrial threshold
- Atrial impedance
- R wave
- Ventricular threshold
- Ventricular impedance

☐ Pacing capture threshold values stable and below 2V at a pulse width of 0.4 ms
☐ Lead impedances 400 to 1500 ohms without any change in trend
☐ Both leads functioning normally (as evaluated during device check-up)

Device settings post MRI:

________________________________________

Follow-up:

________________________________________

Device Clinic Nurse signature: __________________________ Printed name: __________________________
Informed Consent

• As MRI imaging of “Non MRI Conditional” CIED systems is not routinely performed, it is not considered to be standard of practice.

• Signed informed consent should be obtained.

• Patient should be made aware of potential risks including:
  • Pacemaker or ICD dysfunction.
  • Pacemaker or ICD damage, requiring replacement.
  • Arrhythmia.
  • Tissue ablation.
  • Death.
Procedure for MRI with MRI-unsafe Pacemaker or ICD

Patients with MRI-unsafe pacemakers or ICDs may require MRI procedures in extreme cases where the benefits outweigh the potential risks. Please follow the steps listed below to insure the patient’s safety during the MRI:

- MRI procedures may only be approved if the Radiologist has consulted with the referring physician and determined that the exam is absolutely necessary to the patient’s well-being, and the risks associated with the MRI are outweighed by the potential benefits.
- Scanning of the chest area or the area where the pacing device is implanted, including cardiac, brachial plexus or thoracic spine, is not to be performed.
- The pacemaker or ICD must have been implanted for at least 6 weeks.
- No other devices or abandoned/retained leads are present.
- Cardiologist, pacemaker team or Radiologist must confirm that the leads are not broken.
- Patients must sign an informed consent for treatment after having the risks explained to them by the Radiologist (Cardiac Fellow).
- A physician (Cardiac Fellow) must be present at all times during the procedure to monitor the patient’s hemodynamic function.
- Prior to the procedure and approximately 8 hours after the procedure (or next morning if lab visit not possible in the evening) a blood test to measure the patient’s Troponin levels must be performed. Requisition provided by Radiology.
- Prior to the procedure the cardiologist or pacemaker team must turn off the device’s sensing function for the duration of the exam.
- Crash cart with defibrillator must be readily available.
- Patient must be scanned in MRI #1 and hooked up to the ECG monitor, NIBP and pulse oximetry.
- The patient’s chest, including any other area the pacing device is implanted in must be wrapped in RF blankets. The RF blankets must fully encompass the patient’s chest – front, back and sides, and be in continuous contact all the way around.
- Use a Transmit-Receive coil where possible.
- Use “Normal” mode
- Use “Whole” gradients, not “Zoom”.
- Monitor and write down Average (whole body) SAR for all sequences. SAR must be <2.0 W/kg for all sequences.
- Avoid extending FOV or slices to encompass the area where the device is implanted.
- Radiologist should limit the protocol to a minimum number of sequences required for the exam.
- After the procedure the cardiologist or pacemaker team must:
  - Reset the pacemaker/ICD function.
  - Confirm correct operation of the device.
  - Compare the Troponin levels pre and post procedure (Dr. Leipsic gets a copy).
Section A:

Protocol for Conventional Cardiac Devices

MRI procedure approved after consultation by Radiologist and referring physician

- Leads implanted less than 6 weeks prior to MRI
- Abandoned or epicardial leads present
- Scanning of the chest area or area where the cardiac pacing device is implanted (including cardiac, brachial plexus or thoracic spine)

YES

MRI Contraindicated

NO

- Patient information and referral to EP physician for pre-MRI assessment clinic visit
- Blood test to measure troponin level ordered by radiologist
- X-ray ordered by Radiologist

Device Clinic Appointment

- EP physician assessment
- Cardiac device interrogation
- Documentation of clinic assessment and cardiac device testing on form PHC-HH126
- Orders for cardiac device settings during MRI documented by EP physician on form PHC-HH126
MRI

- Informed consent completed with Radiologist
- Cardiac device testing completed prior to scanning by device clinic nurse (documented on form PHC-HH126)
- Cardiac device settings programmed as per EP physician orders (documented on form PHC-HH126)
- Patient scanned in MRI room # 1 and attached to continuous ECG monitoring, NIBP and pulse oximetry
- Radiologist to be present at all times during procedure to monitor patients hemodynamic function
- Cardiac arrest cart with defibrillator readily available
- Patients chest, including an other areas the pacing device is implanted in must be wrapped in RF blankets. RF blankets must fully encompass the patients chest and be in continuous contact all the way around
- Use a transmit-receive coil where possible, use “normal” mode, “whole gradients”, not “zoom”
- Monitor and document average (whole body) SAR for all sequences. SAR must be less than 2 W/kg for all sequences
- Avoid extending FOV or slices to encompass the areas where the device is implanted
- Radiologist should limit the protocol to a minimum number of sequences required for the exam

Post MRI

- Cardiac Device testing completed by device clinic nurse (documented on form PHC-HH126)
- Cardiac device settings reprogrammed to original settings
- Any changes with device testing discussed with EP physician on call
- Blood test to measure troponin level ordered and results reviewed with Radiologist
- Follow-up plan for assessment of cardiac device discussed with patient
St. Paul’s Hospital Experience

• We have done over 70 exams on patients with CIEDs (1/week).
• No incidents of patient injuries or negative outcomes.
• No rise in Troponin levels.
• One instance of a “Power-on Reset” with an old ICD, but no triggering of the ICD and patient noticed no effect.
• PM or ICDs pre-2000 may be prone to “Power-on Resets” occurring when exposed to magnetic fields.
• Minor decrease in battery voltage.
Other Sites

- Many sites in the US have experience with scanning CIEDs in MRI
  - Johns Hopkins
  - Oklahoma Heart Institute
  - Parkwest Hospital, Nashville TN
  - Scripps Institute, La Jolia
  - University of Pennsylvania

- Over 8,000 pacemaker and 2,500 ICD patients scanned worldwide.

“We have turned a once exceptional procedure into one that is now routine at Hopkins.” - Henry Halperin, JHU Nov. 2006
Literature Review – “Non MRI Conditional”

• There have been many small-scale studies, primarily at 1.5T.
• Most had no significant events, other than a few “Power-on Resets”.
• Most had fewer additional safety steps than the SPH paradigm.
• 1043 patients in total.
## Literature Review – “Non MRI Conditional”

<table>
<thead>
<tr>
<th>Study</th>
<th>Total number of patients</th>
<th>Number of pacemaker patients</th>
<th>Tesla (T)</th>
<th>Number of pacemaker-dependent patients</th>
<th>Abnormal device-related findings during or after MR scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sommer et al. [44]</td>
<td>82</td>
<td>82</td>
<td>1.5T</td>
<td>0</td>
<td>Electrical reset (n=7) Increased pacing threshold noted after MR scanning; none of which resulted in changes in the programmed output.</td>
</tr>
<tr>
<td>Nazarian et al. [45]</td>
<td>55</td>
<td>31</td>
<td>1.5T</td>
<td>12</td>
<td>None.</td>
</tr>
<tr>
<td>Nashle et al. [36]</td>
<td>44</td>
<td>44</td>
<td>3.0T</td>
<td>0</td>
<td>None.</td>
</tr>
<tr>
<td>Mollerus et al. [46]</td>
<td>37</td>
<td>32</td>
<td>1.5T</td>
<td>0</td>
<td>None.</td>
</tr>
<tr>
<td>Nashle et al. [47]</td>
<td>47</td>
<td>47</td>
<td>1.5T</td>
<td>NA</td>
<td>Decreased pacing thresholds and battery voltage with repetitive MR scanning (171 scans in 47 patients). These changes did not lead to changes in programmed output.</td>
</tr>
<tr>
<td>Mollerus et al. [48]</td>
<td>52</td>
<td>46</td>
<td>1.5T</td>
<td>0</td>
<td>Asymptomatic ventricular ectopy during MR scanning; some was secondary to the noise reversion function of the device. (n=4)</td>
</tr>
<tr>
<td>Pulver et al. [49]</td>
<td>8</td>
<td>8</td>
<td>1.5T</td>
<td>0</td>
<td>None.</td>
</tr>
<tr>
<td>Mollerus et al. [50]</td>
<td>127</td>
<td>105</td>
<td>1.5T</td>
<td>0</td>
<td>None.</td>
</tr>
<tr>
<td>Study</td>
<td>Total number of patients</td>
<td>Number of pacemaker patients</td>
<td>Tesla (T)</td>
<td>Number of pacemaker-dependent patients</td>
<td>Abnormal device-related findings during or after MR scanning</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------</td>
<td>------------------------------</td>
<td>-----------</td>
<td>----------------------------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>Halshok et al. [51]</td>
<td>18</td>
<td>9</td>
<td>1.5T</td>
<td>6</td>
<td>Power-on-reset. (n=2)</td>
</tr>
<tr>
<td>Strach et al. [52]</td>
<td>114</td>
<td>114</td>
<td>0.2T</td>
<td>Yes (exact number unknown)</td>
<td>None.</td>
</tr>
<tr>
<td>Burke et al. [53]</td>
<td>38</td>
<td>24</td>
<td>1.5T</td>
<td>6 in total (unclear how many patients had pacemakers)</td>
<td>None.</td>
</tr>
<tr>
<td>Buendia et al. [54]</td>
<td>33</td>
<td>28</td>
<td>1.5T</td>
<td>4 in total (unclear how many patients had pacemakers)</td>
<td>Temporary communication failure. (n=2) * Oversensing due to EMI. (n=1) * Safety signal. (n=1)</td>
</tr>
<tr>
<td>Nazarian et al. [55]</td>
<td>438</td>
<td>237</td>
<td>1.5T</td>
<td>53</td>
<td>Power-on-reset (n=2).</td>
</tr>
<tr>
<td>Cohen et al. [57]</td>
<td>109</td>
<td>69</td>
<td>1.5T</td>
<td>29 in total (unclear how many patients had pacemakers)</td>
<td>Changes in various lead parameters were noted (2-12%) that were not statistically different than a historical control group.</td>
</tr>
<tr>
<td>Boilson et al. [56]</td>
<td>32</td>
<td>32</td>
<td>1.5T</td>
<td>0</td>
<td>Power-on-reset. (n=5) * Magnet mode asynchronous pacing. (n=3)</td>
</tr>
</tbody>
</table>
## Literature Review – “Non MRI Conditional”

<table>
<thead>
<tr>
<th>Study</th>
<th>Total number of patients</th>
<th>Number of ICD patients</th>
<th>Tesla (T)</th>
<th>Number of pacemaker-dependent patients</th>
<th>Abnormal device-related findings during or after MR scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giambel et al. [57]</td>
<td>7</td>
<td>7</td>
<td>1.5T</td>
<td>0</td>
<td>Power-on-reset. (n=1)</td>
</tr>
<tr>
<td>Nazarian et al. [45]</td>
<td>55</td>
<td>24</td>
<td>1.5T</td>
<td>0</td>
<td>None.</td>
</tr>
<tr>
<td>Mollerus et al. [46]</td>
<td>37</td>
<td>5</td>
<td>1.5T</td>
<td>0</td>
<td>None.</td>
</tr>
<tr>
<td>Nashle et al. [58]</td>
<td>18</td>
<td>18</td>
<td>1.5T</td>
<td>0</td>
<td>Decrease in battery voltage. (n=2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Oversensing of EMI as ventricular fibrillation; no ICD therapy was delivered. (n=2)</td>
</tr>
<tr>
<td>Mollerus et al. [48]</td>
<td>52</td>
<td>6</td>
<td>1.5T</td>
<td>0</td>
<td>Asymptomatic ventricular ectopy during MR scanning; some was secondary to the noise reversion function of the device (n=3).</td>
</tr>
<tr>
<td>Mollerus et al. [50]</td>
<td>127</td>
<td>22</td>
<td>1.5T</td>
<td>0</td>
<td>Decreased sensing amplitudes and pace impedances.</td>
</tr>
<tr>
<td>Halshok et al. [51]</td>
<td>18</td>
<td>9</td>
<td>1.5T</td>
<td>0</td>
<td>None.</td>
</tr>
<tr>
<td>Buhe et al. [53]</td>
<td>38</td>
<td>14</td>
<td>1.5T</td>
<td>0</td>
<td>None.</td>
</tr>
</tbody>
</table>
Determining the Risks of Magnetic Resonance Imaging at 1.5 Tesla for Patients with Non-MRI Conditional Pacemakers and Implantable Cardioverter Defibrillators: Final Results of The MagnaSafe Registry

November 18, 2014, 8:21 - 8:31 AM
MagnaSafe Registry

- Patient with cardiac device and MRI clinically indicated
  - Subjects enroll in study
  - Device parameters recorded
  - Magnetic resonance imaging

Device parameters recorded
- Restore or Adjust settings
- Parameter Change?
  - Yes: Follow-up interrogation within 7 days
    - Follow-up interrogation at 3 months
  - No: Follow-up interrogation at 3-6 months when clinically indicated
**Inclusion Criteria**

- Male or female 18 years of age or older
- Able to provide informed consent
- Permanent pacemaker or ICD placement after 2001
- Strong clinical indication for MRI
- Scheduled for non-thoracic MRI

**Exclusion Criteria**

- Metallic objects or implanted devices that represent a contraindication to MRI
- ICD patients who are pacemaker dependent
- Abandoned pacemaker or ICD leads
- Abdominal device placement
- Device generator battery voltage at ERI
- Claustrophobia unresponsive to sedatives
- Morbid obesity (abdominal diameter > 60 cm)
Magnasafe

- 1,500 exams (1,000 PM, 500 ICD)
- All “Non MRI Compatible”
- Pacemaker dependent patients were included in the PM group, but not in the ICD group.
- Scans lasted an average of 45 minutes.
- Some patients had multiple exams done (up to 10)
- No exams of the thorax were done (40% spine, 35% brain, 10% joints, 5% abdo/pelvis, 10% other)
Magnasafe

• No patients died.
• No leads failed.
• In 1 patient with an inappropriately programmed ICD, the generator failed and was immediately replaced.
• No patient had ventricular arrhythmia.
• 6 patients had episodes of atrial fibrillation (note: 5 had known atrial fibrillation normally and were on warfarin, and all cases resolved prior to discharge).
Magnasafe

- 6 patients had “Power-on Reset”
- Change in lead impedance was not associated with clinically significant parameter changes.
MagnaSafe - Conclusions

• Patients with devices need to be evaluated going into and coming out of the scanner. They need continuous-pulse oximetry during the exam so pulse rates may be monitored.

• Programming of the device (rendering it inactive) prior to the exam is critical.

"clinically indicated nonthoracic MRI at 1.5 T can be performed for patients with standard nonconditional devices at no significant clinical risk when patients are appropriately screened and the device is appropriately programmed”
More Studies in Progress

- 438 patients with CIEDs underwent 555 MRI exams without significant complications.
Role of MRI-Compatible CIEDs

- Companies are investing large amounts of money into developing and validating MRI-conditional CIEDs.
- Certainly these devices add to the safety level of performing an MRI in the presence of a CIED, however they are still not widely accepted at all sites due to the requirement that in-magnet monitoring take place.
- They are also more expensive than conventional CIED.
- Many are being implanted with easier to use leads, which results in the combination of generator and lead not being validated (must be treated as “non MRI compatible”).
"Considering the millions of dollars of industry support, it would be career suicide for a key opinion leader in electrophysiology to take a strong stand in this debate.” - Anon

“The profusion of MRI conditional products is hyper-expensive psychotherapy for our radiologists (who feel the "rules" must be followed no matter how inane), and the increased cost of the devices another FDA-Society Guideline-Corporate boondoggle. Health care providers, patients and payers are all losers with MRI conditional products” – Dr. Frank Tyers
Barriers to performing MRI with CIEDs

- Historical perception that they are “MRI-Unsafe”.
- Cost and requirement for MRI-compatible monitoring equipment.
- MRI exam time is longer (time in bore is the same or shorter, but prep time is longer)
- Buy-in from EP lab and/or Cardiology.
- Fear of litigation.
- Cost of RF Shielding Blankets (approx. $5,000).
- Exams take longer to co-ordinate.
Overcoming the Barriers

• There is risk associated with performing MRI on patients with “non MRI compatible” CIEDs.
• The risk can be minimized by adopting appropriate strategies.
• Sites with the capacity to monitor patients during an MRI procedure should consider implementing a program to service these patients.
• The need is there……
Patient example:

- 49 year old male with known Oligodendroglioma resected.
- ? Recurrence.
- Pacemaker implanted May 2015.
Small enhancing lesion. Not evident on CT. Needs 3-6 month follow-up with MRI.
Patient example

- 52 year old male with previous cervical intramedullary tumor removed.
- Condition deteriorating, ? Recurrence.
- Non-compatible pacemaker implanted April 2005.
Post surgical changes only. No new tumor enhancement on T1 post gad. Further imaging recommended only if patient’s clinical presentation worsens.
Summary

• “MRI Unsafe” for CIEDs is a misnomer.
• “Non-Conditional” CIEDs can be safely exposed to MRI exams if appropriate protocols are followed.
• The patient need is growing and MRI services should not be withheld from this patient population.
Special Thanks

• Drs. Darra Murphy, Jonathon Leipsic, Cameron Hague and Jen Ellis
• Cardiac Imaging Fellows at St. Paul’s Hospital
• Electrophysiology Team at SPH
• The MRI Technologists at St. Paul’s Hospital