Devices and EP- Safety in MRI

Mohammad Shenasa M.D. FACC, FHRS, FESC
O’Connor Hospital
San Jose, CA
Biblioteca-Alexandria
Alexandria-Egypt
Cardio Alex
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Effect of External Electrical and Magnetic Fields on Pacemakers and Defibrillators

- Annual implants
- >700,000 pacemakers
- >200,000 ICDs
- Exponential increase in medical imaging modalities
- It is estimated that up to 75% of pacemaker patients will have a medical need for an MRI over the lifetime of their device

Magnetic Resonance Imaging (MRI) advantages

• No ionizing radiation

• No contrast media nephrotoxicity

• Tissue characterization

• Very important in the study of:
  − Central nervous system
  − Malignancies
  − musculoskeletal system

• Growing importance in the study of cardiovascular disease (myocardium evaluation)
MRI and cardiac devices (1)

- Growing use in several different clinical scenarios
- Rising number of patients with an implantable device – advanced age
- Up to **75%** of device patients will develop an indication for MRI
Radiofrequency energy (2)

- **Leads** can act as an antenna and concentrate RF energy on the tip causing **heating and necrosis of the adjacent myocardial tissue**.

- **Pacing threshold elevation**, sensing reduction, troponin rising, myocardial perforation, burning.

- RF can induce **electrical currents** within conductor coils and leads that can **directly stimulate heart** (unintended cardiac stimulation) and cause arrhythmias.

- Inappropriate antitachycardia therapies (e.g. ICD shock)
MRI and cardiac devices: current recommendations

Table 3 Magnetic resonance imaging and pacemakers: safety concerns and guidelines

<table>
<thead>
<tr>
<th>Patients are divided into three groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Pacemaker-dependent patients (very high risk)</td>
</tr>
<tr>
<td>2) ICD patient (non-dependent)³ (high risk)</td>
</tr>
<tr>
<td>3) Pacemaker patient (non-dependent) (low risk)</td>
</tr>
<tr>
<td>If underlying rhythm is too slow—re-consider indication. The threshold for imaging and the safety requirements are higher, but no absolute contraindication</td>
</tr>
<tr>
<td>The patient must have a documented extremely serious, life threatening or severely quality-of-life limiting condition</td>
</tr>
<tr>
<td>The patient must have a documented very serious, life threatening or severely quality-of-life limiting condition</td>
</tr>
</tbody>
</table>
³Because of higher degree of interaction between MR imaging and ICD, the threshold for imaging is higher than for pacemakers.

Table 2. Recommendations for the Performance of MR Examinations in Patients With Pacemakers or ICDs

General recommendations:
MR examination of non–pacemaker-dependent patients is discouraged and should only be considered in cases in which there is a strong clinical indication and in which the benefits clearly outweigh the risks
MR examination of pacemaker-dependent patients should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks
MR examination of patients with ICDs should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks
Scanning should only be performed at extremely experienced centers with expertise in MR imaging and electrophysiology.
Establish and document the risk-benefit ratio for the patient.

Roguin et al. Europace 2008;336-340

**Electromagnetic Interference**

**What is EMI?**

- EMI is the term used to describe the effect of an electromagnetic field on the operation of an implanted heart rhythm device.
- Electromagnetic fields are invisible lines of force due to a combination of electrical fields (produced by voltage) and magnetic fields (produced by current flow) that an object emits.
- EMI occurs when the signals from an electromagnetic field temporarily interfere with the intended operation of the implanted device.
Definitions

• 1 Tesla = 10,000 Gauss = 796 A/m

• Tesla; intensity of static magnetic field

• It is accepted that local field strength of 10 Gauss is causing Electromagnetic Interference (EMI).

• In contrast to static and spatial gradient magnetic fields, gradient coils in MRI scanners produce time varying gradient magnetic filed for spatial encoding of the MRI signal generating EMI.
New terminology for medical device labeling in MRI environment

**MRI safe**
An item that poses no known hazards in any MR environment.

**MRI conditional**
An item that has been demonstrated to pose no known hazards in a specified MR imaging environment with specified conditions of use (specific MRI settings and configurations of the item)

**MRI unsafe**
An item that is known to pose hazards in all MR environments
CIEDs and MRI

• Mechanism of interaction between MRI and cardiac devices

• MRI scan in patients with a cardiac device

• MRI-compatible devices

• How to perform a safe MRI in patients with a MRI conditional device

• Implantation: when and to who
Potential Cardiac Implantable Device Complications from MRI

- Inappropriate defibrillator firing
- Asynchronous pacing
- Inhibition of pacing
- Battery depletion
- Induction of malignant tachyarrhythmias
- Power-on-reset
- Reed switch malfunction
- Image artifacts
- Device malfunction and damage
- Force and torque leading to device or lead dislodgement
- Thermal injury leading to myocardial necrosis or perforation
- Death

In comparison to MRI magnetic field strength of 1.5Tesla (15,000Gauss), earth magnetic field is about 0.65Gauss only.
How to prevent EMI

Current devices

- Shielding
- Filters
- Bipolar leads
Pacing/ICD system integrity checks

- Pacemaker and both leads implanted >6 weeks
- Pectoral implantation
- No other active pacing or implantable cardioverter-defibrillator devices or leads
- No abandoned leads, lead extenders, or adapters
- Leads electrically intact, with stable and normal function
- Lead impedance between 200 and 1,500 Ω
- Capture threshold <2.0 V and 0.4 ms

How could EMI affect my device?

• In some cases, an implanted device may sense the electromagnetic signals produced by some objects and misinterpret them as a rapid signal coming from your heart.

• A pacemaker (including the pacemaker contained within a defibrillator) may interpret the signals as heart rhythm. It may respond by withholding its pacing.

• A defibrillator may interpret the signals as a heart rhythm that needs therapy. This could cause the device to deliver a shock that is not needed. In rare cases, the device could withhold a necessary shock.

• The effects of EMI are temporary. The closer your implanted device is to the item, the stronger the effect. The farther away, the less effect you will experience. EMI effects do not usually harm the device.
How can a magnet affect the device?

• A magnet can also cause the implanted device to respond differently if the device gets within six inches of the magnet.

• The defibrillator will respond to a magnet based on how the doctor has programmed the device to respond. A pacemaker will respond by temporarily pacing at a different pre-set rate.

Case Study

- 71 year old male
- Nonsustained VT
- Intermittent Brugada Syndrome
- Mild HCM
- Device: Single chamber
- Medtronic Maximo VR 7232
- Patient received an inappropriate shock while in his Jacuzzi.
High-frequency noise and noise response ventricular pacing are noted on the bipolar ventricular channel from a single-chamber pacemaker during magnetic resonance imaging.
MRI-compatible devices

Still represent a contraindication to MRI:

• Abandoned leads

• Non MRI-compatible leads, even in the presence of a MRI-compatible generator

• Extensions/adapters

• Leads implanted less than 6 weeks earlier
Technical Test Set up

Helmholtz coils for the generation of magnetic fields.

EMF exposure: inappropriate atrial oversense and inappropriate V pacing, inadequate mode switch

Inadequate $A_{\text{sense}} \rightarrow V_{\text{pace}}$

Inadequate mode switch

Inadequate $V_{\text{sense}}$

EMF exposure

Biotronik Lumax 540 DR-T

EMF exposure (25.5kV/m /2150μT); V oversense in the VF zone

Ventricular oversensing

Unfiltered SNR (signal-to-noise ratio) vs. Filtered SNR (signal-to-noise ratio)

<table>
<thead>
<tr>
<th></th>
<th>Unfiltered</th>
<th>Filtered</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA</td>
<td>58</td>
<td>231</td>
</tr>
<tr>
<td>His</td>
<td>3.7</td>
<td>72</td>
</tr>
<tr>
<td>RV</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Background

• MRI can provide information not readily obtained from other imaging modalities
• Estimated that at least half of all patients with implanted device could benefit from an MRI
• But - MRI currently contraindicated in most centers
  – Theoretical effects
    • Forces and torques on generator and lead
    • Generator damage and/or reprogramming
    • Heating of tissue
    • Inhibition of pacemaker
    • Rapid pacing
    • Image distortion
  – 13 deaths reported (none during monitoring)
Early Devices – Not Safe

• Fetter, Hayes et al. *Pace* 7:720-727, 1984
  – 0.15 T, 6.5 MHz, Reed Switch activated
  – Some inhibited; Some triggered at Gradient Freq

  – 0.5 T, 20.9 MHz; DDD pacemakers (4)
  – 3 Inhibited; 1 pulsed at 800/min

• Hayes et al, *JACC*, 10:782-786, 1987
  – 1.5 T, 63.9 MHz; Dual chamber with unipolar leads
  – 7 triggered at 300/min
Modern Systems Have Evolved

Should our Thinking Evolve?
Modern Devices

• Smaller

• Have less ferromagnetic material

• Have improved EMI protection
Conclusion: These data suggest that certain modern pacemaker and ICD systems may indeed be MRI Safe. This may have major clinical implications for current imaging practices.
## Temperature Changes in ICD Leads

<table>
<thead>
<tr>
<th>Length (cm)</th>
<th>Name</th>
<th>maximal heating (T°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>58</td>
<td>Medtronic 6945 58cm *</td>
<td>3.0</td>
</tr>
<tr>
<td>65</td>
<td>Medtronic 6945 65cm *</td>
<td>7.2</td>
</tr>
<tr>
<td>75</td>
<td>Medtronic 6945 75cm *</td>
<td>0.8</td>
</tr>
<tr>
<td>65</td>
<td>Medtronic 6944 65cm</td>
<td>1.8</td>
</tr>
<tr>
<td>65</td>
<td>Medtronic 6942 65cm</td>
<td>0.3</td>
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<td>65</td>
<td>Medtronic 6947 65cm *</td>
<td>0.2</td>
</tr>
<tr>
<td>65</td>
<td>Medtronic 6932 65cm</td>
<td>1.2</td>
</tr>
<tr>
<td>65</td>
<td>St Jude RIATA 1580 65cm *</td>
<td>1.6</td>
</tr>
<tr>
<td>65</td>
<td>St Jude RIATA 1571 65cm</td>
<td>2.5</td>
</tr>
<tr>
<td>64</td>
<td>Guidant Endotak Reliance 64cm</td>
<td>1.5</td>
</tr>
</tbody>
</table>

* Active leads

Temperature

- *In vitro*, Clinical MRI protocols: temperature rise $\leq 0.9\, ^\circ C$.
- *In vivo* ($n=3$), SAR up to 3.9 W/kg: temperature rise $\leq 0.2\, ^\circ C$

Torque

- Modern devices: torque $\leq 150\, \text{g-cm}$

Force

- Modern devices: force $\leq 120\, \text{gm (2 golf balls)}$
### In Vitro ICD Function

<table>
<thead>
<tr>
<th>Device</th>
<th>Number of devices tested</th>
<th>FDA Year</th>
<th>Battery Change</th>
<th>Parameters Change</th>
<th>Memory Change</th>
<th>Problems in Interrogation</th>
<th>Comments</th>
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<tr>
<td><strong>St Jude</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>ANGSTROM II</td>
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<tr>
<td>Photon DR</td>
<td>2</td>
<td>2000</td>
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<tr>
<td>Photon μ DR</td>
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<td></td>
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<tr>
<td>Atlas</td>
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<td>2001</td>
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<td></td>
<td></td>
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<tr>
<td>Epic</td>
<td>4</td>
<td>2002</td>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td></td>
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<tr>
<td><strong>Guidant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>VENTAK MINI II 1762</td>
<td>2</td>
<td>1996</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Yes</td>
<td>&quot;Out of Range&quot;</td>
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<tr>
<td>VENTAK AV 1810</td>
<td>1</td>
<td>1997</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Yes</td>
<td>&quot;Out of range&quot; → Warning: A pulse generator fault has occurred</td>
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<tr>
<td>VENTAK MINI III 1783</td>
<td>1</td>
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<td>NA</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>VENTAK MINI IV 1790</td>
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<td>Yes</td>
<td>-</td>
<td>Yes</td>
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<tr>
<td>Prizm VR</td>
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<td>2000</td>
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<td>Prizm DR</td>
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<td>2000</td>
<td>Yes</td>
<td>-</td>
<td></td>
<td>No</td>
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<td>-</td>
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<td>-</td>
<td></td>
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<tr>
<td><strong>Medtronic</strong></td>
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<tr>
<td>GEM I DR 7271</td>
<td>4</td>
<td>1998</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Electrical RESET occurred.(x3) interrogation inoperative (x1)</td>
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<tr>
<td>GEM II DR 7273</td>
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<td>1999</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>GEM III DR 7275</td>
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<tr>
<td>Marquis DR 7274</td>
<td>3</td>
<td>2002</td>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

In vivo Protocol

- ICDs implanted in 15 dogs 35-45 Kg (with MRI scan)
  - 5 Marquis, 5 Epic, 5 Prizm 2
- ICDs implanted in 3 additional dogs (No MRI scan)

![Diagram showing implantation of device, MRI, sacrifice, and interrogation over 8 weeks.](image-url)
Pacing Thresholds (n=15): Different Pulse Widths

Volts

Weeks

MRI

0.1msec
0.2msec
0.5msec
1.0msec
1.5msec

0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5

0 1 2 3 4 5 6 7 8

Weeks
Gross and Histopathology

No adverse effects with modern devices, with device programmed inhibited or fixed rate, patient monitored

Protocol

- Generator previously tested to be MRI safe
- Device interrogated pre MRI
  - P/R amplitudes, pacing threshold, lead impedance
- Device programmed inhibited or fixed rate (ICD off)
- Monitoring during scan (EP/cardiology fellow/device nurse)
- Device interrogated post MRI
- Device reprogrammed to pre-MRI parameters

Nazarian, et al, Circulation. 2006;114(12):1277-84
Adequate Image Quality

Adequate Image Quality

Conclusion: With appropriate precaution, MRI can be done safely in patients with selected cardiac devices. Because changes in device variables and programing may occur, electrophysiologic monitoring during MRI is essential.
Clinical Study

- 555 MRI examinations performed in 438 pts
  - 55% with permanent pacemaker
  - 45% with ICD
- Monitoring/programming by device nurse
- No significant adverse events – a few POR
- Trivial changes in pacing parameters
- Diagnostic question answered in 95%
  
- Now over 1500 scans – similar results
- CMS approved
## Parameter Changes

### Associated Factors

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Acute right ventricular R-wave amplitude, mV</th>
<th>Long-term battery voltage, V</th>
<th>Acute right ventricular lead impedance, Ω</th>
<th>Acute battery voltage, V</th>
<th>Long-term right ventricular R-wave amplitude, mV</th>
<th>Long-term right ventricular lead impedance, Ω</th>
<th>Long-term right ventricular capture threshold, V</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First: 0 (−1.0 to 0)</td>
<td>No association</td>
<td>No association</td>
<td>No association</td>
<td>First: 0 (−0.4 to 0.4)</td>
<td>No association</td>
<td>No association</td>
</tr>
<tr>
<td></td>
<td>Second: 0 (−0.7 to 0.05)</td>
<td></td>
<td></td>
<td></td>
<td>Second: −0.1 (−0.8 to 0.6)</td>
<td></td>
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<tr>
<td></td>
<td>Third: −0.3 (−0.9 to 0)</td>
<td></td>
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<td></td>
<td>Third: −0.2 (−0.8 to 1.8)</td>
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</tr>
<tr>
<td></td>
<td>$P = 0.059$</td>
<td></td>
<td></td>
<td></td>
<td>$P = 0.081$</td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>46 cm: 0 (−0.5 to 0.1)</td>
<td>No association</td>
<td>No association</td>
<td>No association</td>
<td>46 cm: −0.1 (−0.8 to 1)</td>
<td>No association</td>
<td>No association</td>
</tr>
<tr>
<td></td>
<td>52 cm: 0 (−0.4 to 0)</td>
<td></td>
<td></td>
<td></td>
<td>52 cm: 0 (−0.7 to 1.8)</td>
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<tr>
<td></td>
<td>59 cm: −0.1 (−1.0 to 0)</td>
<td></td>
<td></td>
<td></td>
<td>59 cm: 0.4 (−3.1 to 1.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>64 cm: 0 (−0.8 to 0.7)</td>
<td></td>
<td></td>
<td></td>
<td>64 cm: −0.4 (−1.1 to 1.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$P = 0.033$</td>
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<td>$P = 0.022$</td>
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<td>Nonthoracic: 0 (−0.6 to 0)</td>
<td>No association</td>
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<td>Nonthoracic: 0 (−0.8 to 0.4)</td>
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<tr>
<td></td>
<td>Thoracic: 0 (−0.8 to 0)</td>
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<td>Thoracic: −1.4 (−2.5 to 0)</td>
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<tr>
<td></td>
<td>$P = 0.044$</td>
<td></td>
<td></td>
<td></td>
<td>$P = 0.009$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MRI in ICD Patients

- 24 patients (59±7y) with CMP (EF 23±11%; 78% ischemic)

- Remote ICD implantation (1367±438 days)
  - Single (9), dual (12), BiV (3) ICD
  - Medtronic (10), BSC (7), SJM (7)

- Exclusion criteria
  - Epicardial/abandoned leads
  - ICDs manufactured before 2002
  - <6 weeks after ICD implantation
  - Creatinine clearance <30ml/min
  - Need for MRI sequences>2W/kg

Dickfeld et al. Circ Arrhythm Electrophysiol. 2011;4:172
## Results: ICD Parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Pre-MRI</th>
<th>Post-MRI</th>
<th>Follow-Up (72±23d)</th>
<th>p-value (pre/post)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-wave amplitude [mV]</td>
<td>3.3±2.1</td>
<td>3.0±1.4</td>
<td>3.1±1.6</td>
<td>p=0.24</td>
</tr>
<tr>
<td>R-wave amplitude [mV]</td>
<td>9.7±5.1</td>
<td>10.2±5.4</td>
<td>10.1±5.9</td>
<td>p=0.12</td>
</tr>
<tr>
<td>Atrial lead impedance [Ω]</td>
<td>484±79</td>
<td>476±69</td>
<td>462±83</td>
<td>p=0.39</td>
</tr>
<tr>
<td>Ventricular imp. [Ω]</td>
<td>451±89</td>
<td>451±89</td>
<td>450±95</td>
<td>p=0.58</td>
</tr>
<tr>
<td>Shock impedance [Ω]</td>
<td>45±8</td>
<td>45±8</td>
<td>44±7</td>
<td>p=0.41</td>
</tr>
<tr>
<td>Atrial capture [V]</td>
<td>1.6±0.9</td>
<td>1.4±0.9</td>
<td>1.5±1.0</td>
<td>p=0.34</td>
</tr>
<tr>
<td>Atrial capture [V]*[ms]</td>
<td>0.41±0.23</td>
<td>0.41±0.22</td>
<td>0.41±0.28</td>
<td>p=0.34</td>
</tr>
<tr>
<td>Ventricular capture [V]</td>
<td>1.4±0.9</td>
<td>1.6±0.7</td>
<td>1.5±0.7</td>
<td>p=0.33</td>
</tr>
<tr>
<td>Ventricular capture [V]*[ms]</td>
<td>0.43±0.18</td>
<td>0.44±0.16</td>
<td>0.44±0.15</td>
<td>p=0.65</td>
</tr>
<tr>
<td>Battery [V]</td>
<td>2.97±0.21</td>
<td>2.97±0.21</td>
<td>2.95±0.22</td>
<td>p=0.08</td>
</tr>
</tbody>
</table>

Dickfeld et al. Circ Arrhythm Electrophysiol. 2011;4:172
Results
- MRI: 3D Imaging Extraction -

SA MRI Slices

RV Myocardium

LV Endocardium

LV Epicardium

LV Scar

Dickfeld et al. Circ Arrhythm Electrophysiol. 2011;4:172
Safe Imaging with MRI Conditional Device

- Medtronic EnRhythm (Now Revo) pacemaker
  - 464 patients randomized to MRI 9-12 weeks post implant
  - 1.5 T scanner – isocenter not in chest

- MRI in 258, No MRI in 206

- Pre and post exam interrogation, including 1 wk, 1 mo

- Monitoring with cardiologist, ECG, pulse oxymetry

- No pacing dysfunction/arrhythmias, reprogramming

- Minimal changes in sensing and capture thresholds

- MRI and control group similar

Image Artifacts
Cardiac MRI and pacemakers (1)

Cardiac magnetic resonance imaging at 1.5 T in patients with cardiac rhythm devices

Francisco Buendia, Óscar Cano, Juan Miguel Sánchez-Gómez, Begoña Igual, Joaquín Osca, María José Sancho-Tello, José Otagüe, and Antonio Salvador

MRI image artifacts

- **Mild**: No influence on diagnosis (Group A)
- **Moderate**: No influence on diagnosis (Group B)
- **Severe**: Prevent diagnosis (Group C)

IMAGING ARTIFACT

- **GROUP A**: 28
- **GROUP B**: 3
- **GROUP C**: 5

9.7% Significant artifacts (Group B and C)

Caused from the generator

Much less from leads

Consider right-sided implantation?
Artifacts – Cine MRI
Image Artifacts:
Different Pulse Sequences and imaging planes

- No device malfunction
- No change in parameters
- Did not feel any pulling or pain in area
- Had successful detection of VT and ICD firing 2 weeks later

29 yo man with ARVD
Mitigating Artifacts

- Imaging sequences – Spin Echo vs Gradient
  - Newer sequences under development
- Imaging planes
- Device away from heart
  - Patient size
  - Implant higher up on chest
  - Implant on right side
- New shimming techniques
  - In NMR and MRI, shimming is used prior to the operation of the magnet to eliminate inhomogeneities in its field.
MRI and extraction of anatomy in patients with ICDs. A, Inverse recovery serial short-axis MRI images (apical-to-base scan plane, 1 to 6).

Visualization of anterior scar, artifact, and viable myocardium.

Dickfeld T et al. Circ Arrhythm Electrophysiol. 2011;4:172-184
MRI-compatible devices
<table>
<thead>
<tr>
<th>Modification</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced content of ferromagnetic components</td>
<td>Reduced device movement and torsion</td>
</tr>
<tr>
<td>Internal circuits modified to minimize unintended</td>
<td>No arrhythmia induction</td>
</tr>
<tr>
<td>stimulation</td>
<td></td>
</tr>
<tr>
<td>Circuits protection filter</td>
<td>No risk of electrical reset</td>
</tr>
<tr>
<td>Reed switch replaced with Hall sensor</td>
<td>Avoids asynchronouse/competitive pacing with risk of VF –</td>
</tr>
<tr>
<td></td>
<td>predictable response of the sensor</td>
</tr>
<tr>
<td>Leads redesigned with modifications in metal spiral,</td>
<td>No lead tip overheating</td>
</tr>
<tr>
<td>diameter and filters to reduce RF conductivity</td>
<td></td>
</tr>
<tr>
<td>Dedicated software with MRI mode</td>
<td>No asistole, asynchronous pacing and inappropriate therapies</td>
</tr>
<tr>
<td>Radiopaque markers</td>
<td>Identification of the MRI-conditional device</td>
</tr>
</tbody>
</table>
Implantable loop recorders

- MRI conditional – 3 Tesla
- Any time after implantation
- No adverse events reported
- Possible sensation of movement at the pocket level
- Possible cancellation of the events in memory
- Possible registration of false arrhythmias during MRI

→ Device check before and after MRI scan
Performing magnetic resonance imaging in patients with implantable pacemakers and defibrillators: results of a European Heart Rhythm Association survey

Germanas Marinskis, Maria Grazia Bongiorni, Nikolaos Dagres, Dan Dobreanu, Thorsten Lewalter, Carina Blomstrom-Lundqvist, and conducted by the Scientific Initiative Committee, European Heart Rhythm Association

Table 1 Responding centres’ experience in performing magnetic resonance imaging scans in implanted cardiac implantable electronic device patients (total numbers)

<table>
<thead>
<tr>
<th></th>
<th>Never (no experience) (%)</th>
<th>1–5 cases (%)</th>
<th>5–20 cases (%)</th>
<th>More than 20 cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-MRI-certified pacemakers</td>
<td>55.2</td>
<td>18.4</td>
<td>23.7</td>
<td>2.6</td>
</tr>
<tr>
<td>Non-MRI-certified ICDs</td>
<td>65.8</td>
<td>26.3</td>
<td>7.9</td>
<td>None</td>
</tr>
<tr>
<td>MRI-certified pacemakers</td>
<td>35.1</td>
<td>43.2</td>
<td>13.5</td>
<td>8.1</td>
</tr>
<tr>
<td>MRI-certified ICDs</td>
<td>73</td>
<td>21.6</td>
<td>5.4</td>
<td>None</td>
</tr>
</tbody>
</table>

Only 5.7% of centres stated that MRI-certified devices represent more than half of total implants.

Indications for MRI-certified CIEDs

- Pts with indication for MRI
- All patients
- No response
Performing magnetic resonance imaging in patients with implantable pacemakers and defibrillators: results of a European Heart Rhythm Association survey

Germanas Mariniskis¹, Maria Grazia Bongiorni², Nikolaos Dagres³, Dan Dobreanu⁴, Thorsten Lewalter⁵, Carina Blomström-Lundqvist⁶, and conducted by the Scientific Initiative Committee, European Heart Rhythm Association

Conclusion

This survey on clinical practice to perform MRI scans showed limited experience of performing MRI studies in patients with implanted pacemakers and ICDs. In concordance with available guidelines, most centres limit MRI scans in patients with non-MRI-certified devices. The implant numbers for MRI-certified devices and experience with performing MRI scans in these patients are still low.
Conclusions (2)

Critical elements to perform a safe MRI scan (valid also for MRI-conditional devices):

- Centers with expertise in MRI and electrophysiology
- Device reprogramming (in MRI mode) before the exam
- Pre and post-procedural device check
- Periprocedural monitoring!
Conclusions (3)

• Considerations on device choice at implantation:

  • Contraindications to MRI (es. epicardial/abandoned leads)
  • Poor prognosis in a short term

  • Patients clinical conditions with probable need for MRI
  • Older patients → multiple disease with need for MRI
  • Younger patients → more probability of a need for MRI due to the longer life expectancy
Summary

• When the device patient can have an MRI
  – If there is an MRI conditional device
  – Non-MRI Conditional: Indication is strong enough and proper precautions taken
• Image distortion occurs: generator and leads
• Image distortion can be reduced by proper image sequences, planes, and device placement
• Newer devices are needed that are prospectively designed to be MRI compatible
• Gadolinium-Enhanced contrast cannot be used in renal failure
Effects of MRI on PM/ICD

Table 1  Theoretical effects of static magnetic field, gradient magnetic fields and radiofrequency energy

<table>
<thead>
<tr>
<th></th>
<th>Static</th>
<th>Gradient</th>
<th>Radiofrequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case heating</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Force and torque</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Device interactions</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Lead heating</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Stimulation</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

- Not uniform nor reproducible, not predictable (different types of MRI scanner; different features of PM/ICD, different companies)
- Long term follow-up not available
MRI Safe Devices

- Medtronic: Revo MRI SureScan Pacing System
- St. Jude: Accent MRI Pacemaker, MRI Activator
- Biotronik: ProMRI
Consensus that data from MRI is required and is likely to change clinical management

- Abandoned lead or
- Conventional pacemaker implanted before 1998 or ICD before 2000

YES Consider alternative imaging

NO

Conventional pacemaker implanted after 1998 or ICD after 2000

MRI-conditional cardiac implantable device

Lead implanted >6 weeks

YES Full device interrogation

Underlying rhythm present?

YES

- Very slow underlying rate
  Program to asynchronous pacing (VOO/DOO) at a faster than intrinsic rate

- Low frequency of pacing
  - Adequate underlying rate
  Program to inhibited pacing mode (VVI/DDI)

- Assess risk and benefits with patient and referring physician.
  - If MRI absolutely necessary, program to asynchronous pacing (VOO/DOO)

NO

- Adjust device parameters (turn off rate response, tachycardia therapies, magnet rate, noise reversion)
- Continuous patient monitoring (oximetry, ECG, BP, responsiveness)
- Recheck all device parameters after MRI
- Reprogram device to original settings after MRI

## Current Approved MRI-Condition Cardiac Implantable Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Thoracic Exclusion</th>
<th>Lead Fixation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estella (ProMRI)</td>
<td>Biotronik</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active and passive</td>
</tr>
<tr>
<td>Evia (ProMRI)</td>
<td>Biotronik</td>
<td>Pacemaker</td>
<td>Yes</td>
<td>Active and passive</td>
</tr>
<tr>
<td>Evia HF-T (ProMRI)</td>
<td></td>
<td>CRT-P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advisa DR MRI SureScan</td>
<td>Medtronic</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active and passive</td>
</tr>
<tr>
<td>EnRhythm MRI SureScan</td>
<td>Medtronic</td>
<td>Pacemaker</td>
<td>Yes</td>
<td>Active and passive</td>
</tr>
<tr>
<td>Ensura MRI SureScan</td>
<td>Medtronic</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active and passive</td>
</tr>
<tr>
<td>Revo MRI SureScan</td>
<td>Medtronic</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active and passive</td>
</tr>
<tr>
<td>Accent MRI</td>
<td>St. Jude Medical</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active</td>
</tr>
<tr>
<td>Advantio MRI</td>
<td>Boston Scientific</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active and passive</td>
</tr>
<tr>
<td>Ingenio MRI</td>
<td>Boston Scientific</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active and passive</td>
</tr>
<tr>
<td>Reply MRI</td>
<td>Sorin</td>
<td>Pacemaker</td>
<td>No</td>
<td>Active</td>
</tr>
<tr>
<td>Lumax 740</td>
<td>Biotronik</td>
<td>ICD CRT-D</td>
<td>No</td>
<td>Active and passive</td>
</tr>
</tbody>
</table>

Safety of Computed Tomography in Patients with Cardiac Rhythm Management Devices

- **Study Design:**
  - 516 CT scans (332 defibrillations, 184 pacemakers)

- **Primary outcome:**
  - Inappropriate ICD shocks, device replacement, or significant change in device parameters,
  - Death, bradycardia/tachycardia requiring termination of the scan

- **Results:** None of the CT were associated with any adverse outcomes

- **Conclusion:** Presence of cardiac rhythm management devices should not result in the delay or cancellation of clinical indicated CT imaging.

Thank you
Safety Protocol for MRI

Was the pacemaker or ICD generator implanted after 1998 or 2000, respectively?*

Yes

Were the leads implanted ≥6 wk before MRI?

Yes

Are nontransvenous epicardial, abandoned, or no-fixation leads present?

No

Yes

Record device variables for comparison after MRI (lead impedance and threshold, P/R wave amplitude, and battery voltage)

Pacemaker-dependent?

No

Deactivate monitoring and tachyarrhythmia therapies (antitachycardia pacing/defibrillation)

Yes

Program pacing to VOO/DDQ (asynchronous)

Pacemaker-dependent?

No

Program pacing to VVI/DDR (inhibited)

No

Deactivate magnet, rate, PVC, noise, ventricular sense, and conducted atrial fibrillation response

Monitor blood pressure, ECG, oxygen saturation, and symptoms during MRI

Recheck device variables and compare with baseline values (lead impedance and threshold, P/R wave amplitude, and battery voltage)

Restore original programming

Follow-up interrogation in 3–6 mo