CRT-D and MRI: is it always a problem?

The role of the new devices

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**Pacing and MRI**

**MRI** was developed in 1946 by physicists Felix Bloch and Edward Purcell: they received Nobel prize for physics in 1952. The great development of the technique came with the studies of Paul C. Lauterbur and Sir Peter Mansfield, who created a system capable of:
- 2-D and 3-D images
- Very fast image acquisition system

**Cardiac pacing** has a history that begins in 1957. Several steps have marked its evolution:
- Development of integrated circuits and size reduction
- RF control
- Double-chamber systems
- Implantable Cardioverter Defibrillator (ICD)
- Cardiac Resynchronization
- Remote Monitoring device control
Advantages and disadvantages of MRI in clinical practice

Advantages:
- Higher contrast 
  resolution for soft tissues
- Main method to evaluate:
  - Central nervous system
  - Skeletal muscle system
  - Oncological conditions
  - Cardiovascular pathologies

- Use of non-ionizing radiation
- Multiplanar
- Multiparametric
- High contrast resolution
- It allows morphological, structural and functional analysis

Disadvantages:
- High costs for purchase and management
- Poor dissemination and availability
- Technically complex and lengthy procedures
- Claustrophobia, metallic implants
In Europe, the annual growth rate (CAGR – Compound Annual Growth Rate) is about 10%.

MRI scans in the world

In the image, the data shows the number of MRI procedures per year in various European countries along with their respective CAGR (Compound Annual Growth Rate). For instance:

- **France**: 1.7 million procedures with a CAGR of 6.8%.
- **Italy**: 1.7 million procedures with a CAGR of 11.9%.
- **Germany**: 4.9 million procedures with a CAGR of 9.3%.
- **Spain**: 1.9 million procedures with a CAGR of 11.9%.
- **Netherlands**: 0.7 million procedures with a CAGR of 0.9%.
- **UK**: 0.9 million procedures with a CAGR of 12%.

The chart illustrates the growth in MRI procedures from 1993 to 2003, distinguishing between non-hospital and hospital sites. The data highlights the significant increase in MRI scans over the years.
Increase of MRI scans

Percentage of MRI performed in relation to districts observed (2007)
Increase of cardio-MRI scans

- Percentage of cardio-MRI exams increased greatly since past years

- **Cardio-MRI**: gold standard in non-invasive measurement of biventricular volumes in resting and exercise states and in the assessment of subendocardial and transmural fibrosis and myocardial viability

- **Selection of CRT patients** could be more accurate by C-MRI; LV lead target vein could be best selected before CRT implantation, according to coronary sinus morphology and to scar zones and electrical activation delay

La Gerche et al, Circ Cardiovasc Imaging, 2012
Ishida et al., Circ J, 2009
Karamtisos et al., J. Am. Coll. Cardiol., 2009
Increase of cardio-MRI scans

La Gerche et al, Circ Cardiovasc Imaging, 2012
Ishida et al., Circ J, 2009
Karamtisos et al., J. Am. Coll. Cardiol., 2009
HF patients

• About 1.7% of European population is suffering from HF and American is settled at about 2.2%

The percentage tends to rise in relation to age of the patients:
✓ it ranges from 0.5% for age lower than 65 years
✓ up to 14% by age over 85 years
Cardiac Pacing today in Europe and US

**Figure 1** Implantable cardioverter defibrillator/CRT-D implantations per million of the population in Europe and the USA from 1990 to 2006.

**Table 2** Patient referrals for implantable cardioverter defibrillators/CRT-Ds by HF physicians

<table>
<thead>
<tr>
<th>Country</th>
<th>Physicians using HF-radar (cumulative)</th>
<th>Screened patients (cumulative)</th>
<th>Indicated patients (cumulative)</th>
<th>Referred patients (cumulative)</th>
<th>Implanted patients (cumulative)</th>
<th>Indicated/Screened (%)</th>
<th>Referred/Indicated (%)</th>
<th>Implanted Indicated (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Netherlands</td>
<td>57</td>
<td>947</td>
<td>432</td>
<td>235</td>
<td>105</td>
<td>46</td>
<td>54</td>
<td>24</td>
</tr>
<tr>
<td>Austria</td>
<td>16</td>
<td>496</td>
<td>233</td>
<td>92</td>
<td>58</td>
<td>47</td>
<td>39</td>
<td>25</td>
</tr>
<tr>
<td>UK</td>
<td>35</td>
<td>414</td>
<td>102</td>
<td>39</td>
<td>25</td>
<td>25</td>
<td>38</td>
<td>25</td>
</tr>
<tr>
<td>France</td>
<td>143</td>
<td>399</td>
<td>150</td>
<td>136</td>
<td>47</td>
<td>38</td>
<td>91</td>
<td>31</td>
</tr>
<tr>
<td>Italy</td>
<td>53</td>
<td>204</td>
<td>81</td>
<td>15</td>
<td>2</td>
<td>40</td>
<td>19</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>304</td>
<td>2460</td>
<td>998</td>
<td>517</td>
<td>237</td>
<td>41</td>
<td>52</td>
<td>24</td>
</tr>
</tbody>
</table>

*Only countries with relevant numbers of screened patients are mentioned and used for the statistics.


*The number of referred and implanted patients can be under-evaluated as they indicate the number of patients reported by physicians through HF-radar.*
Implantable devices and MRI

- 96% of patients with device is 60 years-old or more
- Average age of ICD patients is 70 years
- Life expectancy of a patient with a pacemaker is over 10 years
Implantable devices and MRI

MRI scans – Implants ratio

- More than 650,000 new implants of devices in the world
- MRI exams performed every year:
  - More than 22 millions in US
  - More than 35 millions in the rest of the world

50-75% probability of MRI exam prescription to a patient with device

Roguin et al., Europace 2008;10(3):336-46
History of MRI-conditional devices

Scientific evidences on conventional PM/ICD

Knowledge about potential risks and solutions to minimize them

Development of MRI-conditional PM/ICD
Devices and MRI

- Literature reports some clinical cases and studies on side-effects of MRI scan on pacemaker and ICD patients.

- **Non MRI-compatible generations** of devices already proved to be resistant to the electromagnetic field induced by MR.

Gimbel et al, PACE, 2005
Gimbel, Europace, 2010
Baley et al., accepted article on Heart Rhythm
Maglia et al, J Cardiovasc Med, 2014
Devices and MRI

• Few non-fatal effects and symptoms were reported by patients undergoing MRI scan (warmth, palpitations, tensile forces)

• Major consistence findings were based on ICD programming alterations or software hard-reset, some solved via software, some needed to be solved by device replacement

Gimbel et al, PACE, 2005
Gimbel, Europace, 2010
Baley et al., accepted article on Heart Rhythm
Maglia et al, J Cardiovasc Med, 2014
### Devices and MRI: reported effects

**Table 1** Clinical trials of magnetic resonance imaging in pacemaker patients

<table>
<thead>
<tr>
<th>Field strength</th>
<th>Trial</th>
<th>No. of patients</th>
<th>Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5</td>
<td>Coman et al.</td>
<td>11</td>
<td>One short asymptomatic pause in pacing during scanning, One power-on-reset</td>
</tr>
<tr>
<td></td>
<td>Gimbel et al.</td>
<td>7</td>
<td>One power-on-reset</td>
</tr>
<tr>
<td></td>
<td>Nazarian et al.</td>
<td>24 (55 total)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mollerus et al.</td>
<td>5 (37 total)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pulver et al.</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mollerus et al.</td>
<td>22 (127 total)</td>
<td>Decreased sensing amplitudes and impedances</td>
</tr>
<tr>
<td></td>
<td>Halshtok et al.</td>
<td>9 (18 total)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Burke et al.</td>
<td>14 (38 total)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Buendia et al.</td>
<td>5 (33 total)</td>
<td>One sensing error</td>
</tr>
<tr>
<td></td>
<td>Nazarian et al.</td>
<td>201 (438 total)</td>
<td>One power-on-reset, changes in pacing threshold</td>
</tr>
<tr>
<td></td>
<td>Cohen et al.</td>
<td>40 (109 total)</td>
<td>Decreases in battery voltage, pacing threshold increases, and impedance changes</td>
</tr>
</tbody>
</table>

**Table 2** Clinical trials of magnetic resonance imaging in implantable cardioverter defibrillator patients

<table>
<thead>
<tr>
<th>Field strength</th>
<th>Trial</th>
<th>No. of patients</th>
<th>Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Del Ojo et al.</td>
<td>13</td>
<td>Decreased sensing amplitudes and impedances</td>
</tr>
<tr>
<td></td>
<td>Naehle et al.</td>
<td>44</td>
<td>Five power-on-resets</td>
</tr>
<tr>
<td></td>
<td>Gimbel</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Nordbeck et al, Eur Heart J, 2015
# Devices and MRI: reported effects

## Table 1: In Vitro Studies Analyzing the Safety of Pacemakers With MRI

<table>
<thead>
<tr>
<th>Study</th>
<th>MRI Scanner</th>
<th>Type of Scan</th>
<th>MRI Location</th>
<th>Field Strength (T)</th>
<th>Pacemaker Manufacturer</th>
<th>Specific Absorption Rate</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nordbeck et al. (2009) [18]</td>
<td>Magn See Mea Hea</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Note
- Position 1 of the three-letter pl sensing. Position 2 refers to how the pacemaker responds to sensed events. 1 = sensed event inhibits the output pulse, 0 = no response to sensed input. Sensing delays per minute, NMR = nuclear magnetic resonance, N5 = not specified.
ICD and MRI

Interference due to the MRI scan interpreted incorrectly by ICD as ventricular fibrillation: (A) pulse sequence; (B) continuous sequence
Figure 3. Representative magnetic resonance imaging artefacts in patients with a left thoracic cardiovascular implanted electronic device. (A) Four-chamber view. (B) Short-axis view. Image distortion/void hampering diagnostic image quality particularly regarding the right ventricle and anterior wall of the left ventricle is apparent. RV, right ventricle; LV, left ventricle.
Each manufacturer of implantable cardiac devices certifies the system as MRI compatible only if:

**MRI compatible device + MRI compatible leads**

(according to tested configurations)
Timeline of MRI compatible CRT-D devices

- **2012**
  - **Biotronik**: first MRI-conditional CRT-D devices (Lumax 640/740 HF-T ProMRI)

- **2013**
  - **Biotronik**: second generation of MRI-conditional CRT-D devices (Iforia/Ilesto/Idova HF-T ProMRI)

- **2014**
  - **Biotronik**: third generation of MRI-conditional CRT-D devices (Iperia/Itrevia/Inventra HF-T ProMRI)
  - Reduction of limiting conditions during MRI scans (exam duration, absorption rate, other devices in patient’s body, ...)

- **2015**
  - **Biotronik**: Combined tests and retroactive MRI compatibility approval on previous generations of Biotronik atrial, defibrillation and LV leads
  - **Boston Scientific**: MRI-conditional CRT-D devices (DF-4/IS-4 versions only)
  - **Biotronik**: Introduction of first Quadripolar MRI-compatible LV leads (Biotronik)
  - **Biotronik**: Total-body 1.5 T MRI compatibility approval for Biotronik CRT-Ds
No longer a problem...MRI compatible solutions

- Modifications to the internal circuitry to avoid interference with the operations performed by the device
- Significant reduction of the ferromagnetic components to decrease the magnetic susceptibility
- Modifications to the geometry of the lead to prevent interactions with gradient and RF fields, including heating
- Development of dedicated MRI programming software to ensure the correct programming of the device
Pre- and post-MRI check lists

Pre-MRI

Check pacing system: MRI-compatible
(check patient identification card or check MRI-compatibility via dedicated on-line website www.promricheck.com)
MRI-compatible systems on-line check

www.promricheck.com
Pre- and post-MRI check lists

Pre-MRI

Check pacing system: MRI-compatible
(check patient identification card or check MRI-compatibility via dedicated on-line website www.promricheck.com)

Check manufacturer conditions
Old and current MRI conditions

- No other protheses/devices in patient’s body
- No local coils allowed (for head and extremities)
- Battery percentage > 30%
- MRI exam duration time < 30 min

- MRI scans: 1.5 Tesla, total-body
- Device + leads = MRI-compatible tested system
- Other devices allowed only if MRI-compatible certified by respective manufacturer
- Time from implant > 6 weeks
- Electrical parameters in range
- Body specific absorption rate < 2.0 W/kg
- Activation of MRI mode
Pre- and post-MRI check lists

**Pre-MRI**

Check pacing system: MRI-compatible
(check patient identification card or check MRI-compatibility via dedicated on-line website www.promricheck.com)

Check manufacturer conditions

Perform a device follow-up, check tests measurements

Set MRI mode program and transmit to the device
MRI mode ICD programming

- Pacing mode: D00, V00, OFF
- Pacing frequency: 70 ÷ 160 bpm
- High output pacing voltage: 5 V @ 1 ms
- Detection and ICD therapy OFF

MRI checklist

Check device and leads
- A dedicated Biotronik MR conditional lead and pacemaker form an MRI-tested system
- Device has been implanted in the pectoral region for more than 6 weeks
- Follow-up was successful and threshold does not exceed 2.0 V at 0.4 ms
- No additional active medical devices present
- No additional leads, wire adapters or lead extenders present

Radiological considerations
- Standard 1.5 T cylindrical scanner architecture required
- Continuous patient monitoring required during MR scan
- Observe specific conditions for MR Conditional devices (BIR, scan zone, field strength ...)
- After MR scan, restore previously programmed parameters, program and confirm settings.

MRI mode
- V00
- Basic rate [bpm]

- I accept the conditions for MRI examinations

- Please select an MRI mode. After clicking ‘OK’ the MRI parameters will be displayed.
- Selecting ‘Program’ on the next screen will program the implant accordingly.
- Any parameter change will result in the loss of the MRI program.
Pre- and post-MRI check lists

**Pre-MRI**

1. Check pacing system: MRI-compatible
   (check patient identification card or check MRI-compatibility via dedicated on-line website www.promricheck.com)

2. Check manufacturer conditions

3. Perform a device follow-up, check tests measurements

4. Set MRI mode program and transmit to the device

**Post-MRI**

1. Restore permanent programming mode

2. Run a device follow-up

3. Check or double-check current tests measurements with previous
Conclusions

- CRT-D systems are **tested and certified** to be safely subjected to MRI scans

- Technology is very recent, MRI compatibility is still subject to conditions less restrictive than in the years before; **conditions will be reduced** or made less restrictive **with the progress of testing and certification**

- **MRI exams are no longer a problem for CRT-D patients**, they are a strong point and a safe ally for them and for physicians in the field of diagnostics

- **With a step-by-step approach**, same used by Biotronik as first worldwide MRI-compatible CRT-D manufacturer, **MRI implants will be accessible to a wider range of HF population**
Future Aspects

• Now patients with CRT-D implants can access and undergo MRI scans with 1.5 T scanners in every district of their body

• Future will hold the possibility to perform full-body MRI scans with 3 T high-contrast scanners, with no exclusion-zone of the body

• Further tests on leads and configurations will allow all patients to access MRI without compromising technology
Thanks

ITALIAN SNIPERS
On-going Biotronik *Really ProMRI* study will assess current accesses to MRI scans of a pool of 600 patients with MRI-conditional PMs or ICDs, taking into account pre-MRI and post-MRI conditions of implanted systems.

Maglia et al, J Cardiovasc Med, 2014
MRI-compatible CRT-D devices and leads

- Since 2012, Biotronik has tested different device cans, leads and relative configurations to assess and certify MRI conditional safety for CRT-D patients during MRI exams.

- Since 2012, Biotronik has the most complete range of devices and leads for CRT-D therapy:
  - Active fixation leads
  - DF-4 and DF-1 connections
  - Single and dual-coil ICD leads
  - Bipolar and quadripolar LV leads, with different tip shapes

- Since 2012, Biotronik can offer patients with different needs, undergoing CRT-D implants or already implanted, safe access to MRI scans.

- Since 2015, Boston Scientific offers CRT-D MRI-compatible implants (only DF-4 and IS-4 leads).