Dispositivi Impiantabili Attivi RM Conditional: problematiche a confronto

11 Dicembre 2015

Meeting Room
Nuovo Ospedale Sant’Agostino Estense di Modena

I Dispositivi Impiantabili Attivi RM Conditional nella pratica clinica.

Mauro Zennaro
U.O. Cardiologia
More than \textbf{2.000.000} patients in U.S.A had a permanent Pacemaker. Because the \textit{advancing age} and \textbf{expanding indication} for \textit{pacing} and \textbf{prophylaxis} of ventricular arrhythmia the number of patients with implantable cardiac devices will likely to increase

The combination results in an estimated \textbf{50-75\% probability} of a patient being indicated for an MR study, creating an estimated \textbf{200.000} cardiac device patients who were denied MR scan

Brown DW. Am J Cardiol. 2005;95:409-411

Piramidi delle età della popolazione italiana tra il 1951 e il 2024
ATTIVITA’ ELETTROFISIOLOGIA 2014

U.O Cardiologia
NOCSAE-AUSL Modena
PM-PMCRT: 258
ICD-ICDCRT: 64
Visite di controllo: 2.222
(1626 pz)

Popolazione Modena 2014
702.761 di cui 22% over 65aa
Every 6 minutes in Europe an MRI scan is denied to a cardiac device patient*

Patient required to undergo an MRI scan within 1 year from the implant**

Estimated probability that an MRI scan will be required to a cardiac device patient within the lifetime of the device**

** Roguin et al., Europace, 2008,
**MR safe**  An item that poses no known hazards in any MR environment.

Non conducting, non magnetic, nonmetallic items

**MR conditional**  An item demonstrated to pose no known hazards in a specified MR imaging environment with specified condition use……

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

ASTM. http://www.astm.org
Static magnetic field
- Mechanical forces of ferromagnetic components (e.g., pacemaker displacement)
- Unpredictable magnetic sensor activation
- Reed-switch closure and sudden loss of pacemaker function
- Changes in electrocardiograms

Gradient magnetic field
- Possible induction of serious arrhythmias (rare)
- Induced voltages on leads causing over- and/or undersensing

Modulated radiofrequency field
- Heating of cardiac tissue adjacent to lead electrodes
- Possible induction of serious arrhythmias (rare)
- Pacemaker reprogramming or power-on-reset
- RF interactions with the device (over- and undersensing)

Combined field effects
- Sudden and unexpected loss of device function
- Alteration of device function because of EMI
- Mechanical forces (vibration)
- Power-on-reset of the pacemaker or ICD pulse generator
- Damage to pacemaker or ICD pulse generator
- Damage to pacemaker or ICD lead(s)

Imaging-related
- Artifacts that prevent adequate image visualization

CHRS and CAR Consensus on MRI With CIEDs Canadian Journal of Cardiology 2014
**POSSIBILI COMPLICANZE**

<table>
<thead>
<tr>
<th>Potential hazard</th>
<th>Mechanism</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead heating, increased pacing threshold and potential loss of capture</td>
<td>RF energy dissipates through the lead tip, causing heating of the cardiac tissue</td>
<td>Extensive testing with multiple lead and device combinations and a variety of lead positions</td>
</tr>
<tr>
<td>Inappropriate pacing</td>
<td>▪ Over/undersensing ▪ Unintentional stimulation</td>
<td>▪ Specific MRI mode settings ▪ Dedicated testing performed to avoid inappropriate stimulation</td>
</tr>
<tr>
<td>Device malfunction</td>
<td>Hardware/software failure caused by strong forces</td>
<td>Specially selected, developed and tested materials, components and hybrid design</td>
</tr>
</tbody>
</table>
POSSIBILI COMPLICANZE

**Batteria**

Negli anni da materiali ferromagnetici (nichel-cromo etc) si è giunti agli ioni di lito.

**Cassa**

Il titano è un materiale non magnetico che opportunamente trattato presenta una ridottissima permeabilità magnetica.

**Cateteri**

Sono composti di una lega metallica MP35N (lega di nichel, cobalto cromo e molibdeno: non ferromagnetici).

From Reed switch to Hall sensor

Feedthrough: protezione del circuito di alimentazione e della batteria
Valhaus. 32 patients. 34 MR 0,5T. **Battery voltage decreased** and recovered. **Reed switch activation** is not predictable  
Valhaus C. PACE 2001;24:489-95

**Martin ET.** 54 non-PM dependent. 64 MR 1.5T.9.4% **leads thresholds changes**  
Martin ET. J.Am. Coll Cardiol 2004;43:1315-24

**Schmiedel.** 45 patients. 63 MR images 1.5T. All programmed asynchronous. **Maximum SARS 1.2 W/Kg. No complications**  
Schmiedel et al Rofo 2005;177:731-44

**Sommer.** 82 patients. 115 MR 1.5T. Single manufacturer. PM dependent excluded if thoracic region. **SAR 1.5 W/Kg. Pacing captured threshold increased** (p=0.017). 1 case cTnI increased  
Sommer T. Circulation 2006;114:1285-92

**Nazarian.** 55 patients. 68 MR. 31 PM, 24 ICD. Average SAR<2.0W/Kg. Maximal capture change <1V. **Diagnostic questions answered in 100% non-thoracic and 93% thoracic**  
Nazarian S. Circulation 2006;114:1277-84
MRI of Patients With Cardiac Pacemakers: A Review of the Medical Literature

514 Titles and abstracts were identified through database searches:
- 216 (Pacemaker MRI) + 71 (Cardiac Pacemaker MRI Safety) + 209 (MRI Pacemaker)
  Medline/PubMed
- 18 (MRI)
  Cochrane Library

Reference lists from identified publications were manually scanned.

107 Publications selected after review of titles and abstracts and elimination of duplicates.

31 Publications included in review that involved human, animal, or in vitro studies.

Joseph F. Zikria AJR: 196, February 2011
15 Publication involved humans

1419 MRI examinations

In vivo studies concluded that MRI examinations affect pacemaker function, ECG readings, reed switch activity, symptoms and battery changes.

However, the clinical significance of the trials in this review was minor

Joseph F. Zikria AJR:196, February 2011
Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment.

OBJECTIVE:
The purpose of this prospective, randomized, controlled, worldwide clinical trial was to evaluate the safety and effectiveness of a pacemaker system designed for safe use in MRI for any bradycardia indicated patient.

METHODS:
Patients (n = 464) were randomized to undergo an MRI scan between 9 and 12 weeks postimplant (MRI group, n = 258) or not to undergo MRI (control group, n = 206) after successful implantation of the specially designed dual-chamber pacemaker and leads.

Willkoff, et al., Heart Rhythm Journal 2010
RESULTS:

No MRI-related complications occurred during or after MRI, including sustained ventricular arrhythmias, pacemaker inhibition or output failures, electrical resets, or other pacemaker malfunctions. Pacing capture threshold and sensed electrogram amplitude changes were minimal and similar between study groups.

LE EVIDENZE

Willkoff, et al., Heart Rhythm Journal 2010
A Detailed View on Pacemaker Lead Parameters Remotely Transmitted after Magnetic Resonance

CHRISTIAN G. WOLLMANN, M.D.,*,†

A total of 2,428 data sets (mean 80 ± 20 per patient)

Pacemakers (PMs) were interrogated immediately before and immediately after MR to assess potential changes of lead parameters (right atrial, right ventricular, sensing [mV], PCT [V/0.4 ms], pacing impedance, as well as of battery status

Patients were followed for 3 months with in-office visits at 1 month and 3 months after MR.

Patients were remotely monitored using HM based on routinely scheduled 30-day or event triggered transmissions.

This study is the first to report about remotely transmitted automatically implantable pulse generator (IPG)-based assessed lead parameters after MR.

No systematic (or clinically relevant) effects of MR on PM lead parameters could be found.

PACE 2015
Raccomendations for the Performance of MR Examinations in patients with Pacemakers or ICD

MR examinations of non pacemaker-dependent patients is discouraged and should only be consider 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.

American College of Radiology guidelines

the presence of implanted cardiac pacemakers should be considered a “relative contra-indication” for MRI and should be considered only in a case by case and site by site

Levine G.N. Circulation 2007;116:2878-2891
Kanal E. AJR 2007;188:1447-1474
Linee guida AIAC
all’impianto di pacemaker, dispositivi per la resincronizzazione cardiaca, defibrillatori automatici e loop recorder
update 2011
2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Europace (2013) 15, 1070–1118

6. Management considerations ........................................1110
   6.1 Pacing from alternative right ventricular sites .............1110
   6.2 Re-implantation of pacemaker/cardiac resynchronization therapy after device explantation for infection ..............1111
   6.3 Magnetic resonance imaging in patients with implanted cardiac devices ........................................1111
   6.4 Emergency (transvenous) temporary pacing ..............1113
   6.5 Remote management of arrhythmias and device .........1113
### 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy:

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Conventional cardiac devices. In patients with conventional cardiac devices, MR at 1.5 T can be performed with a low risk of complications if appropriate precautions are taken (see additional advice).</td>
<td>IIb</td>
<td>B</td>
<td>160–172</td>
</tr>
<tr>
<td>2) MR-conditional PM systems. In patients with MR-conditional PM systems, MR at 1.5 T can be done safely following manufacturer instructions.</td>
<td>IIA</td>
<td>B</td>
<td>173</td>
</tr>
</tbody>
</table>
2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy:

Implanted PM/ICD

Conventional PM/ICD

Exclude patients with:
- leads implanted <6 weeks before
- abandoned or epicardial leads

Record devices variables
(lead impedance/threshold, P/R wave amplitude and battery voltage)

Not PM-dependent

PM-dependent

Programme VVI/DDI (inhibited)

Programme VOO/DOO (asynchronous)

- Deactivate other pacing functions
- Deactivate monitoring and ATP/shock therapies (ICD)

Monitor ECG and symptoms during MRI

- Re-check device variables and compare with baseline
- Restore original programming

MRI-compatible PM/ICD

Follow manufacturer's instructions
Dalle risposte si evince un utilizzo relativamente frequente dei device MRI conditional, che vengono impiantati nell’81% dei centri, mentre solo il 19% non li ha ancora utilizzati. Relativamente alla scelta del paziente, il 52% ha risposto che li utilizzerebbe in tutti i pazienti ed il 46% solo in alcuni pazienti selezionati.

Tra i Centri che hanno risposto, risulta già abbastanza diffusa la disponibilità di servizi diagnostici di riferimento con RMN ad altissima risoluzione (3 T), che sono presenti in percentuale del 45%. **Non è ancora abituale ma attuata nel 51% dei centri l’esecuzione di esami RMN nei pazienti portatori di defibrillatori MRI conditional**
Dispositivi cardiaci impiantabili attivi e risonanza magnetica: aspetti tecnologici, inquadramento normativo e modelli organizzativi
<table>
<thead>
<tr>
<th>Feature</th>
<th>BOSTON</th>
<th>Medtronic</th>
<th>St. Jude</th>
<th>Biotronik</th>
<th>Sorin (H2 '13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Body MRI</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y (Only Safio)</td>
<td>Y</td>
</tr>
<tr>
<td>No limit on Scan time</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y (Only Safio)</td>
<td>Y</td>
</tr>
<tr>
<td>SAR @ 1.5T (W/kg)</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Automatic repro after scan</td>
<td>Y</td>
<td>NO</td>
<td>(activator)</td>
<td>NO</td>
<td>Y</td>
</tr>
<tr>
<td>DR and SR models</td>
<td>Y</td>
<td>NO</td>
<td>Y</td>
<td>Y</td>
<td>NO</td>
</tr>
<tr>
<td>Different price tier</td>
<td>Y</td>
<td>Y</td>
<td>NO</td>
<td>Y</td>
<td>NO</td>
</tr>
<tr>
<td>Using of existing leads</td>
<td>Y</td>
<td>Y</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Same handling lead</td>
<td>Y</td>
<td>Y</td>
<td>NO</td>
<td>Y</td>
<td>NO</td>
</tr>
<tr>
<td>Active and Passive Fixation</td>
<td>Y</td>
<td>Y</td>
<td>NO</td>
<td>N (Total body)</td>
<td>NO</td>
</tr>
<tr>
<td>Introducer size</td>
<td>6 Fr</td>
<td>7 Fr</td>
<td>8 Fr</td>
<td>7 Fr</td>
<td>7 Fr</td>
</tr>
<tr>
<td></td>
<td>BOSTON</td>
<td>BOSTON</td>
<td>Medtronic</td>
<td>St. Jude</td>
<td>Biotronik</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Fixation</td>
<td>INGEVITY</td>
<td>FINELINE II</td>
<td>CapSureFix MRI</td>
<td>TENDRIL MRI</td>
<td>Safio / Solia</td>
</tr>
<tr>
<td></td>
<td>Active (E/R helix) and Passive</td>
<td>Active (fix helix) and Passive</td>
<td>Active (E/R helix) and Passive</td>
<td>Active (E/R helix) and Passive</td>
<td>Active (E/R helix) and Passive</td>
</tr>
<tr>
<td>Shape</td>
<td>Straight and J</td>
<td>Straight and J</td>
<td>Straight and J</td>
<td>Straight</td>
<td>Straight and J</td>
</tr>
<tr>
<td>Backward compatibility</td>
<td>NO</td>
<td>Yes</td>
<td>CapsureFix 5086 MRI</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Capsure Sense</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CapsureFix 5076 yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead Body Diameter</td>
<td>5.7 Fr</td>
<td>5.1 Fr</td>
<td>Min 5.3 Fr</td>
<td>6.6 Fr</td>
<td>5.6 Fr</td>
</tr>
<tr>
<td>Introducer Size</td>
<td>Min 6 Fr</td>
<td>Min 7 Fr</td>
<td>Min 7 Fr</td>
<td>Min 8 Fr</td>
<td>Min 6 Fr</td>
</tr>
<tr>
<td>Estimated implanted Leads*</td>
<td>Fineline: 1'300'000</td>
<td>CapSure Sense: 420'000</td>
<td>CapSure Fix: 2.8 Mln</td>
<td>-</td>
<td>Setrox: 307'000</td>
</tr>
<tr>
<td>Follow-up time*</td>
<td>-</td>
<td>&gt; 11 yrs</td>
<td>10-12 yrs</td>
<td>-</td>
<td>Senterox: 5 years</td>
</tr>
<tr>
<td></td>
<td>BSC</td>
<td>MDT</td>
<td>STJ</td>
<td>BIO</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------------------------------</td>
<td>----------------------------------------</td>
<td>------------------------------------------</td>
<td>------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Full Body MRI Allowed</td>
<td>Yes – All combinations</td>
<td>Yes – All combinations</td>
<td>Yes – Pacing Off No [C1 to L2] – Pacing On</td>
<td>Yes – All combos above No – Other products and 3T</td>
<td></td>
</tr>
<tr>
<td>RV Leads</td>
<td>Active and Passive</td>
<td>Only Active</td>
<td>Only Active</td>
<td>Only Active</td>
<td></td>
</tr>
<tr>
<td>RA Leads</td>
<td>Active and Passive</td>
<td>Active and Passive</td>
<td>Only Active</td>
<td>Only Active</td>
<td></td>
</tr>
<tr>
<td>New or Existing</td>
<td>Existing</td>
<td>New</td>
<td>Existing</td>
<td>Existing</td>
<td></td>
</tr>
<tr>
<td>Magnetic Field</td>
<td>1.5T</td>
<td>1.5T</td>
<td>1.5T</td>
<td>1.5T (3T for other select products)</td>
<td></td>
</tr>
<tr>
<td>SAR (W/kg)</td>
<td>2.0 – All combinations</td>
<td>2.0 – All combinations</td>
<td>1.6 – 65cm 7122QQ / LDA210, 2.0 – 65cm 7120QQ / LDA220, 2.0 – 58cm all others listed</td>
<td>2.0 – All combinations</td>
<td></td>
</tr>
<tr>
<td>Tachy Therapy During Scan</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pacing Therapy During Scan</td>
<td>No</td>
<td>DOO / AOO / VOO</td>
<td>DOO / VOO</td>
<td>DOO / AOO / VOO</td>
<td></td>
</tr>
<tr>
<td>Auto Time Out</td>
<td>Yes – 3, 6, 12 hr or OFF</td>
<td>Yes – 6 hrs (fixed)</td>
<td>No Also, No SJM MRI Activator</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Speaker Active After MRI</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Treshhold Limit</td>
<td>NO</td>
<td><a href="mailto:2.0v@0.4ms">2.0v@0.4ms</a></td>
<td><a href="mailto:2.5V@0.5ms">2.5V@0.5ms</a></td>
<td><a href="mailto:2.0V@0.4ms">2.0V@0.4ms</a></td>
<td></td>
</tr>
<tr>
<td>Transmit/Receive coils limitation</td>
<td>R coil: no limit</td>
<td>R coil: no limit</td>
<td>R coil: no limit</td>
<td>R coil: no limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T-T/R coil: no on system directly</td>
<td>T-T/R coil: no limit for limbs and head</td>
<td>T-T/R coil: only head, upper extremity (wrist) and lower extremity (below hip)</td>
<td>T-T/R coil: no torax</td>
<td></td>
</tr>
</tbody>
</table>
The long-term reliability and performance of MR-conditional devices are unknown.

Some MR-conditional leads are stiffer and larger than standard leads. In some reports, their use was associated with higher rates of dislodgment, repeated surgery, and perforation.

MR-conditional CIEDs and leads are generally more expensive than traditional ones at the current moment.
Other factors that might influence whether an Mr conditional CIED should be implanted include:

The patient’s age, the presence of concomitant conditions, and the existence of known absolute contraindications to MR scanning.

Younger patients are more likely to require MR imaging at some point during their lifetimes.

If a patient has a concomitant disease (eg, malignancy) for which serial MR monitoring is required, an MR-conditional device should be strongly considered.

If a patient already has an absolute contraindication to MR scanning such as abandoned leads, CIED remnants, or other metallic prostheses (eg, mechanical valves, brain clips), then implantation of an Mr conditional CIED will be of little benefit.
Conventional Pacemaker

MR Conditional Pacemaker