MRI AND CARDIAC IMPLANTABLE DEVICES
STATE OF THE ART

Roberto Verlato, MD
U.O.Cardiologia, Camposampiero, Padova

VENICE ARRHYTHMIAS 2015
MRI AND CIEDS: (ILS, PM, CRT, ICD)
OPEN ISSUES

• MEDICO-LEGAL

• TECHNICAL

• CLINICAL DATA
MEDICO-LEGAL ISSUES

- NO AVAILABLE CIED IS “MR SAFE”
- CIEDs can be “MR-UNSAFE or MR-CONDITIONAL”
- “MR unknown” in case of missing informations
## MRI Hazards

<table>
<thead>
<tr>
<th>MRI Hazard</th>
<th>Static</th>
<th>Gradient</th>
<th>RF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force and torque</td>
<td></td>
<td></td>
<td>♦</td>
</tr>
<tr>
<td>Patient discomfort, dislodgement</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Vibration</td>
<td></td>
<td>♦</td>
<td>♦</td>
</tr>
<tr>
<td>Patient discomfort, device damage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Image artifact</td>
<td>♦</td>
<td>♦</td>
<td>♦</td>
</tr>
<tr>
<td>Diagnostic image quality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device interactions</td>
<td></td>
<td>♦</td>
<td>♦</td>
</tr>
<tr>
<td>Therapy delivery, device reset/damage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case heating</td>
<td></td>
<td>♦</td>
<td>♦</td>
</tr>
<tr>
<td>Patient discomfort, necrosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unintended cardiac stimulation (UCS)</td>
<td></td>
<td>♦</td>
<td>♦</td>
</tr>
<tr>
<td>Arrhythmia induction, asystole</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Lead-electrode heating</td>
<td></td>
<td></td>
<td>♦</td>
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<tr>
<td>Therapy delivery, sensing</td>
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MR-UNSAFE
WHAT DOES IT MEAN AND WHICH ARE THE IMPLICATIONS?

Traditional PMs, not labeled as MR-conditional, and almost all implanted ICDs and CRTDs fall in this category.

MR unsafe labeling implies that a certain degree of risk for patients has been recognized by manufacturer in case of any exposition to MR environment.

Physicians will perform MRI at their own responsibility,

THAT MEANS they are assuming on themselves the responsibilities of manufacturer.
MR CONDITIONAL
WHAT DOES IT MEAN AND WHICH ARE THE IMPLICATIONS?

MRI is allowed AND considered possible by manufacturer
UNDER SPECIFIC “CONDITIONS”

CONDITIONS and LIMITATIONS are all
dictated by manufacturer

When / if ALL THE CONDITIONS are not respected MR
EXAMINATION becomes OFF-LABEL

This moves all the responsibilities from manufacturer to physicians

Expert Panel on MR Safety: Emanuel Kanal, MD,¹⁸ A. James Barkovich, MD,² Charlotte Bell, MD,³ James P. Borgstede, MD,⁴ William G. Bradley Jr, MD, PhD,⁵ Jerry W. Froelich, MD,⁶ J. Rod Gimbel, MD,⁷ John W. Gosbee, MD,⁸ Ellisa Kuhni-Kaminski, RT,¹ Paul A. Larson, MD,⁹ James W. Lester Jr, MD,¹⁰ John Nyenhuis, PhD,¹¹ Daniel Joe Schaefer, PhD,¹² Elizabeth A. Sebek, RN, BSN,¹ Jeffrey Weinreb, MD,¹³ Bruce L. Wilkoff, MD,¹⁴ Terry O. Woods, PhD,¹⁵ Leonard Lucey, JD,¹⁶ and Dina Hernandez, BSRT¹⁶
Potential Complications: Unexpected programming changes, inhibition of pacemaker output, failure to pace, transient asynchronous pacing, rapid cardiac pacing, the induction of ventricular fibrillation, heating of the tissue adjacent to the pacing or ICD system and especially cardiac tissue near the lead tip, early battery depletion, and outright device failure requiring replacement may occur during MRI of patients with pacemakers or ICDs (18,29–31). Multiple deaths have been documented to occur under poorly and incompletely characterized circumstances when CIED patients underwent MRI (32–34). These deaths may have occurred as a result of pacemaker inhibition, failure to capture or device failure (resulting in prolonged asystole) and or rapid cardiac pacing or asynchronous pacing (resulting in the initiation of ventricular tachycardia or fibrillation).
WARNING

Modern and/or Recently Manufactured pacemakers and ICDs MUST NOT BE REGARDED AS MRI CONDITIONAL

The committee eschews the term “modern” when referring to a particular device, recognizing that all devices not labeled for use in the MRI contain legacy components and designs that may not be resistant to the forces and electromagnetic interference present in the MRI suite. All devices, unless appropriately tested and labeled, should never be regarded as safe for MRI simply because they are “modern” or recently manufactured.

ACR Guidance on MR Safe Practices

PTS WITH UNLABELED DEVICE SHOULD UNDERGO MRI ONLY FOR “COMPPELLING REASONS” AND AFTER AN INFORMED CONSENT IS OBTAINED

Unlabeled Cardiac Devices: Amongst the patients with MR unsafe CIEDs, many have conditions that would ordinarily be assessed with MRI. While many can have their medical conditions managed without MRI, in some instances, specific clinical circumstances may present compelling reasons for undergoing an MR examination (39). Should MRI be considered, it should be evaluated on a case-by-case and site-by-site basis and only if the site is manned with individuals with the appropriate radiology and cardiology knowledge and expertise on hand.

ACR Guidance on MR Safe Practices

ESC Guidelines on cardiac pacing and cardiac resynchronization therapy (2013)

<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>

MRI = magnetic resonance imaging; PM = pacemaker.

**IIb:** may be considered

**IIa:** should be considered
CONDITIONS REQUIRED BY MANUFACTURERS FOR MR-CONDITIONAL DEVICES

- RELATIVE TO THE HOSPITAL
- RELATIVE TO THE PATIENT
- RELATIVE TO THE IMPLANT
- RELATIVE TO THE MR SCANNER
CONDITIONS RELATED TO THE HOSPITAL ALWAYS REQUIRED (2007 GL)

- **PATIENTS MUST BE MONITORED THROUGHOUT THE WHOLE EXAMINATION**
  (at minimum ECG and pulse oximetry)

- **EMERGENCY EQUIPMENT**
  (defibrillator, programmer, emergency resuscitation equipment, trained personnel)

*Precautions during MRI with CIEDs: Should any MRI examination be contemplated for a patient with an implanted pacemaker or ICD, it is recommended that radiology and cardiology personnel and a fully stocked crash cart be readily available throughout the procedure in case a significant arrhythmia develops during the examination that does not terminate with the cessation of the MR study. The cardiologist should be familiar with the patient's arrhythmia history and the implanted device. A programmer that can be used to adjust the device should be readily available. The goal of pre-MRI programming should be to mitigate the risk to the patient and the device while undergoing MRI (40.41). All such patients should be actively monitored throughout the examination. A central*
CONDITIONS RELATED TO THE PATIENT

- **HEIGHT** (Biotronik, > 140 cm)
- **NO FEVER** (Boston Sc, Biotronik?)
- **NO ABANDONED LEAD** either functional or not-functional, even if MR conditional
- **NO CAP, LEAD EXTENDER, ADAPTER**
- **NO MIX and MATCH** : no labeled and unlabeled hardware, or MRC from different manufac
- **FULL-BODY OR LIMITED TO ANATOMICAL DISTRICTS**
CONDITIONS RELATED TO THE SCANNER

• **TYPE OF SCANNER** cilindrical closed bore required for most conditional CIEDs

• **STATIC MAGNETIC FIELD** 1.5 Tesla only for most conditional CIEDs

• RF excitation frequency that is approximately 64 MHz

• Maximum gradient slew rate performance per axis $\leq 200 \text{T/m/sec}$

• Whole body averaged specific absorption rate (SAR) $\leq 2 \text{W/Kg}$, + SAR $< 3.2 \text{ W/Kg}$ for the head

• Examination duration
CONDITIONS RELATED TO THE IMPLANT

- MR conditional system (device + leads)
- Implant in pectoral region, either right or left
- Time from implant (> 6 weeks)
- Stimulation threshold (< 2 – 2.5 V)
- Pacing Impedance (200 – 1500 Ohms, but insulation defect must be excluded in case of decreasing impedance)
- Programming of appropriate MRI mode before scanning
<table>
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<tr>
<th>BY &amp; CRTP</th>
<th>Device Type</th>
<th>Scan Conditions</th>
<th>MRI Leads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>SC, DC, CRTP</td>
<td>SC, DC: 1,5T Full Body Scan and body SAR &lt; 4 W/Kg (with Solia S leads) otherwise body SAR &lt; 2 W/Kg SC, DC: 3T Cardiac ExZ and body SAR &lt; 2W/Kg CRTP: 1,5T Cardiac ExZ and body SAR &lt; 2W/Kg</td>
<td>A: tines and screw RV: tines and screw LV: all bipolar leads</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>SC, DC</td>
<td>3T and 1,5T Full Body Scan and body SAR &lt; 4 W/Kg for Essentio MRI, Proponent MRI or Accolade MRI with Ingevity leads 1,5T Full Body Scan and body SAR &lt; 2 W/Kg with Fineline II leads</td>
<td>A: tines and screw RV: tines and screw</td>
</tr>
<tr>
<td>Medtronic</td>
<td>SC, DC</td>
<td>1,5T Full Body Scan and body SAR &lt; 2 W/Kg</td>
<td>A: tines and screw RV: tines and screw</td>
</tr>
<tr>
<td>S. Jude Medical</td>
<td>SC, DC</td>
<td>1,5T Full Body Scan and body SAR &lt; 4 W/Kg with Tendril MRI lead 1,5T Cardiac ExZ and body SAR &lt; 2 W/Kg with Tendril STS and IsoFlex leads Endurity and Endurity Core: 1,5T Cardiac ExZ and body SAR &lt; 2 W/Kg despite Tendril MRI lead</td>
<td>A: tines and screw RV: tines and screw Only Tendril MRI active fixation leads allow FBS MRI</td>
</tr>
<tr>
<td>Sorin</td>
<td>SC, DC</td>
<td>1,5T Full Body Scan</td>
<td>A: screw RV: screw</td>
</tr>
</tbody>
</table>
CLINICAL DATA : MRI IN NON-MR CONDITIONAL PACEMAKERS AND ICDS

A Prospective Evaluation of a Protocol for Magnetic Resonance Imaging of Patients With Implanted Cardiac Devices

Saman Nazarian, MD, Rozann Hansford, RN, MPH, Ariel Roguin, MD, PhD, Dorith Goldsher, MD, Menekhem M. Zviman, PhD, Albert C. Lardo, PhD, Brian S. Caffo, PhD, Kevin D. Frick, PhD, MA, Michael A. Kraut, MD, PhD, Ihab R. Kamel, MD, PhD, Hugh Calkins, MD, Ronald D. Berger, MD, PhD, David A. Bluemke, MD, PhD, and Henry R. Halperin, MD, MA

Johns Hopkins University, Baltimore, Maryland; Rambam Medical Center, Technion Institute of Technology, Haifa, Israel; and Radiology and Imaging Sciences, National Institutes of Biomedical Imaging and Bioengineering, Bethesda, Maryland
MRI AND NON-MR CONDITIONAL PM / ICD

• 438 patients with devices (54% with PM and 46% with ICD)
• 555 MRI studies.

  • EXCLUDED IF epicardial or abandoned leads, recent implant < 6 weeks, pacemaker-dependent pts with an ICD due to lack of asynchronous pacing capability VOO in most of ICDs

RESULTS

3 (0.7%) PM reverted to transient back-up programming (electrical reset) without long-term consequences

Not- significant sensing and pacing threshold / impedance / battery voltage changes

The MagnaSafe Registry: Determining the Risks of MRI in the Presence of Pacemakers and Implantable Cardioverter Defibrillators

The MagnaSafe Registry is a prospective multi-center study designed to determine the risk of non-thoracic 1.5T MRI scanning for patients with implanted cardiac devices.

Caution: INVESTIGATIONAL DEVICE EXEMPTION LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE
1500 non-thoracic MRI

No deaths, no PM/ICD failure, no lead failure, no loss of capture, no ventricular arrhythmia, no parameter change at 6-month follow-up

1 COMPLICATION: an ICD was replaced later for battery depletion; probably due to human error, as tachyarrhythmias therapies had not been de-activated before MRI scan
Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment

Bruce L. Wilkoff, MD, FHRS, CCDS,* David Bello, MD, PhD,† Milos Taborsky, MD, PhD, FESC,* Josef Vymazal, MD, PhD,§ Emanuel Kanal, MD, FACR, FISMRM,‖ Hubertus Heuer, MD,‖ Katrin Hecking, MD,† W. Ben Johnson, MD, CCDS,* William Young, MD,‖ Brian Ramza, MD, PhD,‖ Naveed Akhtar, MD,‖ Bernhard Kuepper, MD,‖ Peter Hunold, MD,‖ Roger Luechinger, PhD,‖ Helmut Puereferreller, MD,‖ Firat Duru, MD,‖ M.J.W. Gottle, MD,‖ Richard Sutton, MD, PhD,‖ Torsten Sommer, MD‖; on behalf of the EnRhythm MRI SureScan Pacing System Study Investigators

From the *Cleveland Clinic, Cleveland, Ohio, 1Orlando Regional Medical Center, Orlando, Florida, 2Na Homolce Hospital, Prague, Czech Republic, 3UPMC Presbyterian, Pittsburgh, Pennsylvania, 4St. Johannes Hospital, Dortmund, Germany, 5Iowa Heart Center P.C./Mercy Hospital, Des Moines, Iowa, 6Mid America Heart Institute, Kansas City, Missouri, 7Elizabeth Krankenhaus, Essen, Germany, 8Institute for Biomedical Engineering, University and ETH Zurich, Zurich, Switzerland, 9A.D. Krankenhaus der Elisabethinen, Linz, Austria, 10University Hospital Zurich, Zurich, Switzerland, 11HAGA Ziekenhuis, Locatie Leyweg, Den Haag, The Netherlands, 12St. Mary’s Hospital, London, United Kingdom, and 13German Red Cross Hospital (DRK) Neuwied, Academic Hospital of the University of Bonn, Neuwied, Germany.

BACKGROUND: Magnetic resonance imaging (MRI) of pacemaker patients is contraindicated due to documented potential risks to the patient from hazardous interactions between the MRI and pacemaker system.

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 = 232) or to undergo MRI (control group, n = 232) after successful implantation of the specially designed dual-chamber pacemaker and leads. Patients were monitored for arrhythmias, symptoms, and pacemaker system function during 14 nonclinically indicated relevant brain and lumbar MRI sequences. Sequences were performed at 1.5 T and included scans with high radiofrequency power deposition and/or high gradient dB/dt. Clinical evaluation of the pacemaker system function occurred immediately before and after MRI, 1 week and 1 month post-MRI, and at corresponding times for the control group. Primary endpoints for safety analyzed the MRI procedure

464 pts randomized to MRI or no-MRI

NO MRI-RELATED COMPLICATION

MINIMAL CHANGES OF PACING AND SENSING TRESHOLDS SIMILAR IN THE TWO GROUPS

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MINIMAL CHANGES OF PACING AND SENSING TRESHOLDS SIMILAR IN THE TWO GROUPS
## MR Conditional TY Systems Overview

<table>
<thead>
<tr>
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<th>Device Type</th>
<th>Scan Conditions</th>
<th>MRI Leads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>VR, DR, DX, CRTD</td>
<td><strong>1,5T Full Body Scan</strong> (LV lead Corox other LV lead cardiac ExZ) 3T Cardiac ExZ (VR,DX,DR)</td>
<td>A: screw RV: screw dual or single coil</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>VR, DR, CRTD</td>
<td><strong>1,5T Full Body Scan</strong> (LV lead: Acuity X4 otherwise no MRI)</td>
<td>A: tines and screw RV: tines and screw dual or single coil</td>
</tr>
<tr>
<td>Medtronic</td>
<td>VR, DR</td>
<td><strong>1,5T Full Body Scan</strong></td>
<td>A: tines and screw RV: screw dual or single coil</td>
</tr>
<tr>
<td>S.Jude Medical</td>
<td>VR, DR</td>
<td><strong>1,5T Full Body Scan</strong> (only Ellipse in MRI mode OFF and Tendril MRI atrial lead otherwise Cardiac ExZ)</td>
<td>A: screw RV: screw dual or single coil</td>
</tr>
</tbody>
</table>

**Scan conditions for all manufacturers:** SAR < 2W/Kg body, SAR < 3,2W/Kg head, Slew rate < 200T/m/s

**Pacing system conditions for all manufacturers:** no abandoned leads, lead adaptors nor lead extenders. (Pacing threshold < 2V@0,4ms). No broken leads as confirmed by lead impedance history. ICD implanted in right or left pectoral region. NO ERI or EOS. Device programmed in MRI mode before MRI scan. System implanted at least 6 weeks before MRI scan.
BUT....TOO MANY DIFFERENCES

• For Boston Sc ICDs MRI cannot be performed in pacemaker – dependent pts because VOO is not available, even in MRI mode

• Alarm Beeps are permanently de-activated after MRI exposure of ICDs to MRI
Full-Body MRI in Patients With an Implantable Cardioverter-Defibrillator
Primary Results of a Randomized Study

Michael R. Gold, MD, PhD,* Torsten Sommer, MD, PhD,† Juerg Schwitter, MD,‡ Ahmed Al Fagih, MD,§
Timothy Albert, MD,∥ Béla Merkely, MD, PhD, DSc,¶ Michael Peterson, MD,¶ Allen Ciufo, MD,∥∥ Sang Lee, MD,∥∥∥
Lynn Landborg, BA,¶¶ Jeffrey Cerkvenik, MS,¶¶ Emanuel Kanal, MD,¶¶¶ on behalf of the Evera MRI Study Investigators

ABSTRACT

BACKGROUND Magnetic resonance imaging (MRI) of patients with conventional implantable cardioverter-defibrillators (ICD) is contraindicated.

OBJECTIVES This multicenter, randomized trial evaluated safety and efficacy of a novel ICD system specially designed for full-body MRI without restrictions on heart rate or pacing dependency. The primary safety objective was >90% freedom from MRI-related events composite endpoint within 30 days post-MRI. The primary efficacy endpoints were ventricular pacing capture threshold and ventricular sensing amplitude.

METHODS Subjects received either a single- or dual-chamber ICD. In a 2:1 randomization, subjects either underwent MRI at 1.5-T of the chest, cervical, and head regions to maximize radiofrequency exposure up to 2 W/kg specific absorption rate and gradient field exposure to 200 T/m/s per axis (MRI group, n = 175), or they underwent a 1-h waiting period without MRI (control group, n = 88). A subset of MRI patients underwent ventricular fibrillation induction testing post-MRI to characterize defibrillation function.

RESULTS In 42 centers, 275 patients were enrolled (76% male, age 60.4 ± 13.8 years). The safety endpoint was met with 100% freedom from the composite endpoint (p < 0.0001). Both efficacy endpoints were met with minimal differences in the proportion of MRI and control patients who demonstrated a ≥0.5 V increase in ventricular pacing capture threshold (100% MRI vs. 98.8% control, noninferiority p < 0.0001) or a ≥50% decrease in R-wave amplitude (99.3% MRI vs. 98.8% control, noninferiority p = 0.0001). A total of 34 ventricular tachyarrhythmia/ventricular fibrillation episodes (20 induced; 14 spontaneous) occurred in 24 subjects post-MRI, with no observed effect on sensing, detection, or treatment.

CONCLUSIONS This is the first randomized clinical study of an ICD system designed for full-body MRI at 1.5-T. These data support that the system is safe and the MRI scan does not adversely affect electrical performance or efficacy. (Confirmatory Clinical Trial of the Evera MRI System for Conditionally-Safe MRI Access; NCT02117414) (J Am Coll Cardiol 2015;65:2581-8) © 2015 by the American College of Cardiology Foundation.)
Summary

• There were no complications associated with MRI in this cohort.

• The Evera MRI ICD system showed no difference in pacing and sensing performance between the MRI and Control group.

• There was no impact on VF detection observed post-MRI exposure.
NO CHANGE IN PACING TRESHOLDS OBSERVED
THE EVERA MRI STUDY CONCLUSIONS

CONCLUSIONS

This is the first-in-human randomized study of an ICD system designed for full-body MRI at 1.5-T. The data support that the system is safe with MRI examinations, showing no evidence of any adverse effect on the electrical performance or the ability to treat ventricular arrhythmias.

Gold M, JACC 2015; 65:2581
HRS Late Breaking Clinical Trial Session II: Friday, May 15, 2015, at 8:00 A.M. – 9:30 A.M. in Ballroom West

BIOTRONIK Presents ProMRI ICD Clinical Study Results at Heart Rhythm 2015 Scientific Sessions

ProMRI Phase C Results Confirm the Safety of Iforia ProMRI Implantable Cardioverter Defibrillator in Thoracic Spine and Cardiac Scans under 1.5 Tesla MRI Scanning Conditions
RESULTS  One hundred seventy patients were enrolled at 39 US centers. One hundred fifty-three patients underwent MRI (25.7% cardiac, 74.3% thoracic spine) and completed follow-up. Freedom from the primary end-points was met in all but 1 subject, in whom reduced R-wave amplitude was detected 1 month post-MRI. No serious adverse device effects occurred during the course of the study.

CONCLUSION  These results demonstrate the clinical safety and efficacy of the ProMRI ICD system in patients subjected to thoracic spine and cardiac MRI imaging in 1.5-T scanners.
CONCLUSIONS

- MRI can be performed safely in patients with cardiac pacemaker and ICDs, in certain conditions, even in patients with UNLABELED DEVICE

- MRI is safe in MR-conditional CIEDS when all requirements are respected

- New families of MR-conditional ICDs have been designed, realized, used in clinical studies and approved or waiting approval from FDA

- MR-conditional CRT-Ps are also facing into the market

- Probably within a very short period of time all new CIEDs will be fully MR conditional