MRI AND CARDIAC IMPLANTABLE DEVICES STATE OF THE ART

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VENICE ARRHYTHMIAS 2015

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

- MEDICO-LEGAL
- TECHNICAL
- CLINICAL DATA

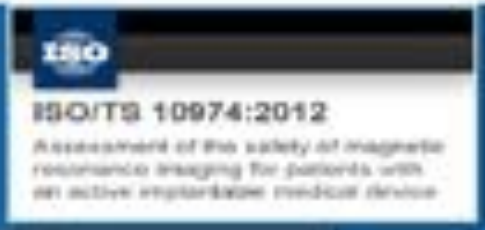
MEDICO-LEGAL ISSUES

- NO AVAILABLE CIED IS "MR SAFE" 

- CIEDs can be "MR-UNSAFE or MR-CONDITIONAL"

- "MR unknown" in case of missing informations

MRI Hazards



MRI Hazard	Static	Gradient	RF
Force and torque Patient discomfort, dislodgement	◆		
Vibration Patient discomfort, device damage	◆	◆	
Image artifact Diagnostic image quality	◆	◆	◆
Device interactions Therapy delivery, device reset/damage	◆	◆	◆
Case heating Patient discomfort, necrosis		◆	◆
Unintended cardiac stimulation (UCS) Arrhythmia induction, asystole		◆	◆
Lead-electrode heating Therapy delivery, sensing			◆

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

2013: DOCUMENT FACING WITH SAFETY ISSUES OF MRI IN CIEDS PATIENTS

JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)

Special Communication

ACR Guidance Document on MR Safe Practices: 2013

Expert Panel on MR Safety: Emanuel Kanal, MD,[1*] 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, BSRT[16]

ACR Guidance on MR Safe Practices

JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)

RISK OF COMPLICATIONS WITH UNLABELED DEVICES IS REAL

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

JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)

PTS WITH UNLABELED DEVICE SHOULD UNDERGO MRI ONLY FOR "COMPELLING 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

JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)

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

Magnetic resonance in patients with implanted cardiac devices

Recommendations	Class [a]	Level [b]	Ref. [c]
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).	IIb	B	160–172
2) MR-conditional PM systems. In patients with MR-conditional PM systems, MR at 1.5 T can be done safely following manufacturer instructions.	IIa	B	173

MRI = magnetic resonance imaging; PM = pacemaker.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendation(s).

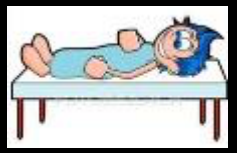
IIb:
may be considered

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 THROUGHT 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 ≤ 200T/m/sec
- Whole body averaged specific absorption rate (SAR) ≤ 2W/Kg, + SAR < 3.2 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 treshold (< 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

MR Conditional BY Systems Overview

BY & CRTP	Device Type	Scan Conditions	MRI Leads
Biotronik	SC,DC, CRTP	SC,DC: **1,5T Full Body Scan and body SAR < 4 W/Kg** (with Solia S leads) otherwise body SAR < 2 W/Kg SC,DC: **3T Cardiac ExZ and body SAR < 2W/Kg** CRTP: 1,5T Cardiac ExZ and body SAR < 2W/Kg	A: tines and screw RV: tines and screw LV: all bipolar leads
Boston Scientific	SC,DC	**3T and 1,5T Full Body Scan and body SAR < 4 W/Kg** for Essentio MRI, Proponent MRI or Accolade MRI with Ingevity leads **1,5T Full Body Scan and body SAR < 2 W/Kg** with Fineline II leads	A: tines and screw RV: tines and screw
Medtronic	SC,DC	1,5T Full Body Scan and body SAR < 2 W/Kg	A: tines and screw RV: tines and screw
S.Jude Medical	SC,DC	1,5T Full Body Scan and body SAR < 4 W/Kg with Tendril MRI lead 1,5T Cardiac ExZ and body SAR < 2 W/Kg with Tendril STS and IsoFlex leads Endurity and Endurity Core: 1,5T Cardiac ExZ and body SAR < 2 W/Kg despite Tendril MRI lead	A: tines and screw RV: tines and screw Only Tendril MRI active fixation leads allow FBS MRI
Sorin	SC,DC	1,5T Full Body Scan	A: screw RV: screw

CLINICAL DATA : MRI IN NON-MR CONDITIONAL PACEMAKERS AND ICDS

Published in final edited form as:
Ann Intern Med. 2011 October 4; 155(7): 415–424. doi:10.7326/0003-4819-155-7-201110040-00004.

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

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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 treshold / impedance / battery voltage changes

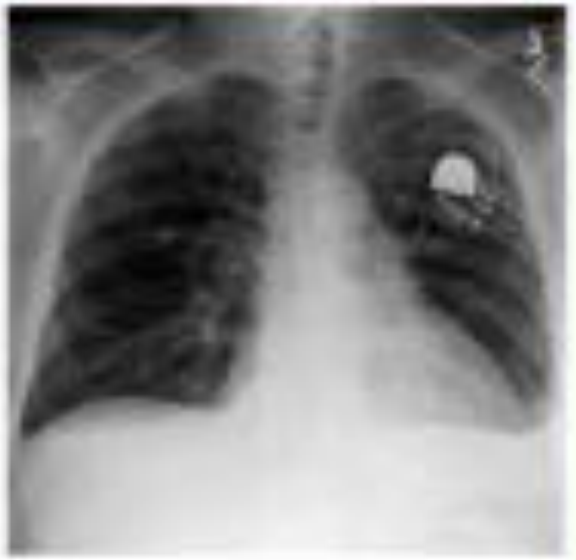
Ann Intern Med. 2011;155:415-424.

The MagnaSafe Registry

Home | About MagnaSafe | Site Qualifications | Protocol Summary | Contacts | Documents and Forms

MagnaSafe

Director:
Robert J. Russo, MD, PhD
Scripps Clinic
La Jolla, CA



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

Chicago

American Heart Association. SCIENTIFIC SESSIONS 2014

Exhibits: Nov. 16–18 | Sessions: Nov. 15–19
ReSS: Nov. 15–16 | CVN: Nov. 16–19
PVD FIT Workshop: Nov. 15
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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

Authors
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Disclosures
R.J. Russo: Research Grant; Significant; Biotronik, Boston Scientific, St. Jude Medical. **I.**
Investigators: None

Abstract

Objective: The MagnaSafe Registry is a multicenter study to determine the risk of clinically-indicated non-thoracic MRI at 1.5T in patients with pacemakers (PM) and implantable cardioverter-defibrillators (ICD).

Methods: Device interrogation was performed pre-/post-MRI using a standardized protocol. Pacemaker non-dependent patients had pacing functions deactivated; dependent patients had the device programmed to an asynchronous mode. For ICD patients all therapies were disabled if non-pacemaker dependent; dependent ICD patients were excluded. Primary endpoints included death, generator/lead failure, or induced arrhythmia. Secondary endpoints were clinically-relevant device parameter changes.

Results: Between April 2009 and April 2014, 1500 clinically-indicated non-thoracic MRI studies (spine 41%; brain 59%) were performed at 21 sites (1000 PMs, 500 ICDs, 2923 leads). No deaths, generator/lead failures, losses of capture, or ventricular arrhythmias occurred during the scan. One ICD generator later required replacement when tachytherapy was inappropriately active during the exam. Six episodes of self-terminating atrial fibrillation (>48 hr) and 6 cases of partial electrical reset were noted. A decrease in battery voltage ≥0.04V occurred in 0.5% of PMs and 7% of ICDs; pacing lead impedance change ≥060 in 3% of PMs and 4% of ICDs; and high-voltage impedance change ≥30 in 17% of ICDs. A decrease of ≥ 50% in P-wave amplitude occurred in 5 PMs and 1 ICD. A decrease of ≥25% in R-wave amplitude occurred in 4% of PMs and 2% of ICDs, and a decrease of ≥50% in 1 ICD. A pacing threshold increase ≥0.5V at 0.4 ms occurred in 1% of PM and ICD leads. Overall, one or more clinically-relevant device parameter changes occurred in 12% of PM and 28% of ICD cases. A previous MRI had been performed in 212 cases (21%), and the frequency of a device parameter change event was 20% in those with, and 17% in those without a previous MRI (p=0.3). At 6-month follow-up no clinically-significant durable device parameter changes were noted.

Conclusions: Final results of the MagnaSafe Registry demonstrate that clinically-indicated non-thoracic MRI at 1.5T may be performed for patients with non-conditional devices at no detectable clinical risk when the device is appropriately programmed.

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

MEDICAL LITERATURE:
RANDOMIZED TRIAL AVAILABLE FOR MDT (SURESCAN SYSTEM)

Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment

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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 = 258) or not to undergo MRI (control group, n = 206) 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 exposure. 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 complication-free rate and for effectiveness compared capture and sensing performance between MRI and control groups.

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.

CONCLUSION This trial documented the ability of this pacemaker system to be exposed in a controlled fashion to MRI in a 1.5 T scanner without adverse impact on patient outcomes or pacemaker system function.

KEYWORDS Bradycardia pacing; CapSureFixMRI; EnRhythmMRI; MRI; Pacemaker; RevoMRI; Safety; SureScan

ABBREVIATIONS **CI** = confidence interval; **MR** = magnetic resonance; **MRI** = magnetic resonance imaging; **PCT** = pacing capture threshold; **RF** = radiofrequency; **SAR** = specific absorption rate; **UCS** = unintended cardiac stimulation

(Heart Rhythm 2011;8:65–73)

464 pts randomized to MRI or no-MRI

NO MRI-RELATED COMPLICATION

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

MR Conditional TY Systems Overview

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

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

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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.

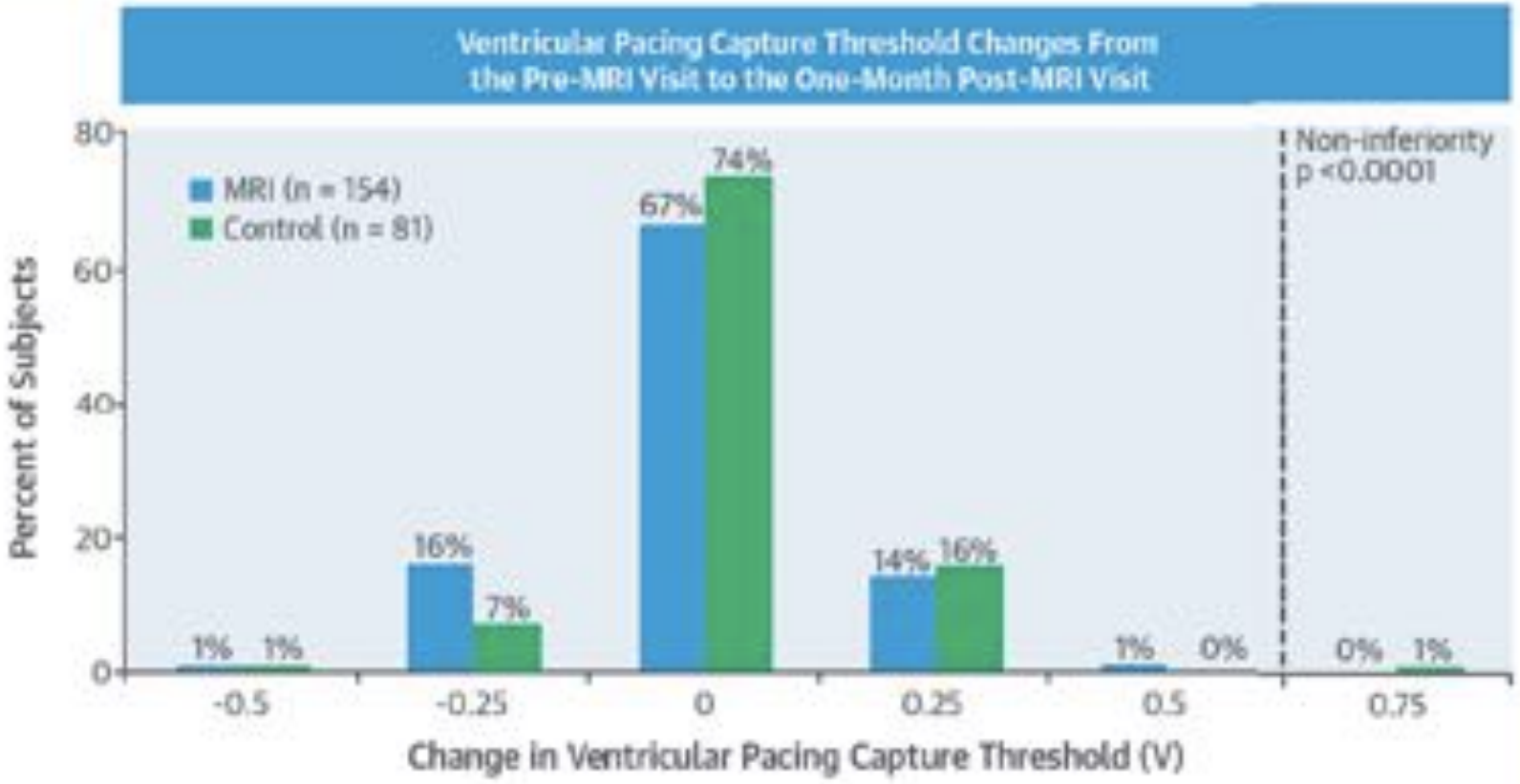
Summary

- 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

JACC VOL. 65, NO. 24, 2015
JUNE 23, 2015:2581–8

CENTRAL ILLUSTRATION **Full-Body MRI Scanning in Patients With Implantable Cardioverter-Defibrillators**



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

Press Release

BIOTRONIK
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Date: May 15, 2015

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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

Clinical safety of the Iforia implantable cardioverter-defibrillator system in patients subjected to thoracic spine and cardiac 1.5-T magnetic resonance imaging scanning conditions

Khaled Awad, MD,* John Griffin, MD,† Thomas C. Crawford, MD, FHRS,‡ S. Lane Cox, MD, FACC,§ Kevin Ferrick, MD, FHRS,‖ Alexander Mazur, MD,¶ Rafael E. Pena, MD,** Steven G. Lloyd, MD, PhD,* Justin Michalski, MS,††

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.

month post-MRI or R-wave amplitude <5 mV at 1 month post-MRI; and (3) MRI and ICD system-related serious adverse device effects.

Dr. Awad has received research support from Biosense Webster. Dr. Crawford is a trial investigator; and has received research support from Biotronik, Boston Scientific, and Medtronic. Dr. Ferrick is a trial investi-

effect; **SAR** = specific absorption rate; **VF** = ventricular fibrillation; **VT** = ventricular tachycardia

(Heart Rhythm 2015;12:2155–2161)

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