

8th RHYTHM Congress 2015



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**MRI compatibility for accurate diagnostic examinations of *'former'* pacemaker & ICD technology**

*Pierpaolo LUPO , Hussam ALI, Guido DE AMBROGGI,*

*Sara FORESTI, Gianluca EPICOCO and Riccardo CAPPATO\**

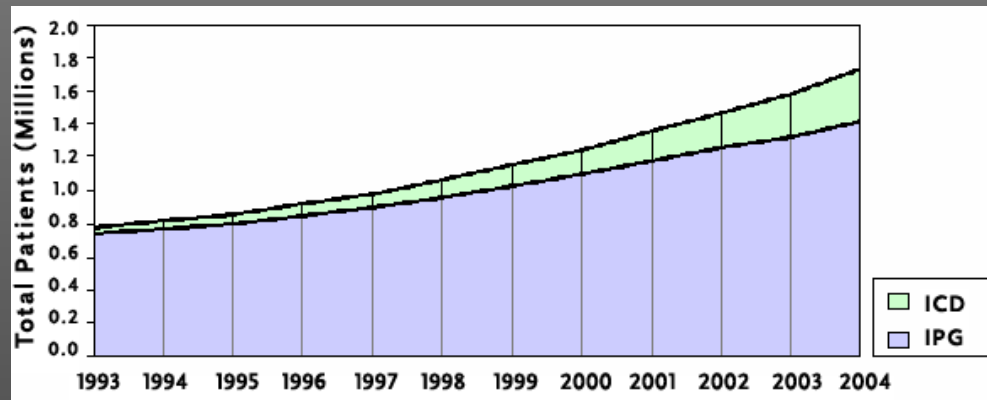
*Arrhythmia & Electrophysiology II Center  
Humanitas-Gavazzeni Hospital  
Bergamo, Italy*

# Background



- The use of permanent implantable pacemakers (PM) and cardioverter-defibrillators (ICD) is widely accepted for the treatment of brady- and tachyarrhythmias and of congestive heart failure
- Because of the advancing age of the population and expanding indications, the number of patients with implantable cardiac devices will likely continue to increase

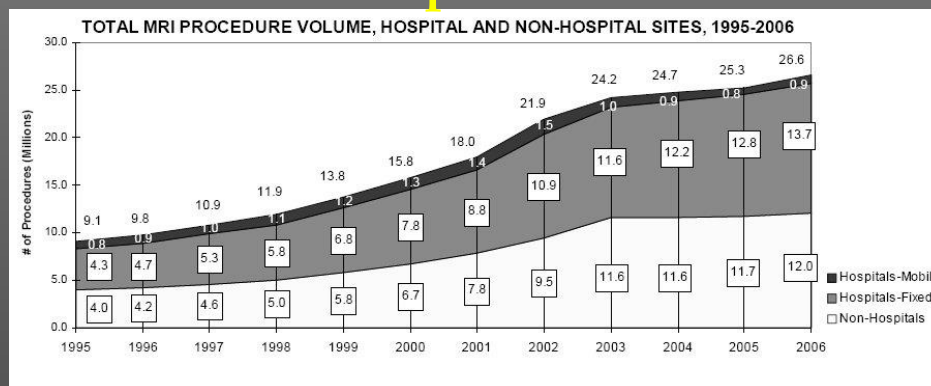
## US Pacemaker / ICD Implants





- Magnetic resonance imaging (**MRI**) is an important diagnostic tool playing an increasing role in the diagnosis and management of both cardiac and extra-cardiac diseases (over 35 millions MRI studies are performed annually, with an annual growth rate of 10%)
- It is estimated that **50% to 75% of patients with implantable cardiac device will require an MRI** at some point after implantation (17% within 12 months of implant)

### US MRI procedures





However, the increasing **PM/ICD population** has been **routinely denied access to MRI** due to safety reasons and both medical community and manufactures considered MRI an ***absolute contrindication*** in these patients.





# Cardiac Devices and MRI

## Why not?

- Patients with cardiac devices (PM/ICD) are restricted from MRI because the **static magnetic field** and the variable electromagnetic fields (**RF pulses** and **gradient system**) are generally believed to be potentially harmful to the patient/device.
- There are some reports of deaths in patients with PM/ICD undergoing MRI studies in **uncontrolled conditions**

Why not?



## **Adverse Interactions between MRI and PM/ICD**

- **Movement of the device (translational attraction, torque) and lead dislodgement**
- **Excessive heating**
- **Inappropriate (asynchronous) pacing (risk of VF) or inhibition of pacing**
- **Activation of tachyarrhythmia therapies (ICD)**
- **MRI-induced arrhythmias associated with current induction in the leads**
- **Functional alterations (programming changes, battery depletion)**
- **Artifacts (pulse generator, leads)**

## Why not?

### Implantable Cardioverter Defibrillator Dysfunction During and After Magnetic Resonance Imaging

OLE-GUNNAR ANFINSEN, ROLF FRANCK BERNTSEN, HALFDAN AASS, ERIK KONGSGAARD, and JAN PEDER AMLIE

From the Department of Cardiology, Rikshospitalet, University Hospital of Oslo, Oslo, Norway



### Suppression of Implantable Cardioverter Defibrillator Therapy During Magnetic Resonance Imaging

JAN NĚMEC, M.D.

From the Minnesota Heart Clinic, Edina, Minnesota, USA

### Rapid Ventricular Pacing in a Pacemaker Patient Undergoing Magnetic Resonance Imaging

JOHN M. FONTAINE, FEROZE B. MOHAMED, CHARLES GOTTLIEB, DAVID J. CALLANS, and FRANCIS E. MARCHLINSKI

From the Allegheny University of the Health Sciences, The Medical College of Pennsylvania and Hahnemann University School of Medicine, Allegheny University Hospitals, MCP Division, Philadelphia, PA

### Complete Loss of ICD Programmability After Magnetic Resonance Imaging

MICHAEL FIEK, THOMAS REMP, CHRISTOPHER REITHMANN, and GERHARD STEINBECK

From the Medical Hospital I, University of Munich - Grosshadern, Germany

Inbar S, Larson J, Burt T, Mafee M, Ezri MD. Case report: nuclear magnetic resonance imaging in a patient with a pacemaker. *Am J Med Sci* 1993; 305:174-5.

Alagona P Jr, Toole JC, Maniscalco BS, et al. Nuclear magnetic resonance imaging in a patient with a DDD Pacemaker. *PACE* 1989; 12:619.

Bartsch Ch, Irnich W, Risse M, Weiler G. Unexpected sudden death of pacemaker patients during or shortly after magnetic resonance imaging (MRI). In: Abstract Book, XIX Congress, Intern Acad Leg Med, Milan (Italy); Sept. 3-6 2003. p. 174. [Abstract # 114].

Rasmussen MJ, Friedman PA, Hammill SC, Rea RF. Unintentional deactivation of implantable cardioverter-defibrillators in health care settings. *Mayo Clin Proc* 2002;77:855-9.

Avery JE. Loss prevention case of the month. Not my responsibility! *J Tenn Med Assoc* 1988;81:523.

Garcia-Bolao I, Albaladejo V, Benito A, Alegria E, Zubietta JL. Magnetic resonance imaging in a patient with a dual-chamber pacemaker. *Acta Cardiologia* 1998;19:33-5.

## Implantable Cardioverter Defibrillator Dysfunction During and After Magnetic Resonance Imaging

OLE-GUNNAR ANFINSEN, ROLF FRANCK BERNTSEN, HALFDAN AASS, ERIK KONGSGAARD, and JAN PEDER AMLIE

From the Department of Cardiology, Rikshospitalet, University Hospital of Oslo, Oslo, Norway



Why not?

**ANFINSEN, O.-G., ET AL.: Implantable Cardioverter Defibrillator Dysfunction During and After Magnetic Resonance Imaging.** *This report describes a patient in whom a MRI of the brain was performed without realizing that an ICD had been implanted 8 days previously. Electromagnetic noise induced during the MRI was detected as ventricular fibrillation and nearly caused inappropriate shocks. Charge time during MRI was prolonged. The battery indicator switched to "end of life," but this was reversed by capacitor reformation. These problems could have been avoided by inactivating the ICD prior to MRI. Three months later, the pacing threshold increased from 0.4 V per 0.5 ms at implantation to 2.8 V per 0.5. It is still uncertain whether radiofrequency current heating at the electrode tip caused the increased pacing threshold or if this would have occurred independently of the MRI. MRI of patients with an active ICD may cause life-threatening complications, and it is unknown if MRI may be safely performed if the ICD is inactivated. Therefore, MRI of patients with an ICD remains contraindicated. (PACE 2002; 25: 1400-1402)*

## Complete Loss of ICD Programmability After Magnetic Resonance Imaging

MICHAEL FIEK, THOMAS REMP, CHRISTOPHER REITHMANN, and GERHARD STEINBECK

From the Medical Hospital I, University of Munich - Grosshadern, Germany

**FIEK, M., ET AL.: Complete Loss of ICD Programmability After Magnetic Resonance Imaging.** *The purpose of this case report is to describe the effects of an MRI performed on a patient without realizing that an ICD has been previously implanted. After a few seconds of imaging the adversity was recognized and the examination was stopped immediately. The patient was not pacemaker dependent and had neither physical complaints nor electrocardiographic changes in the surface ECG. A consecutively performed ICD assessment showed a backup mode with standard parameters for pacing (VVI 50 beats/min) and arrhythmia detection and treatment. The device could not be programmed by the external programmer. With the exception of printing out the parameters, all software functions were no longer feasible. A device examination by the manufacturer after ICD replacement showed that a major portion of the device memory was corrupt. Even ICDs of a newer generation are susceptible to magnetic interference, with the danger of complete loss of programmability. (PACE 2004; 27:1002-1004)*





# Cardiac Devices and MRI

## Why yes?

- Despite the known hazards, numerous patients with PM/ICD have undergone MRI during *carefully monitored procedures*
- No irreversible harm has been reported when patients have been carefully monitored and the devices underwent reprogramming before the scans
- Nowadays, PM/ICDs have less ferromagnetic components as well as improved circuitry, which provide added protection from MRI



## Clinical update

# Magnetic resonance imaging safety in pacemaker and implantable cardioverter defibrillator patients: how far have we come?

Peter Nordbeck<sup>1,2</sup>, Georg Ertl<sup>1,2</sup>, and Oliver Ritter<sup>1,2\*</sup>

> 1000 PM-Pts  
> 350 ICD-Pts  
No Major adverse events  
or deaths

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

Field strength	Trial	No. of patients	Adverse events
0.2	Strach <i>et al.</i> <sup>39</sup>	114	–
0.5	Sommer <i>et al.</i> <sup>36</sup>	18	Reed switch activation, continuous pacing in the static field
	Sommer <i>et al.</i> <sup>37</sup>	44	–
	Valhaus <i>et al.</i> <sup>38</sup>	32	Decrease in battery voltage, reed switch activation
	Gimbel <i>et al.</i> <sup>35</sup>	5	One power-on-reset
1.5	Martin <i>et al.</i> <sup>12</sup>	54	Significant threshold changes in 9% of leads
	Gimbel <i>et al.</i> <sup>40</sup>	10	Seven patients had alterations in pacing thresholds
	Sommer <i>et al.</i> <sup>13</sup>	82	Increased capture threshold. In 4/115 patients troponin increased
	Nazarian <i>et al.</i> <sup>41</sup>	31 (55 total)	–
	Mollerus <i>et al.</i> <sup>42</sup>	32 (37 total)	–
	Mollerus <i>et al.</i> <sup>44</sup>	46 (52 total)	Ectopy
	Naehle <i>et al.</i> <sup>43</sup>	47	Repetitive scans (1)
	Mollerus <i>et al.</i> <sup>45</sup>	105 (127 total)	Decreased sensing
	Halshtok <i>et al.</i> <sup>46</sup>	9 (18 total)	Five power-on-resets
	Burke <i>et al.</i> <sup>47</sup>	24 (38 total)	–
	Buendia <i>et al.</i> <sup>48</sup>	28 (33 total)	Two temporary captures
	Nazarian <i>et al.</i> <sup>49</sup>	237 (438 total)	Two power-on-resets
	Cohen <i>et al.</i> <sup>50</sup>	69 (109 total)	Decreases in battery voltage
	Boilson <i>et al.</i> <sup>51</sup>	32	5 × power-on-resets
2.0	Del Ojo <i>et al.</i> <sup>52</sup>	13	–
3.0	Naehle <i>et al.</i> <sup>53</sup>	44	–
	Gimbel <sup>54</sup>	14	–

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

Field strength	Trial	No. of patients	Adverse events
1.5	Coman <i>et al.</i> <sup>55</sup>	11	One short asymptomatic pause in pacing during scanning, One power-on-reset
	Gimbel <i>et al.</i> <sup>58</sup>	7	One power-on-reset
	Nazarian <i>et al.</i> <sup>41</sup>	24 (55 total)	–
	Mollerus <i>et al.</i> <sup>42</sup>	5 (37 total)	–
	Pulver <i>et al.</i> <sup>57</sup>	8	–
	Mollerus <i>et al.</i> <sup>44</sup>	22 (127 total)	Decreased sensing amplitudes and impedances
	Halshtok <i>et al.</i> <sup>46</sup>	9 (18 total)	–
	Burke <i>et al.</i> <sup>47</sup>	14 (38 total)	–
	Buendia <i>et al.</i> <sup>48</sup>	5 (33 total)	One sensing error
	Nazarian <i>et al.</i> <sup>49</sup>	201 (438 total)	One power-on-reset, changes in pacing threshold
	Cohen <i>et al.</i> <sup>50</sup>	40 (109 total)	Decreases in battery voltage, pacing threshold increases, and impedance changes

## Why Yes?



### Our experience (2009-2013, *Policlinico S.Donato*)

- **120 pts with conventional PM/ICD implanted after 2000 underwent (142) MRI scans based on clinical indications.**
- Local /institutional scientific/ethical comitte approval
- All pacing systems were considered eligible for inclusion
- **Pediatic (<16 y) and PM-dependent patients; recent implants (<2 months), abandoned/fractured/epicardial leads were excluded**
- All MR studies were performed with a Siemens SONATA 1.5 T (64 MHz) equipment.
- **No restrictions were placed on the body segment to be studied**
- Continuous pulse oximetry + ECG monitoring and verbal communication-patient were used during the MR scans.
- **An electrophysiologist with full resuscitation equipment was present during each MRI for the entire examination.**
- Each device was fully interrogated immediately before and after MRI scanning

Why yes?



## Aim of the study

- to assess the immediate and mid-term *safety* of MRI in patients with PM or ICD
- to assess the diagnostic yield (*efficacy*) of MRI in this setting

**120 pts (91 M, 29 F)**

mean age 62 y ( $\pm$  17)

**142 MRI**

**50% ICDs**

**50% PMs**

Mean time from implant to MRI = 33 m ( $\pm$  28)

**MRI segments**

THORACIC 65 (58 Cardiac)

SPINE = 20

BRAIN = 40

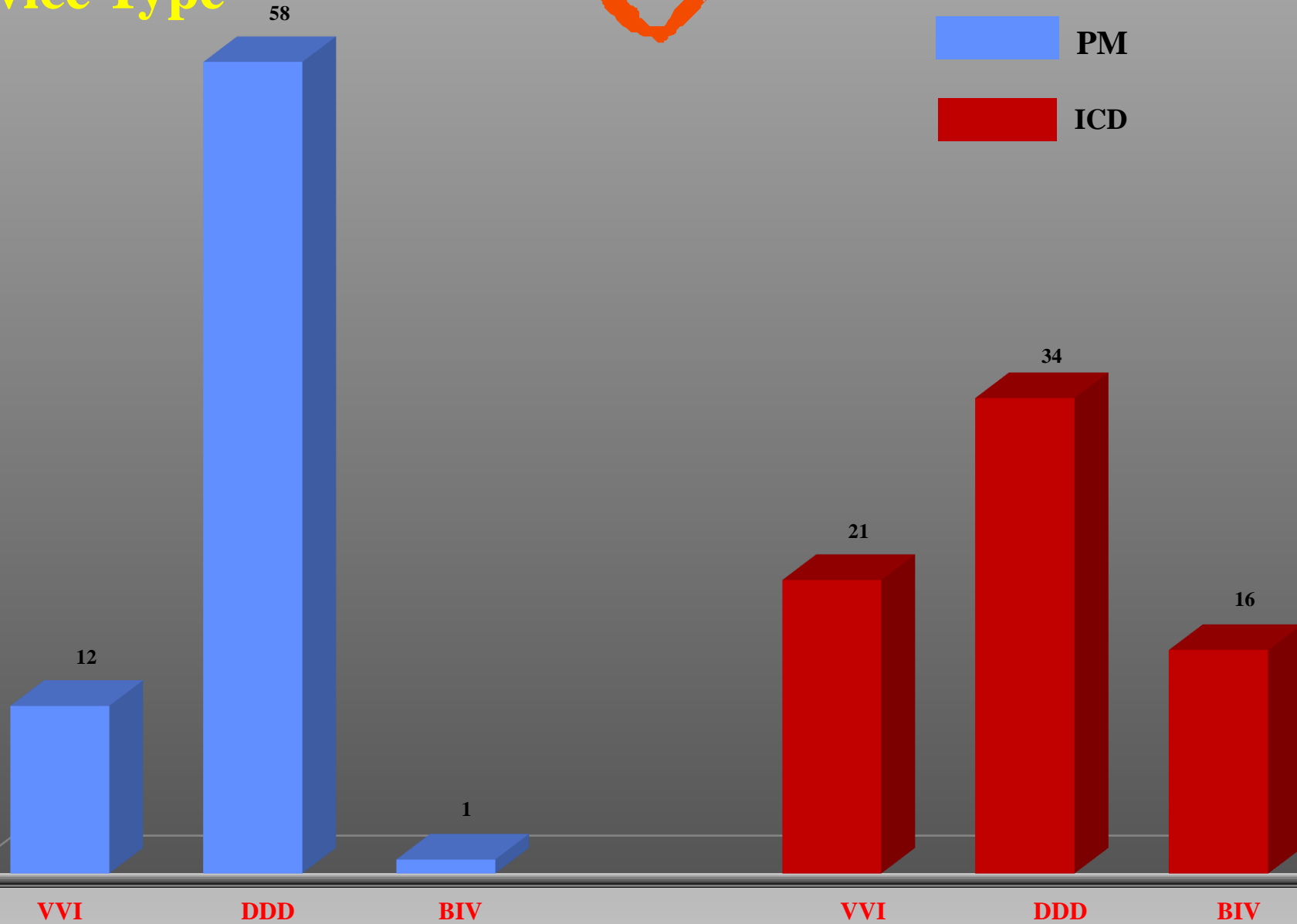
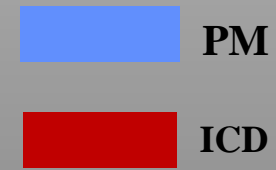
ABDOMEN = 7

LOWER EXTREMITIES = 8

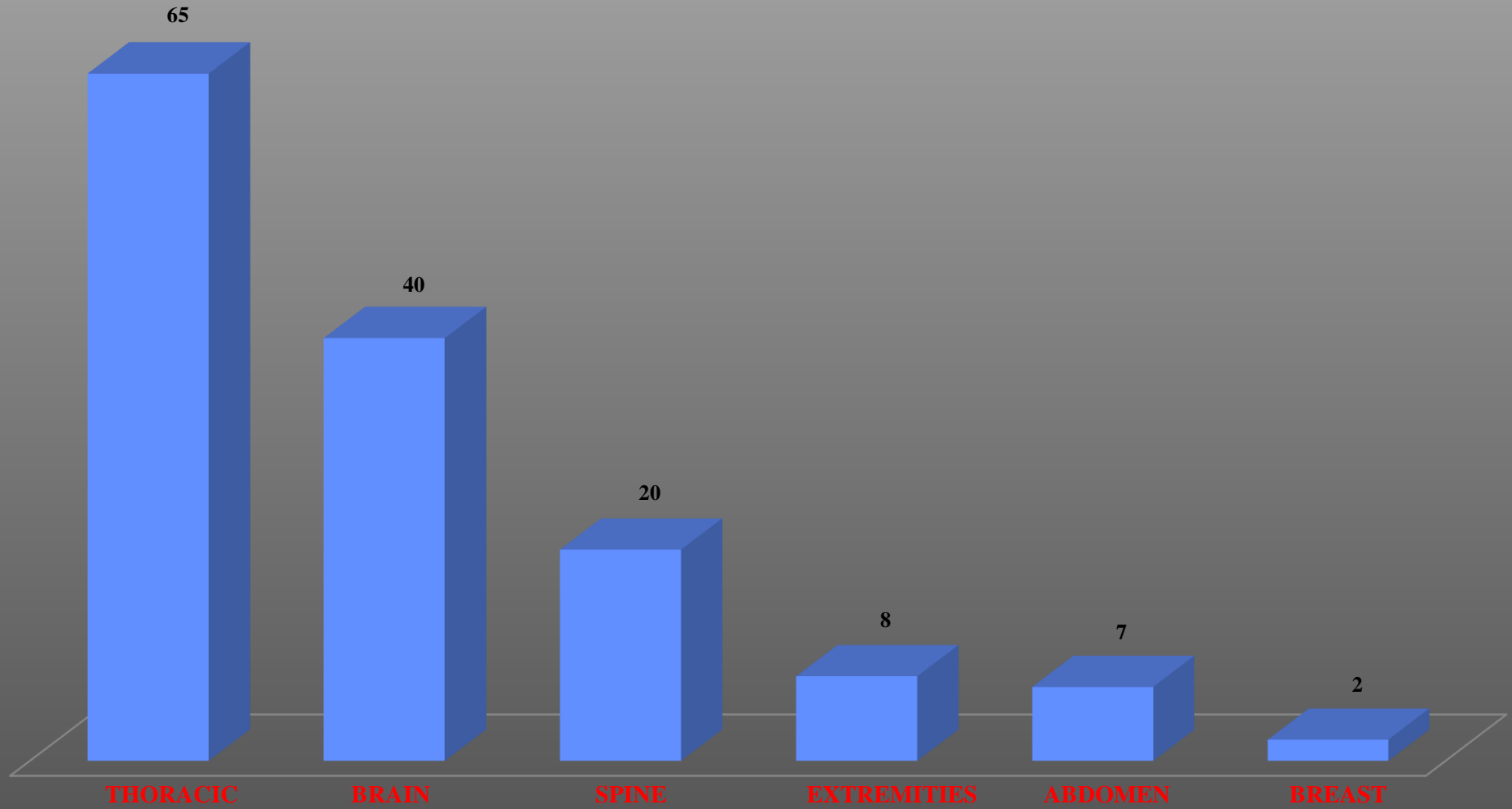
BREAST = 2

*Follow-up 12 m ( $\pm$  5)*

# Device Type



# MRI type

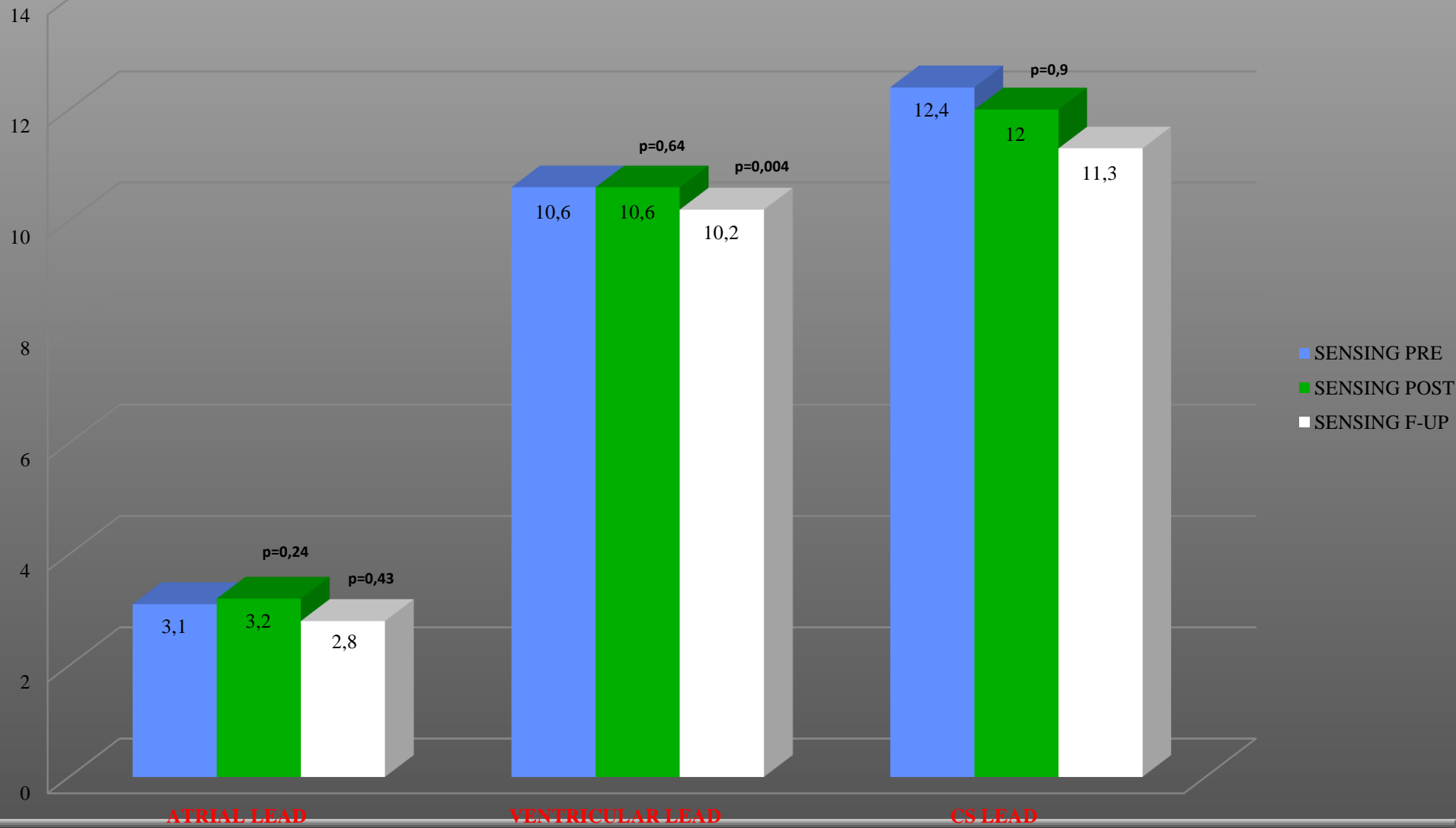


# IMPEDANCE (ohms)

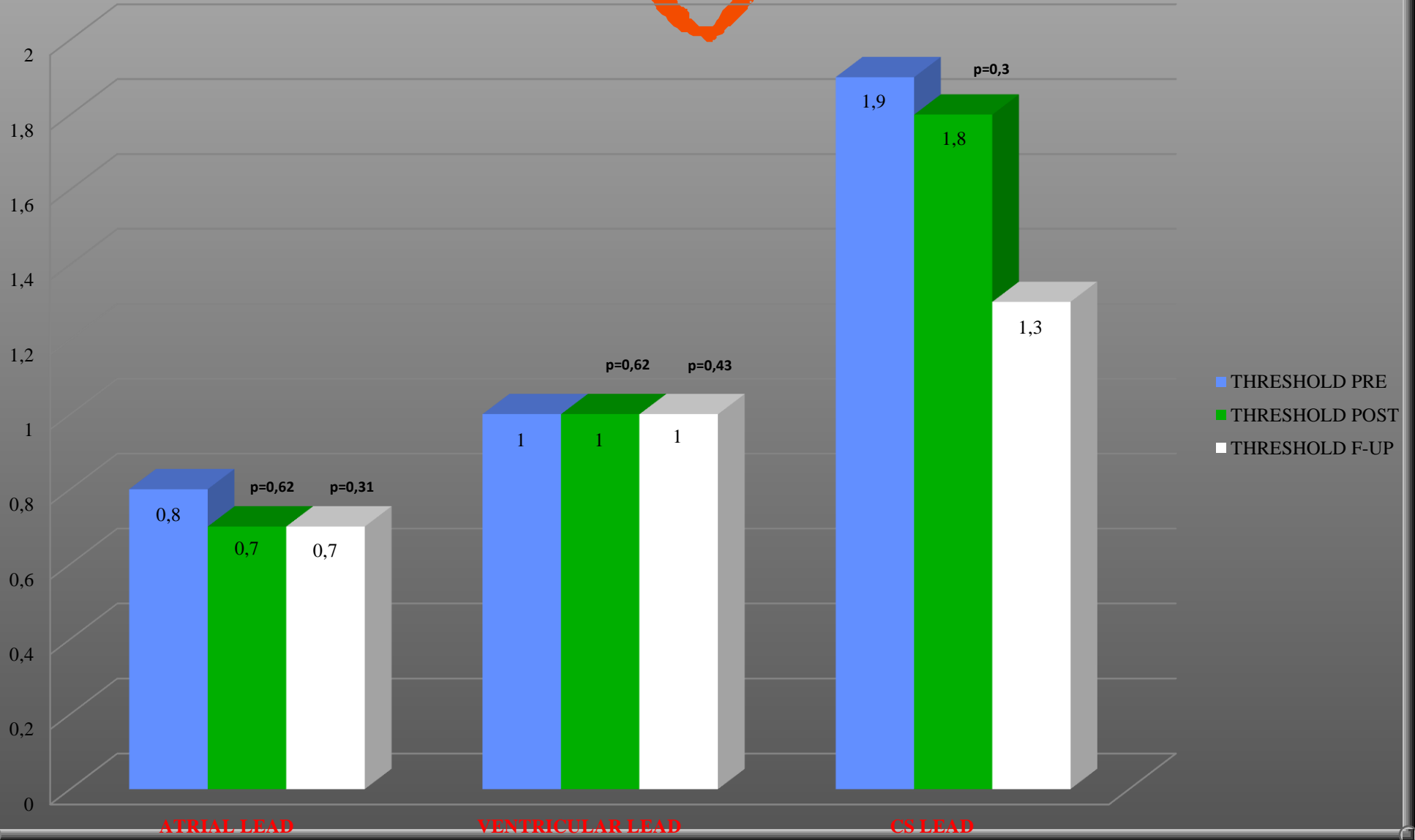




# SENSING (mV)

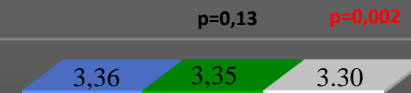
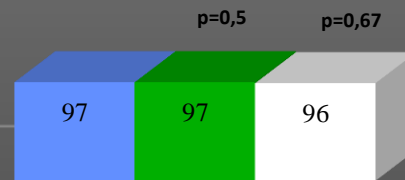


# THRESHOLD (Volts)





## BATTERY PARAMETERS



- PRE
- POST
- F-UP

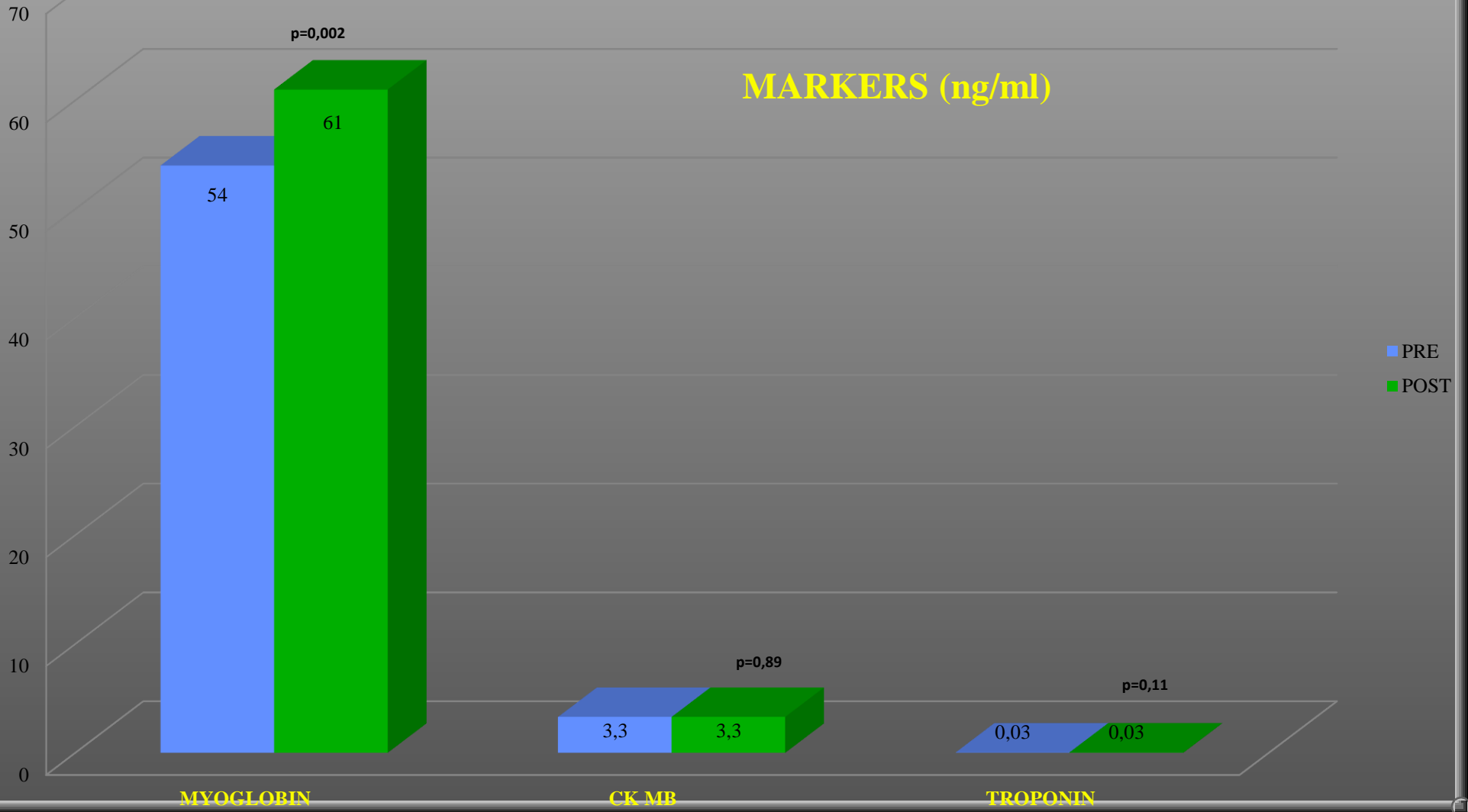
IMPEDANCE (ohms)

MAGNETIC FREQUENCY (bpm)

VOLTAGE (volts)



## MARKERS (ng/ml)



## Why Yes?

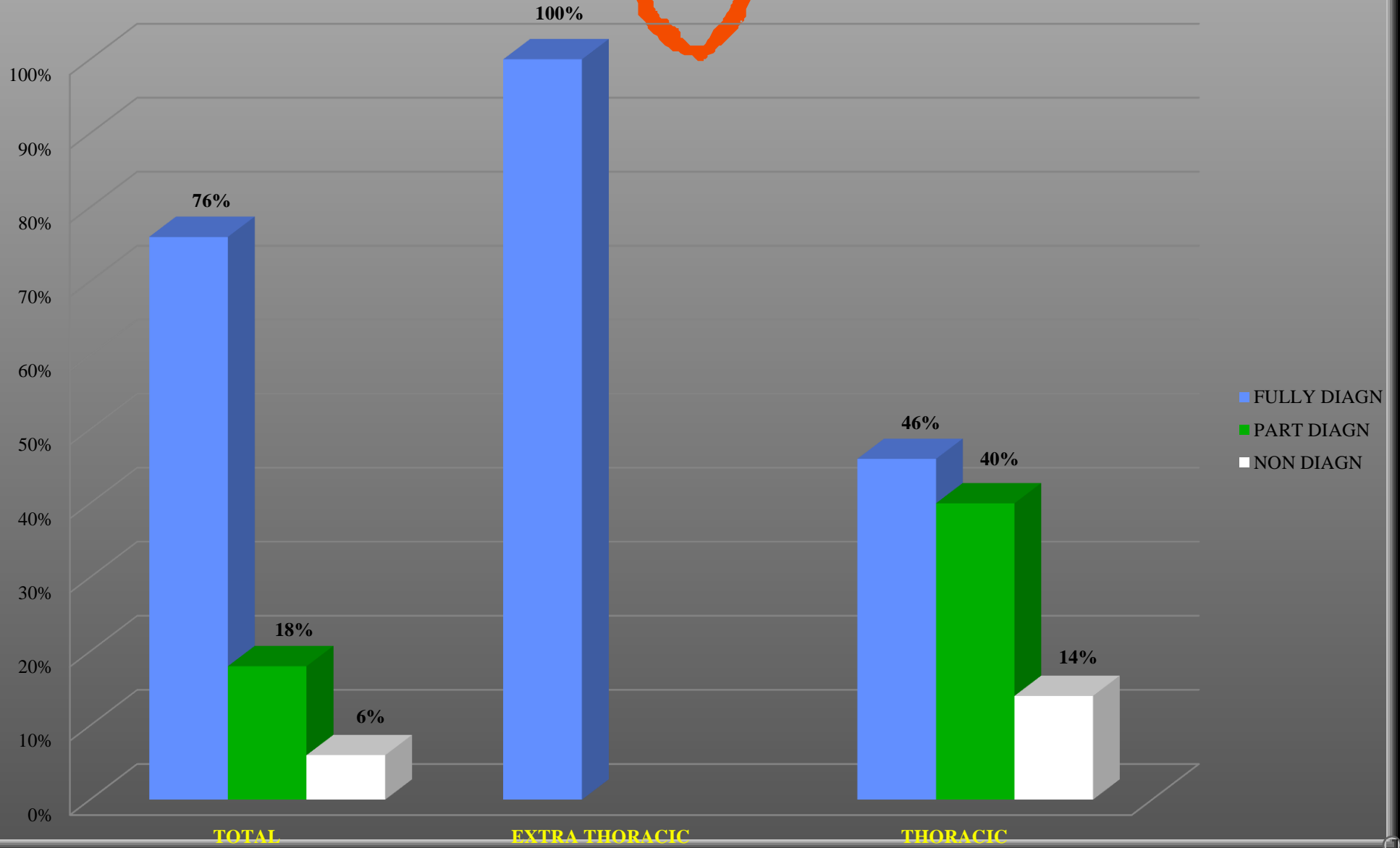


### Results

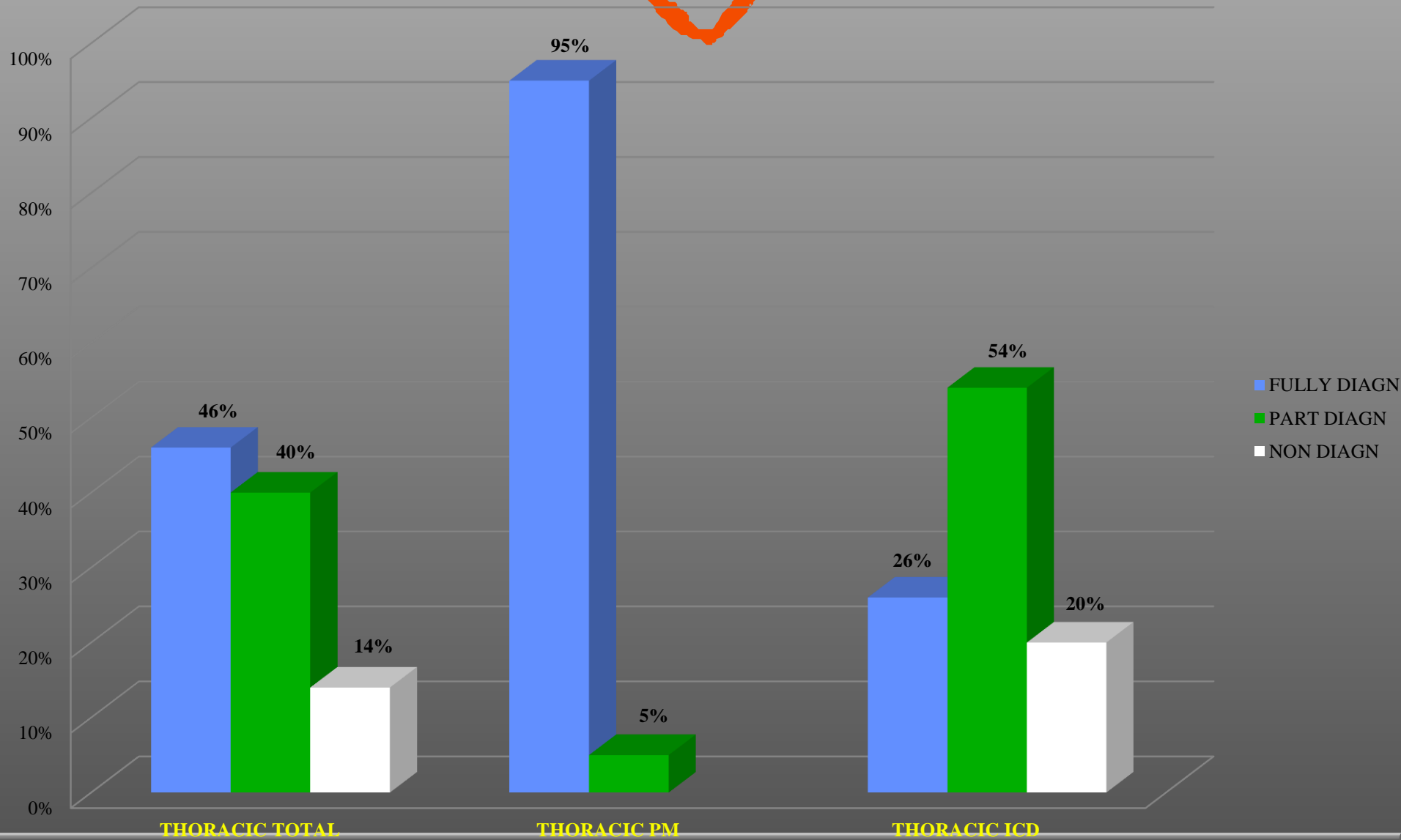
- Post-MRI interrogation and telemetry of each device proceeded without difficulty and the programmed settings remained unchanged
- *There were no significant differences comparing PM/ICD parameters before/after MRI exposure*
- No patient reported significant symptoms during or immediately after the MRI scan
- No rapid activation of pacing was observed during MRI

 **all devices were functioning appropriately after MRI**

# EFFICACY



# EFFICACY THORACIC MRI



# Efficacy



**MRI** n=142

*Fully diagn* (76%)

*Part diagn* \* (18%)

*Non diagn* \* (6%)

\* **Mostly are cardiac/thoracic MRI  
in ICD patients**

**NON CARDIAC MRI** n= 65

100% fully diagnostic

**CARDIAC MRI** n= 57

46% f. diagnostic ←

**MRI in PM pts** n= 71

95% f. diagnostic

**MRI in ICD pts** n= 71

50% f. diagnostic ←

**CARDIAC MRI in ICD pts**

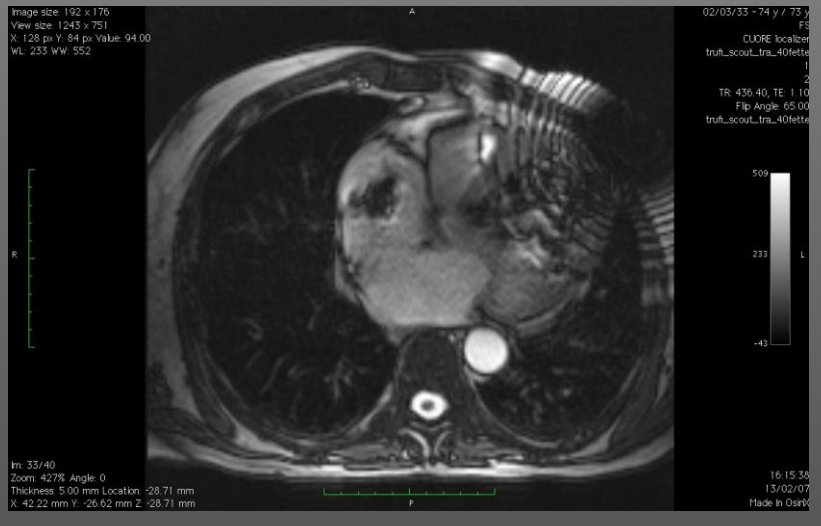
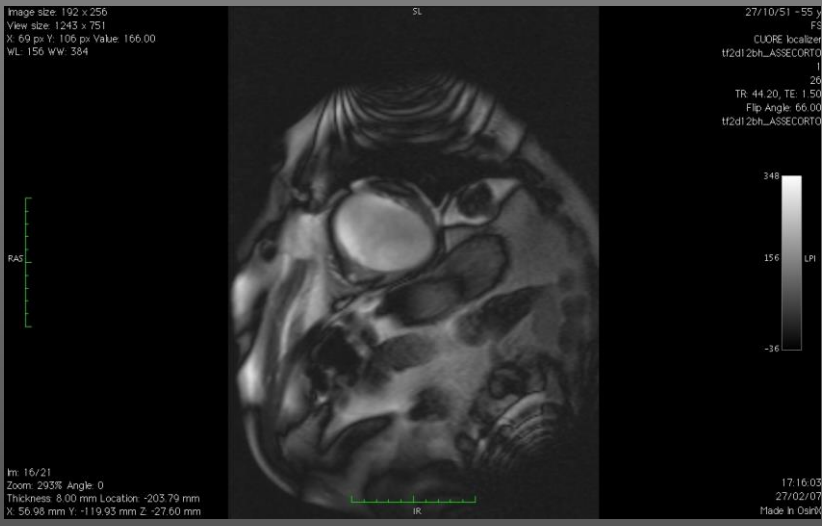
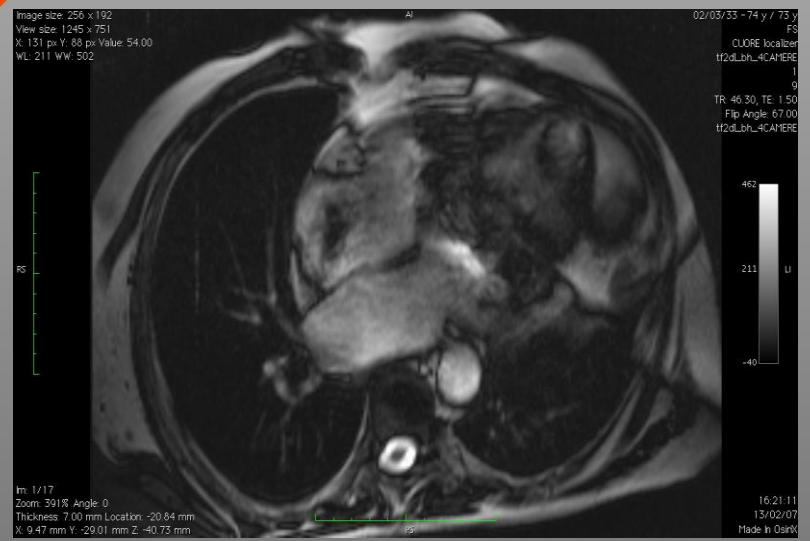
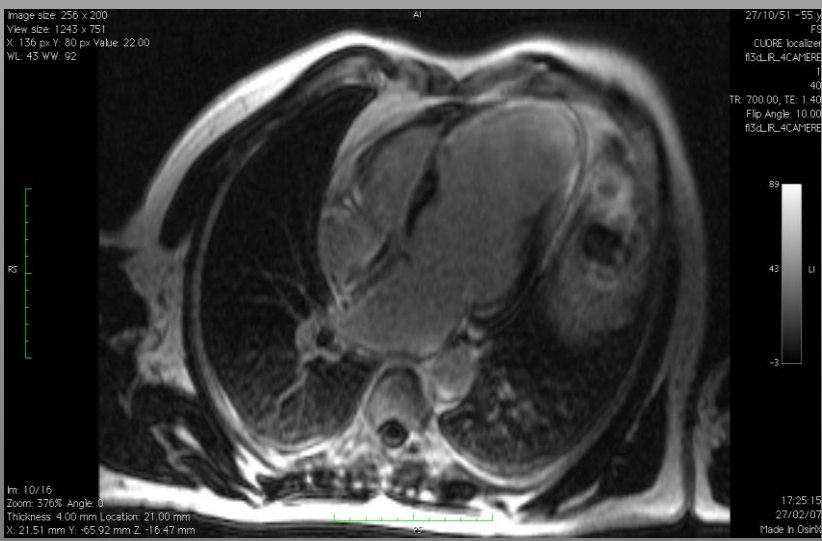
26% fully diagnostic



# DIAGNOSTIC. PM



# NON DIAGNOSTIC. ICD

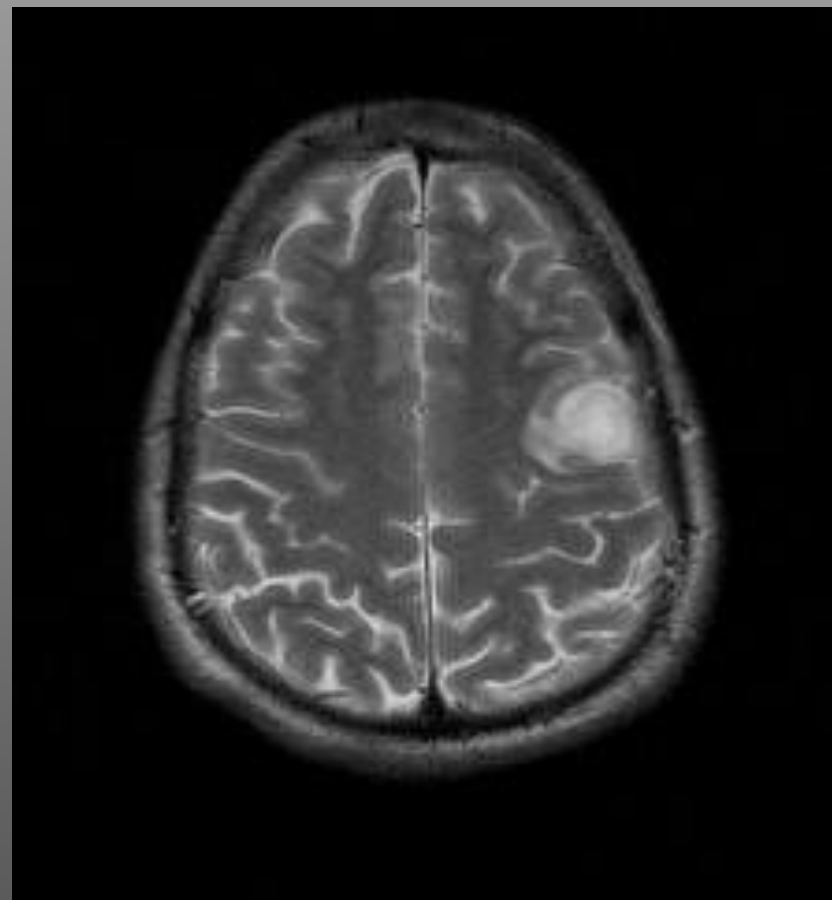




**PVs MRI in a patient with ICD**



**Brain MRI in a patient with ICD**



Why yes?



## Study conclusions

- Under controlled conditions, 1.5-T MRI can be performed in non-PM-dependent patients with a good risk/benefit profile
- Artifacts determined significant diagnostic issues mainly in **ICD** patients who underwent **cardiac/thoracic** MRI

# Novel Technology



## MRI-conditional devices:

### Generator design

- ▶ Ferromagnetic content reduced
- ▶ Replacement of reed switch with solid state technology—for example, Hall sensor
- ▶ Bandstop filter (64 MHz) in casing to shield circuitry

### Lead design

- ▶ Lead pitch of the inner coil redesigned to alter resonant frequency of the lead
- ▶ Lead diameter altered
- ▶ Bandstop filter (64 MHz) at lead tip (St Jude Tendril lead)

Ainslie M, et al. *Heart* 2014;**100**:363–369.

*overcomes technical challenges  
and legal issues*



**Boston  
Scientific**





- *Should we implant all pts with MRI-conditional/compatible devices?*

They should be used in selected pts in whom MRI Follow-up is warranted, and young Pts

- Longer follow-up is required to confirm this new technology performance,
- Its diagnostic efficacy in cardiac MRI is still questionable
- Costs!

## Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management

*This document was endorsed by the American Heart Association (AHA).*

Bruce L. Wilkoff, MD, FHRS,\* Charles J. Love, MD, FHRS,<sup>†</sup> Charles L. Byrd, MD,<sup>‡</sup>  
Maria Grazia Bongiorni, MD,<sup>§</sup> Roger G. Carrillo, MD, FHRS,<sup>||</sup> George H. Crossley, III, MD, FHRS,<sup>¶</sup>  
Laurence M. Epstein, MD,<sup>#</sup> Richard A. Friedman, MD, MBA, FHRS,\*\*<sup>|||</sup>  
Charles E. H. Kennergren, MD, PhD, FHRS,<sup>††</sup> Przemyslaw Mitkowski, MD,<sup>‡‡</sup>  
Raymond H. M. Schaerf, MD, FHRS,<sup>§§</sup> Oussama M. Wazni, MD\*

Heart Rhythm, Vol 6, No 7, July 2009

### Class IIb

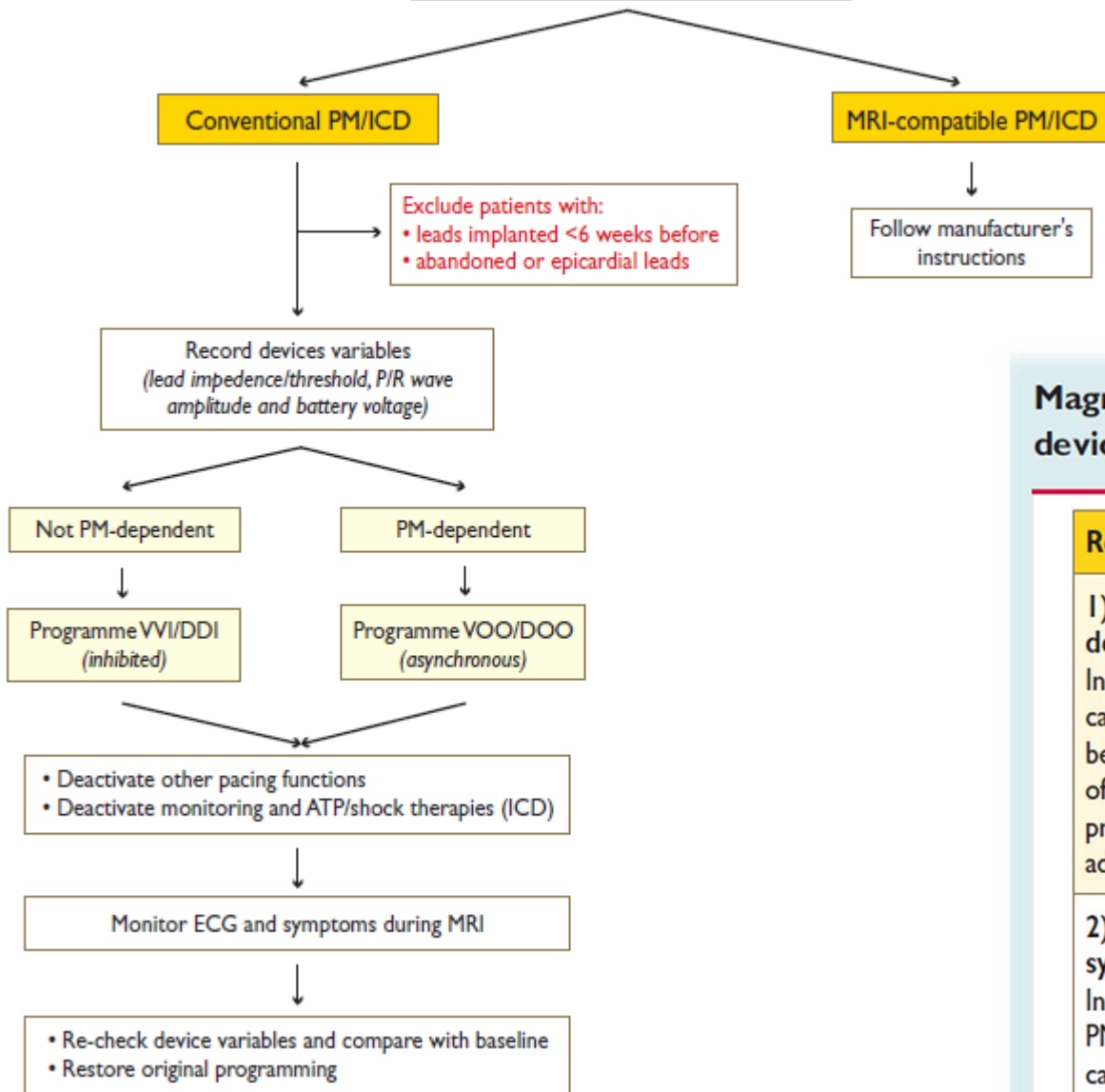
4. Lead removal may be considered in patients who require specific imaging techniques (e.g. MRI) that can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. (Level of evidence: C)

- *Should we replace older devices and leads with MRI-safe devices?*

**MRI in PM/ICD pts might be safer than leads extraction procedures!**

# ESC Guidelines 2013

## Implanted PM/ICD



## Magnetic resonance in patients with implanted cardiac devices

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref. <sup>c</sup>
<b>1) Conventional cardiac devices.</b> 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
<b>2) MR-conditional PM systems.</b> In patients with MR-conditional PM systems, MR at 1.5 T can be done safely following manufacturer instructions.	IIa	B	173



## Cardiac Devices and MRI

### Why not? Why yes?

*“...failing to identify an adverse event is not equivalent to demonstrating safety...”*

JR Gimbel, E Kanal JACC,43,7;2004

#### EDITORIAL COMMENT

**Can Patients With Implantable Pacemakers Safely Undergo Magnetic Resonance Imaging?\***



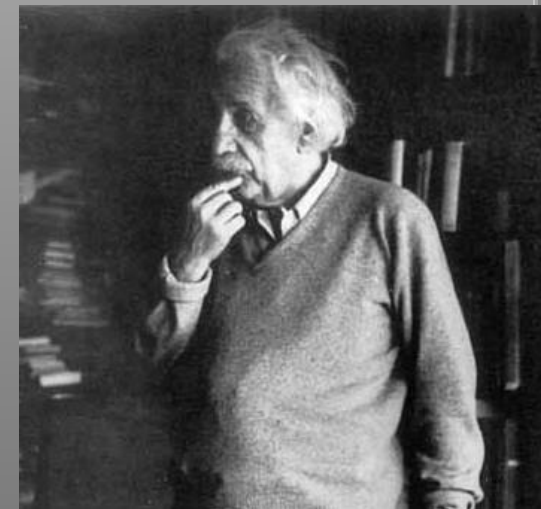


Europace (2010) 12, 915–917  
doi:10.1093/europace/euq174

EDITORIAL

## The safety of MRI scanning of pacemakers and ICDs: what are the critical elements of safe scanning? Ask me again at 10 000.

J. Rod Gimbel\*



“It might be useful to recall that perhaps a mere 1500 or so scans have been reported on device patients in the medical literature. Surely, **not enough safe scans have been done to declare all our previous concerns ‘hysterical’** “





**...Thank you for your attention**