MRI in Patients with Pacemakers and Defibrillators

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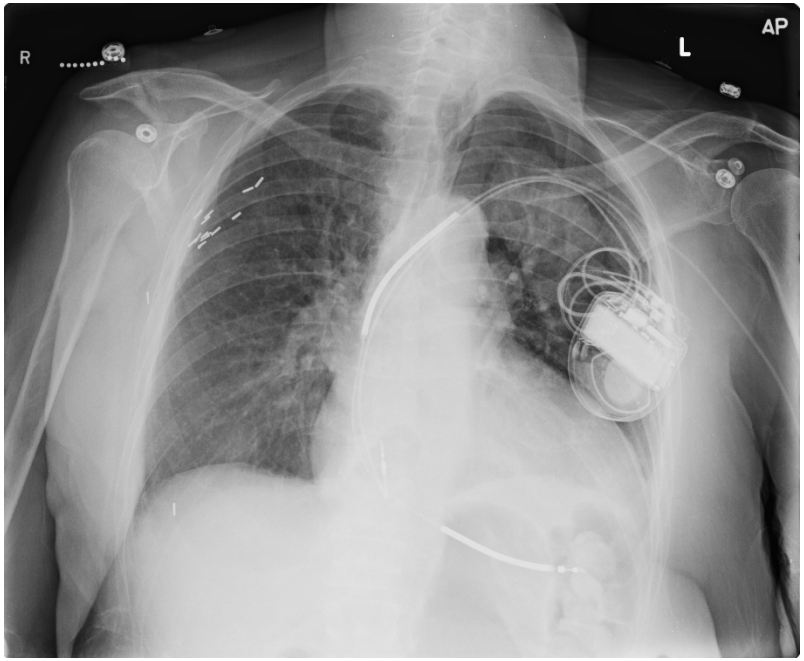
October 2016

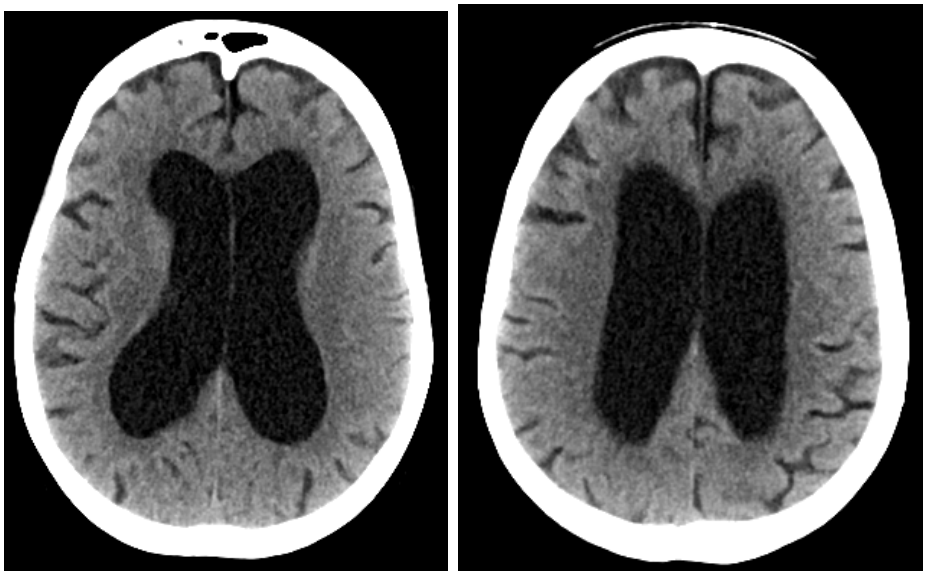
Case

- 71 y/o woman, adriamycin CM since 2001, presents Mar 2013 with AF/MI, symptomatic bradycardia -> BMS
- 3/27/2013: Implant DDD ICD (INR 2.1, taking ASA and Plavix, No defibrillation testing, in NSR)
- Post op sent to x-ray: no movement Left arm/leg, left facial droop, slured speech (10:48 pm), not tPA candidate

- Neuro: CT (-), small vessel disease vs embolic
  - Small vessel disease → medical therapy
  - Embolic → failed triple therapy → close LAA

- MRI would determine whether treatment is warranted
- Underlying rhythm is NSR 50 at present

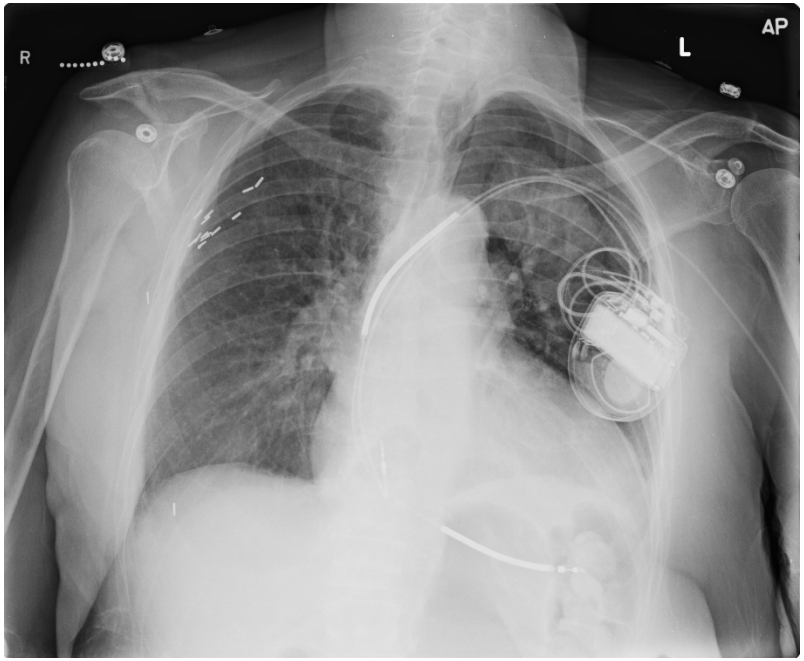


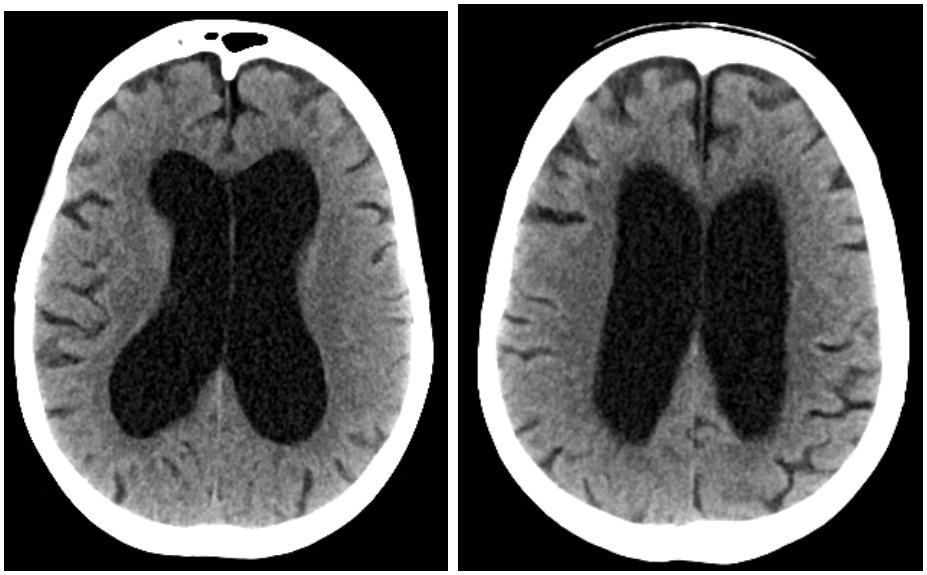


Head CT 3/28/2013

- At this point you recommend

1. Continue medical therapy (MRI too dangerous)
2. Explant ICD, cap leads, perform MRI, then re-implant
3. Explant ICD + leads for MRI
4. MRI brain with ICD in situ





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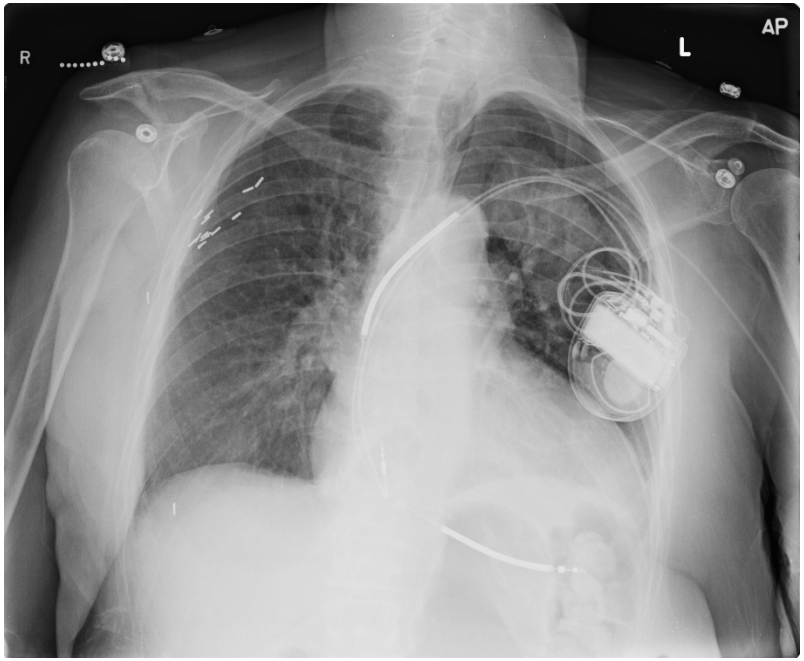

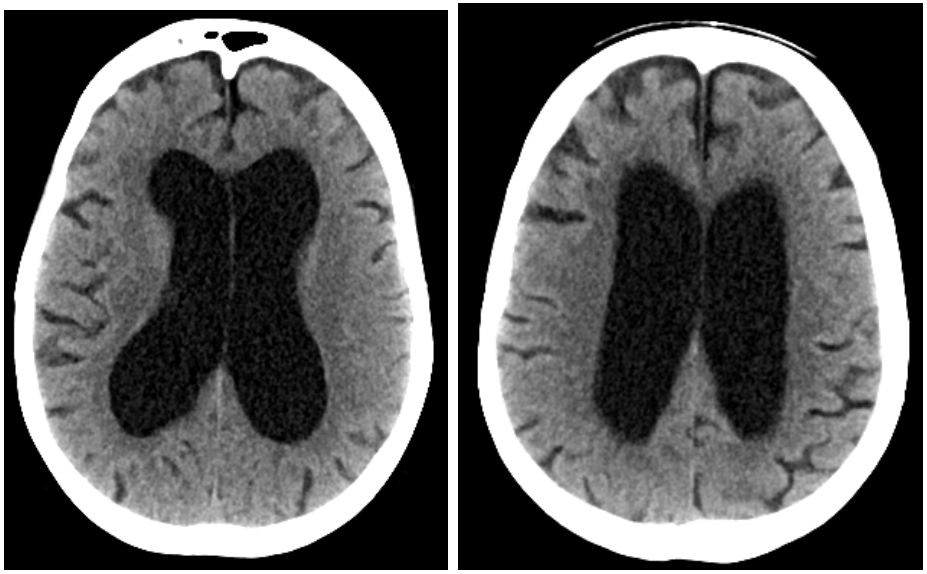

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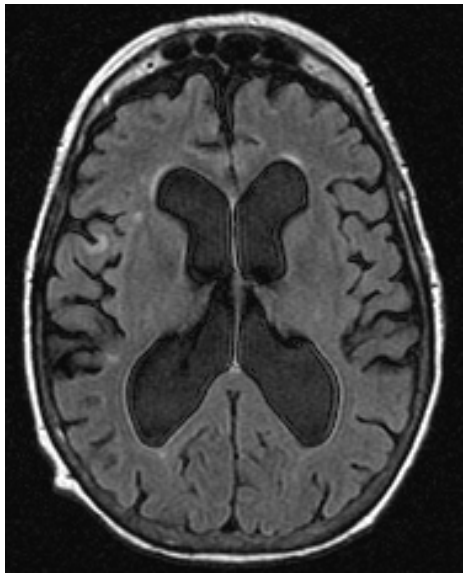
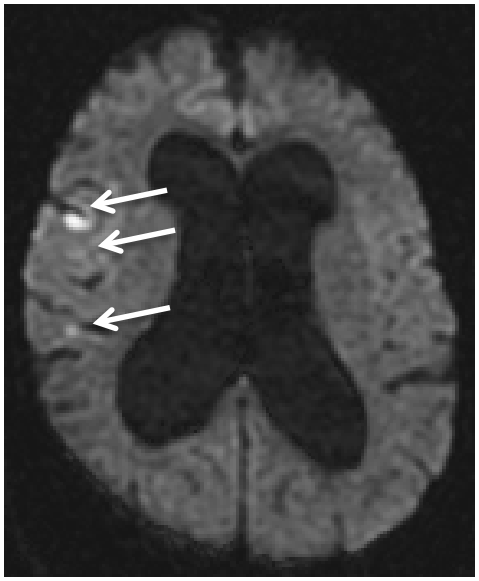
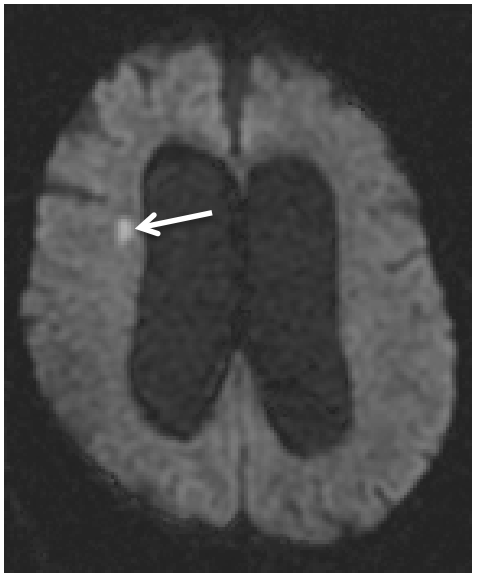


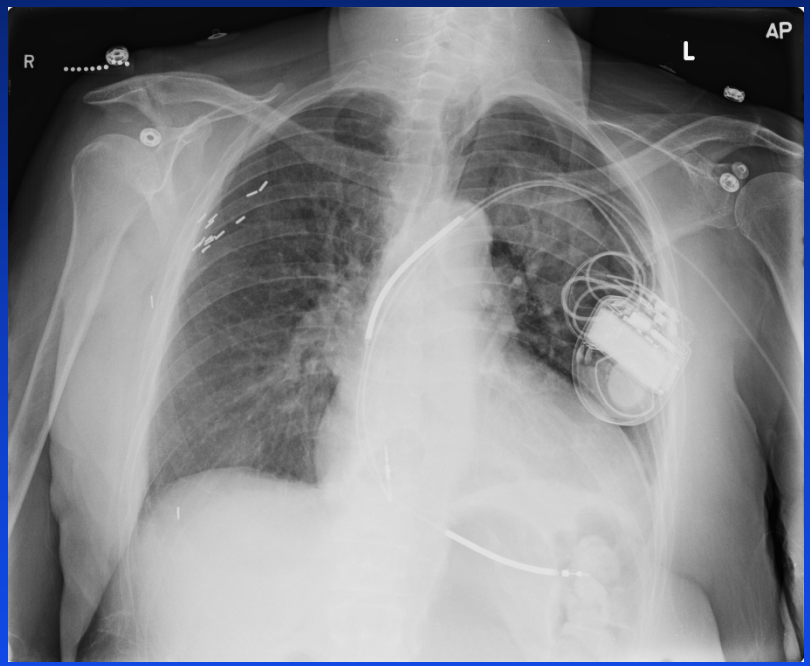




MRI with cardiac implanted device precautions 3/29/2013-embolic pattern: referred LAA closure

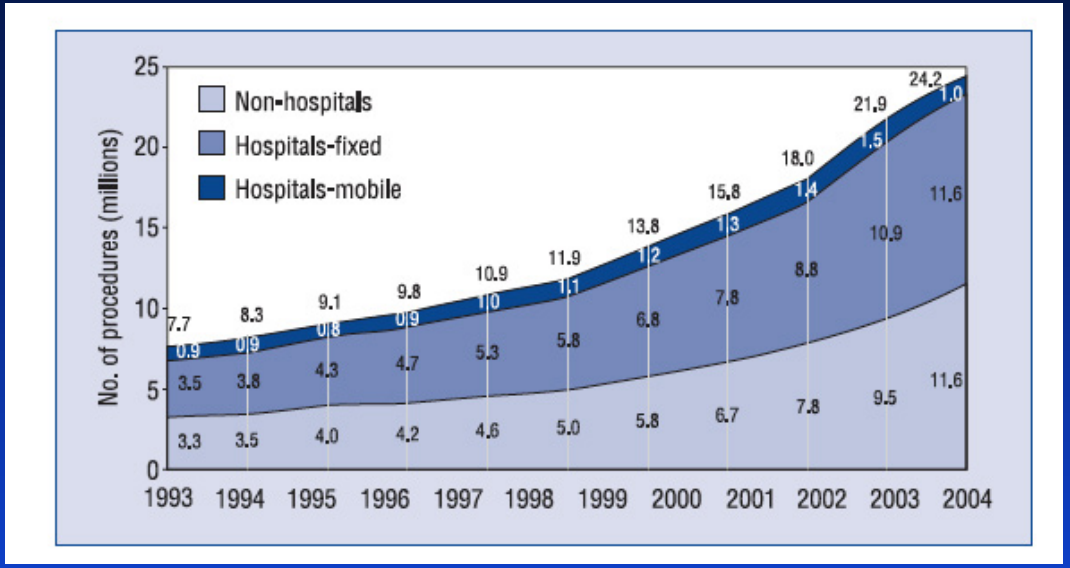
When can MRI safely be performed in patients with pacemakers or ICDs?

- Our patient had an ICD (not pacemaker)
- Her device had been implanted for just 2 days when MRI done

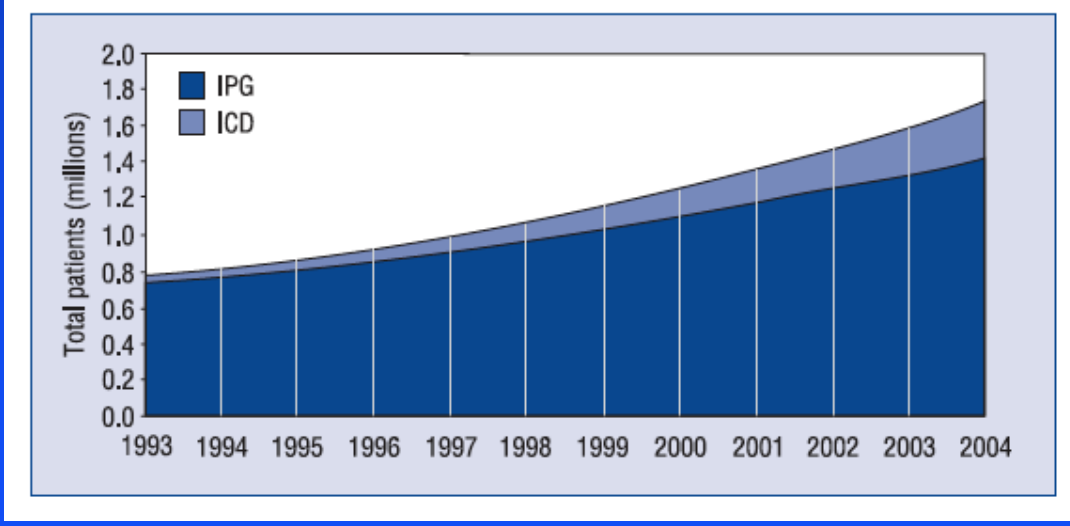


MRI in patients with CIEDs: The intersection of two trends

MRI procedures in US 1993-2003



Prevalence of PM + ICDs In the US1993-2004



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Pacemaker death after error in hospital

By Paul Stokes
12:01AM BST 03 Apr 2004

A former mayor died after hospital staff failed to note that she had a pacemaker when they sent her for a magnetic scan, an inquest was told.

Molly Brown, 83, was admitted to North Tyneside General Hospital twice within weeks because of blackouts and problems in walking.

Her medical notes made clear reference to the pacemaker, the hearing in Newcastle was told, but the matter "slipped the mind" of a consultant and her notes were not checked by a senior house officer, or read by another house officer or ward sister, when she was sent for an MRI scan.

Mrs Brown, a widow, former borough mayor and magistrate, died as radiowaves from the scan scrambled her pacemaker's settings and interfered with her heart rhythm. Recording a verdict of misadventure, David Mitford, the Newcastle Coroner, said the warning system to prevent such happenings was inadequate.

Mrs Brown, a councillor for 37 years and magistrate for 20, also served as a member of the area health authority and lived in Wallsend.

She was sent to the Nuffield Hospital, Newcastle, for the scan and, in a safety questionnaire, indicated that she did not have a pacemaker.

Speaking after the inquest, a spokesman for Northumbria Healthcare NHS Trust said: "The Trust have put in place new procedures to ensure that the safety of all patients requiring MRI scans is protected."

Sue Stokes, 32, one of Mrs Brown's four grandchildren, said the death had shocked the family and the inquest had been upsetting for them.

PRACTICE AREAS

- Children's Injuries
- Elder Abuse
- Employment Discrimination
- Medical Malpractice
- Personal Injury
- Product Liability
- Professional Negligence

MEDICAL MALPRACTICE – MRI PERFORMED ON PATIENT WITH PACEMAKER

Case Name: John Doe v. Dr. Roe and Hospital (Confidential)

Disposition: $250,000 settlement

Description: Magnetic Resonance Imaging (MRI) Performed on Patient with Pacemaker

Facts: Decedent, an 88-year-old male, had a pacemaker implanted to assist him in managing his atrial fibrillation. The pacemaker was regularly checked by Dr. Roe and was considered to be working properly. On May 26th, decedent experienced decreased movement of his left arm and left leg while at his home. Paramedics were called, and he was transported to Defendant Hospital to evaluate his condition for the possibility of a stroke. On examination, it was noted that his left upper extremity strength was 4+/5. His condition appeared to be resolving. A CT scan of the head showed no evidence of acute infarct, and no evidence of acute bleed. He was prescribed aspirin and was provided some physical and

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A carotid artery ultrasound was performed which showed stenosis in the right internal carotid artery bulb. The possibility of corrective surgery was discussed, and it was decided that this would be worked up and performed in the near future. Decedent made plans to be discharged from the hospital. Because he had been experiencing mobility problems with his left leg, which was now suspicious of orthopedic origin, x-rays of the leg were discussed with decedent and his granddaughter. It was decided that the leg would be x-rayed on decedent's way out to be discharged.

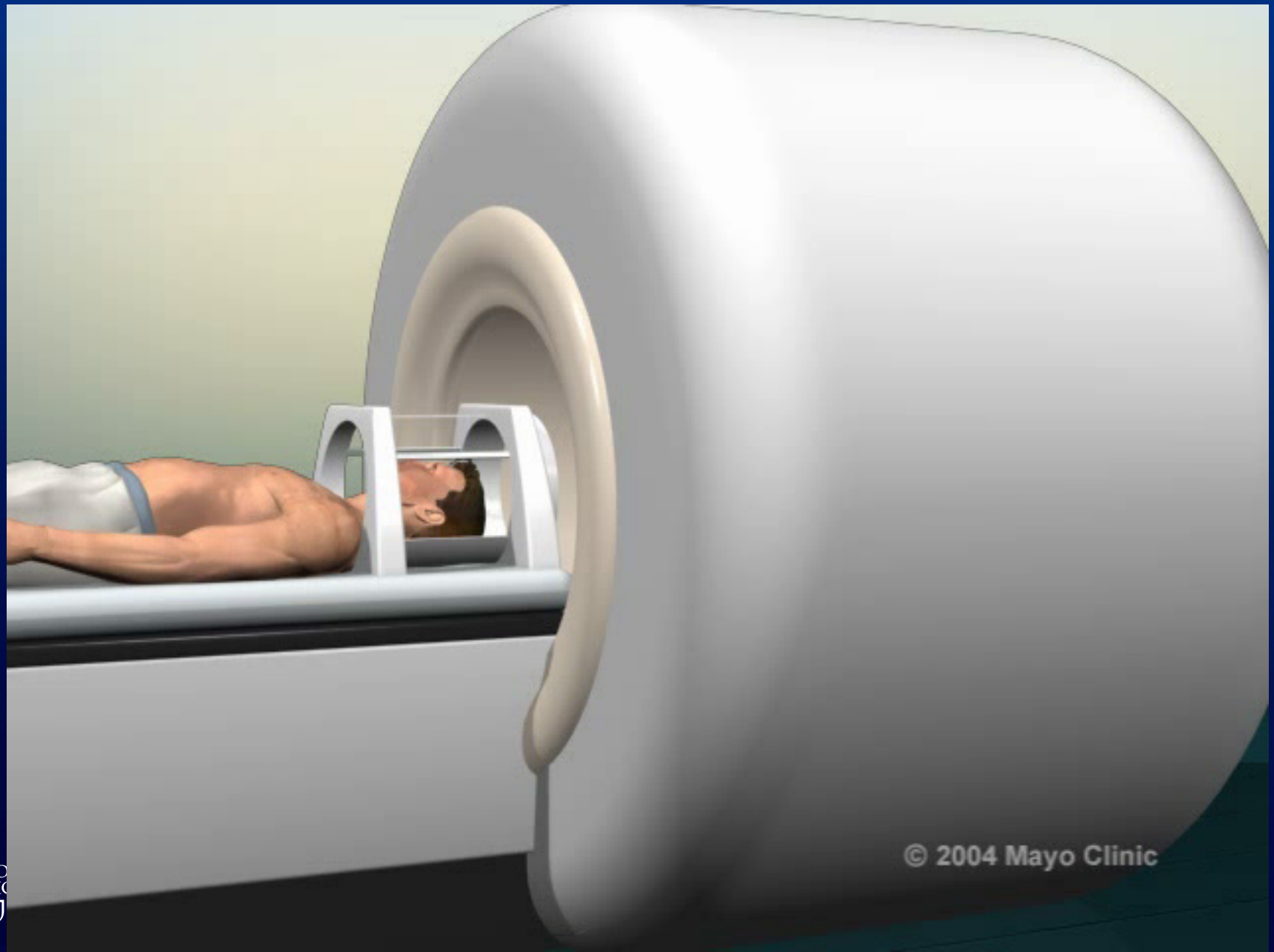
On May 29th, the granddaughter began the trip into town to pick up her grandfather to take him home, believing that he was in radiology having his leg x-rayed. Decedent did not have the leg x-rayed. Instead, he was placed in an MRI machine for a Magnetic Resonance Angiogram (MRA) to image his carotids. The purpose of the MRA was to further define the extent of the carotid occlusion earlier noted in the ultrasound. The medical records state that the MR angiography was performed in lieu of conventional catheter angiography because of the relative risks of invasive angiography. During the scan the attendant noted that on the screen it appeared that decedent's carotids were empty. The scan was ceased and decedent was pulled from the machine in full cardiac arrest. It was at that time, and for the first time, that anyone in the MRI department realized that decedent had a pacemaker. Decedent was revived and admitted to the intensive care department. He never regained consciousness, demonstrated a severely abnormal EEG, slipped into renal failure and died on July 21st.

Injuries/Damages: Death of an 88-year-old male, survived by spouse. $600 for funeral expenses and $25,540 in loss earnings based on a life expectancy of five years.

Plaintiff's Contentions: Plaintiff claimed that defendants knew or should have known that decedent had a pacemaker. It was a violation of the standard of care to attempt to perform any MRI in light of his condition.

Special Notes: The case settled with an agreement by Defendants to indemnify and hold harmless Plaintiff in regard to any monies potentially owed to MediCal or Medicare.

Acquiring an MR Image

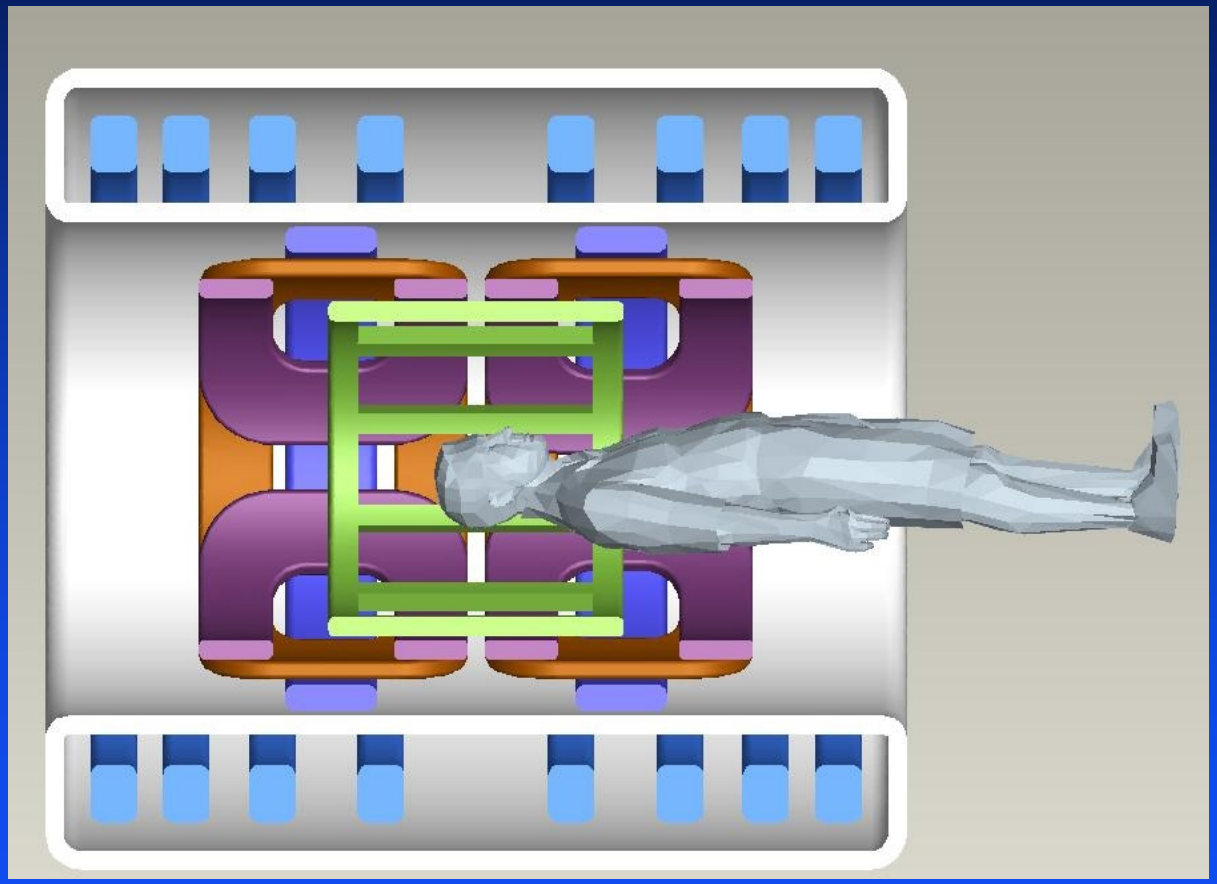


MRI: Three Powerful Fields

Static Field

Gradient Field

RF Field



Officer Hurt When MRI Pulls Gun

Police Say Off-Duty Officer Was At Beaches Open MRI With Her Mom

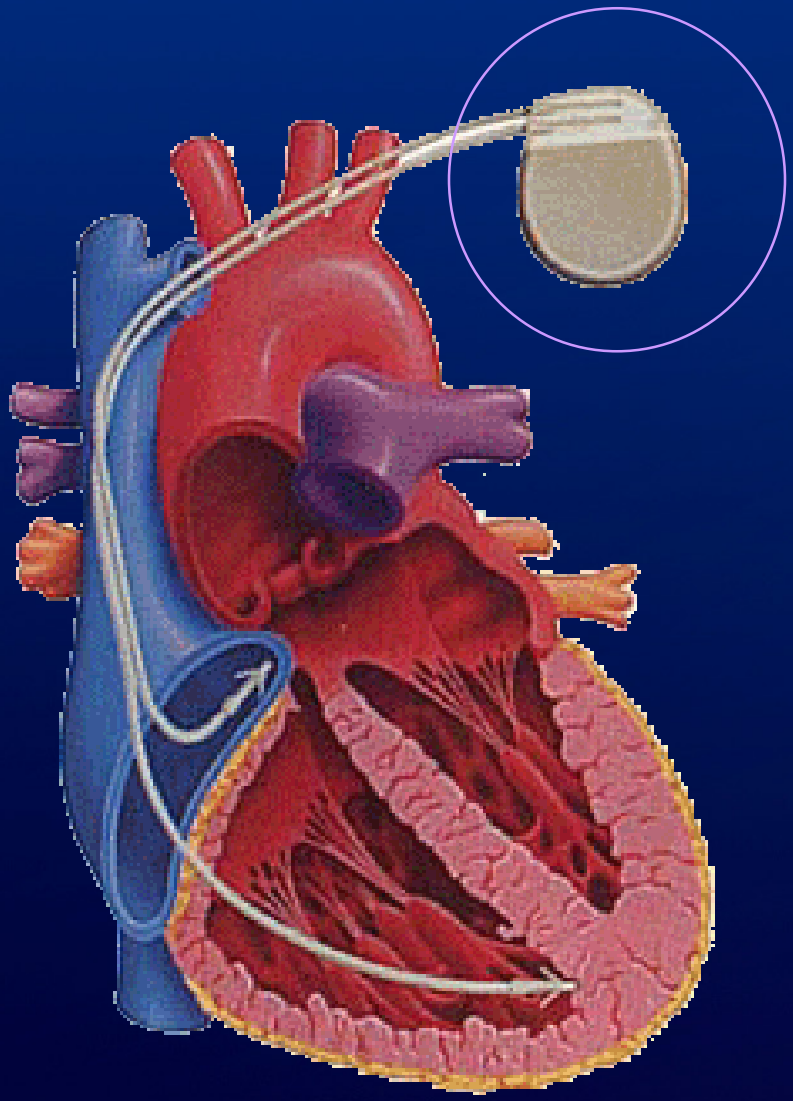
POSTED: Thursday, October 1, 2009

JACKSONVILLE, Fla. -- An off-duty Jacksonville Sheriff's Office deputy was hurt Wednesday when her hand was trapped between her police-issued Glock handgun and the powerful magnet inside an MRI machine.

Police said Joy Smith was in the MRI room with her mother when she apparently forgot about her gun, which was pulled by the magnetic force of the machine, trapping her hand between the gun and the MRI.


WARNING
STRONG MAGNETIC FIELD
NO PACEMAKERS
NO METALLIC IMPLANTS
NO NEUROSTIMULATORS
Persons with pacemakers, neurostimulators, or metallic implants must not enter this area. Serious injury may result.
Iron, steel and other ferrous materials must not be taken into this area. Serious injury or property damage may result.
STOP
Magnet is Always on!

So, what is the problem with PM in MRI?



Early designs from ~pre-1990's were not well shielded, RF from MRI affected sensing circuitry of device causing pacing at RF application rate (T1 weighted spin echo, 20 slices, TR=500 ms)

Hayes DL, Holmes DR Jr, Gray JE. Effect of 1.5 tesla nuclear magnetic resonance imaging scanner on implanted permanent pacemakers.

J Am Coll Cardiol. 1987; 10:782-6.

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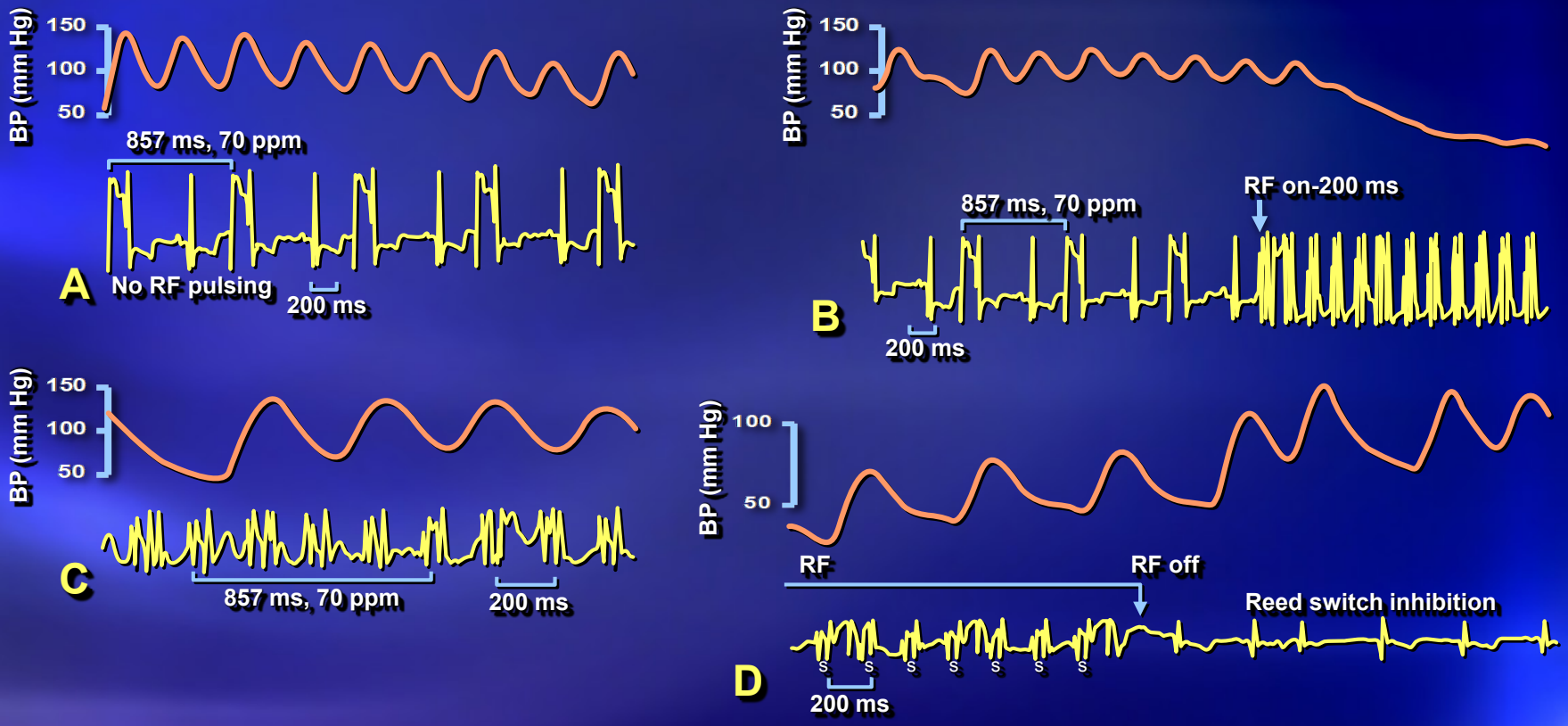
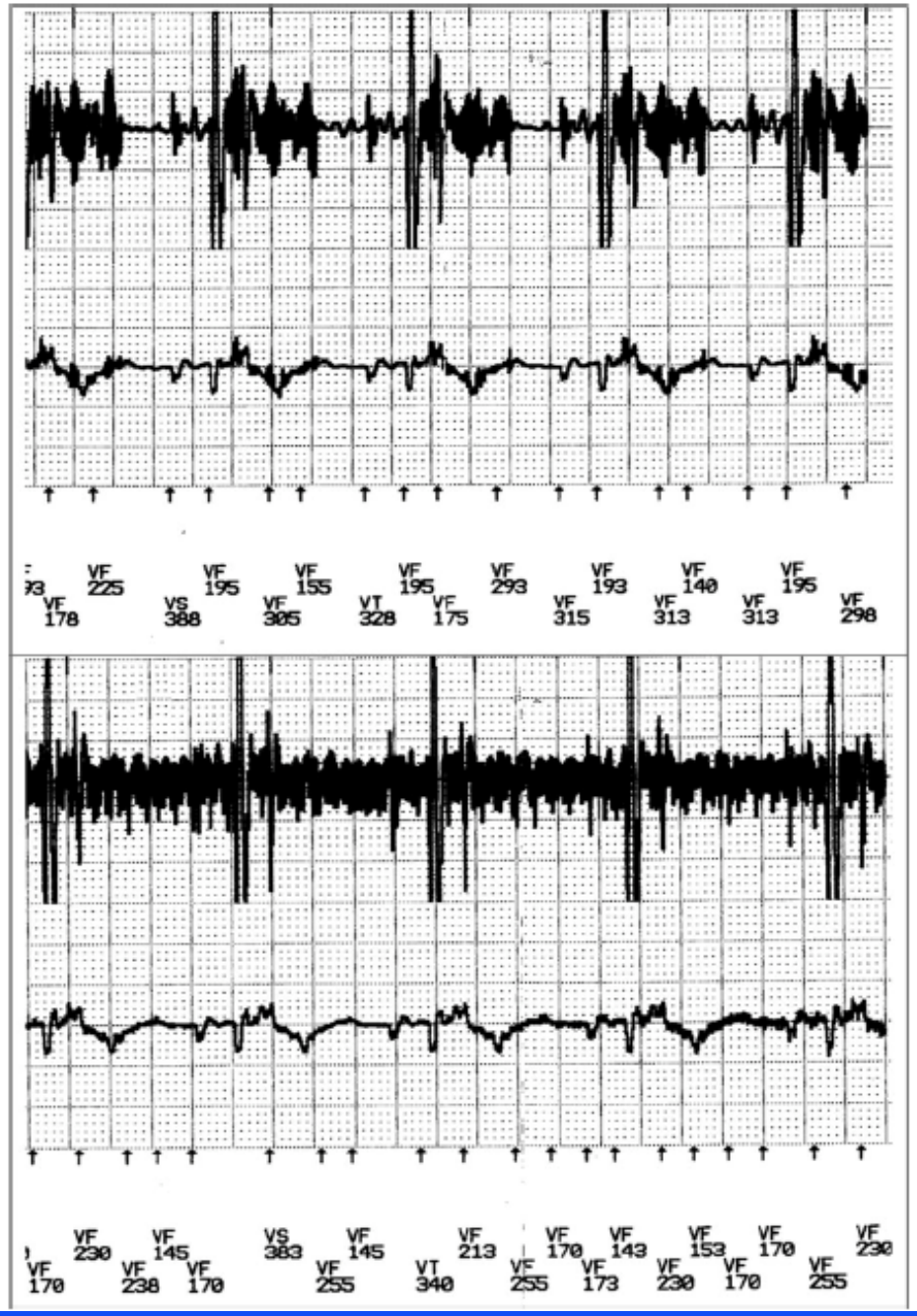
Effect of MRI on Implanted Pacemakers

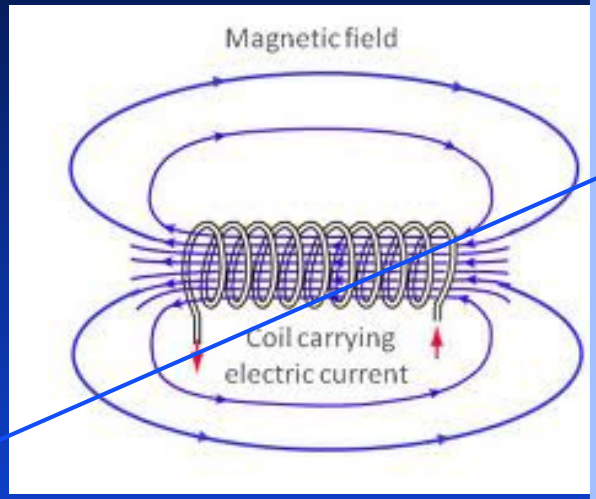


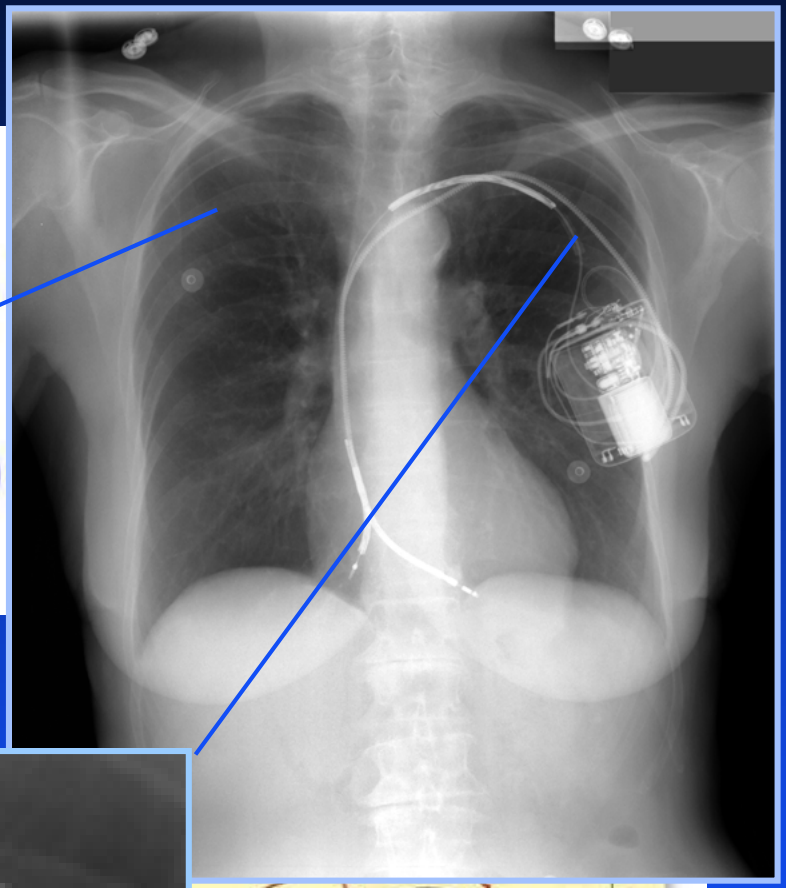
Hayes, et al. JACC 1987;10:782

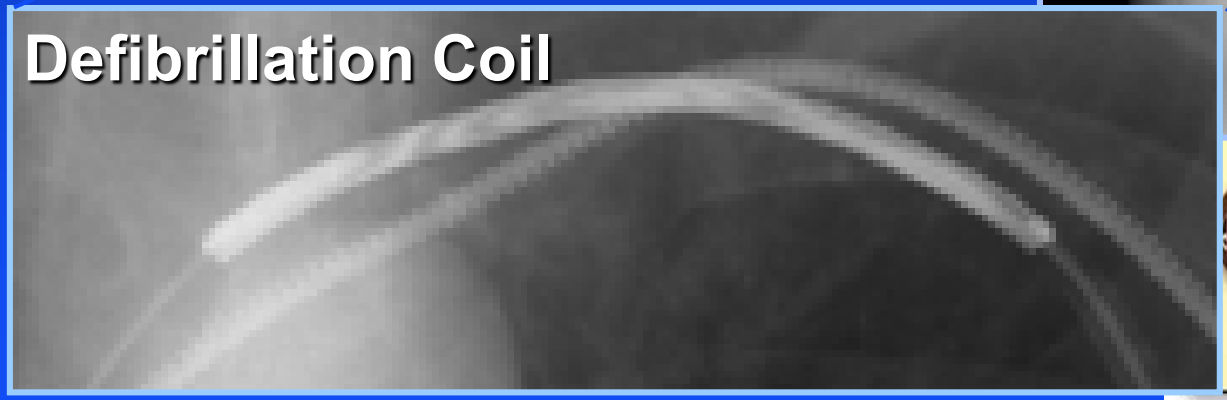


What's happening here?

Coils, Magnets, and Currents







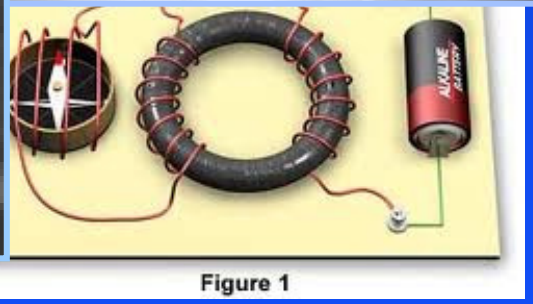
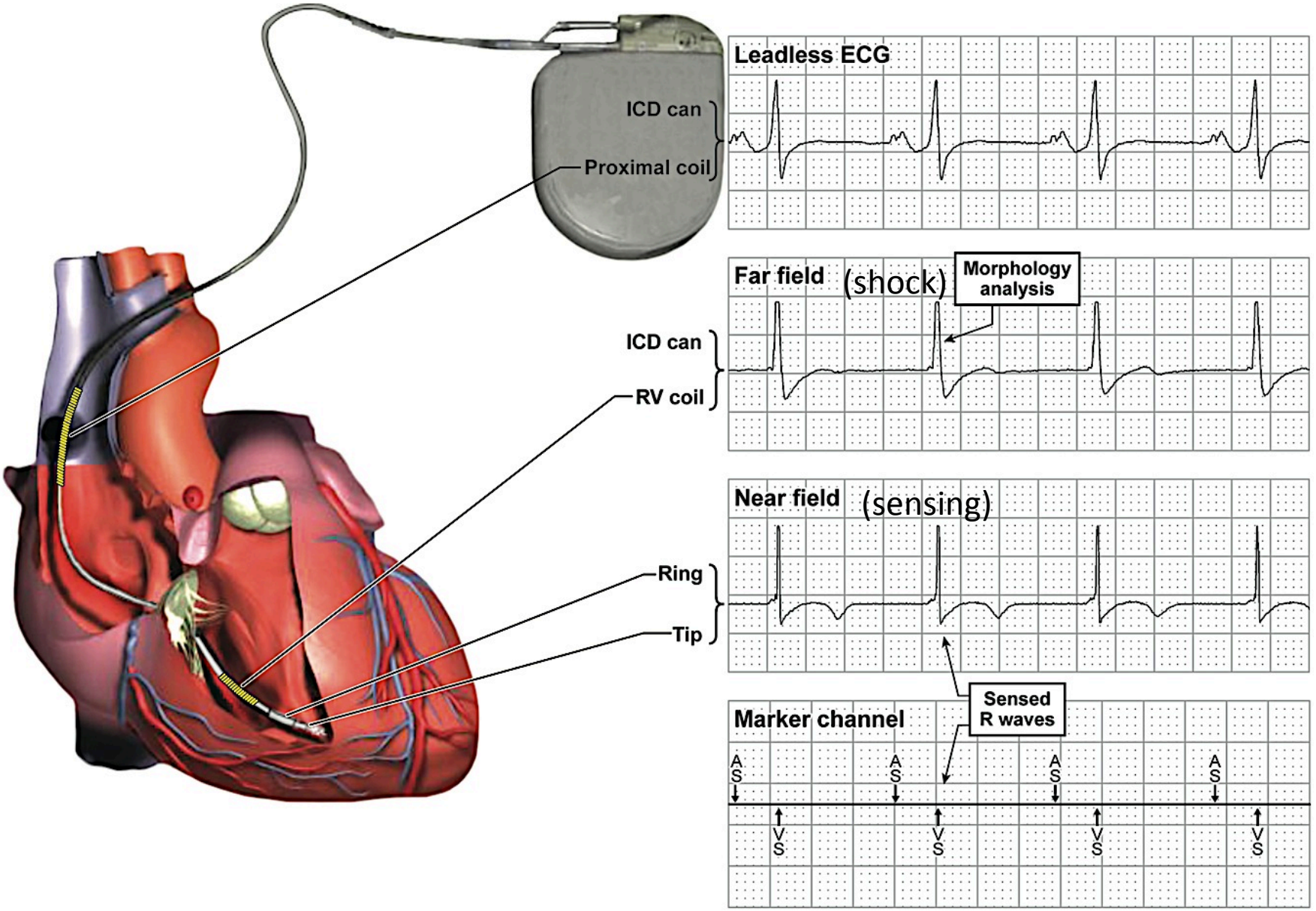
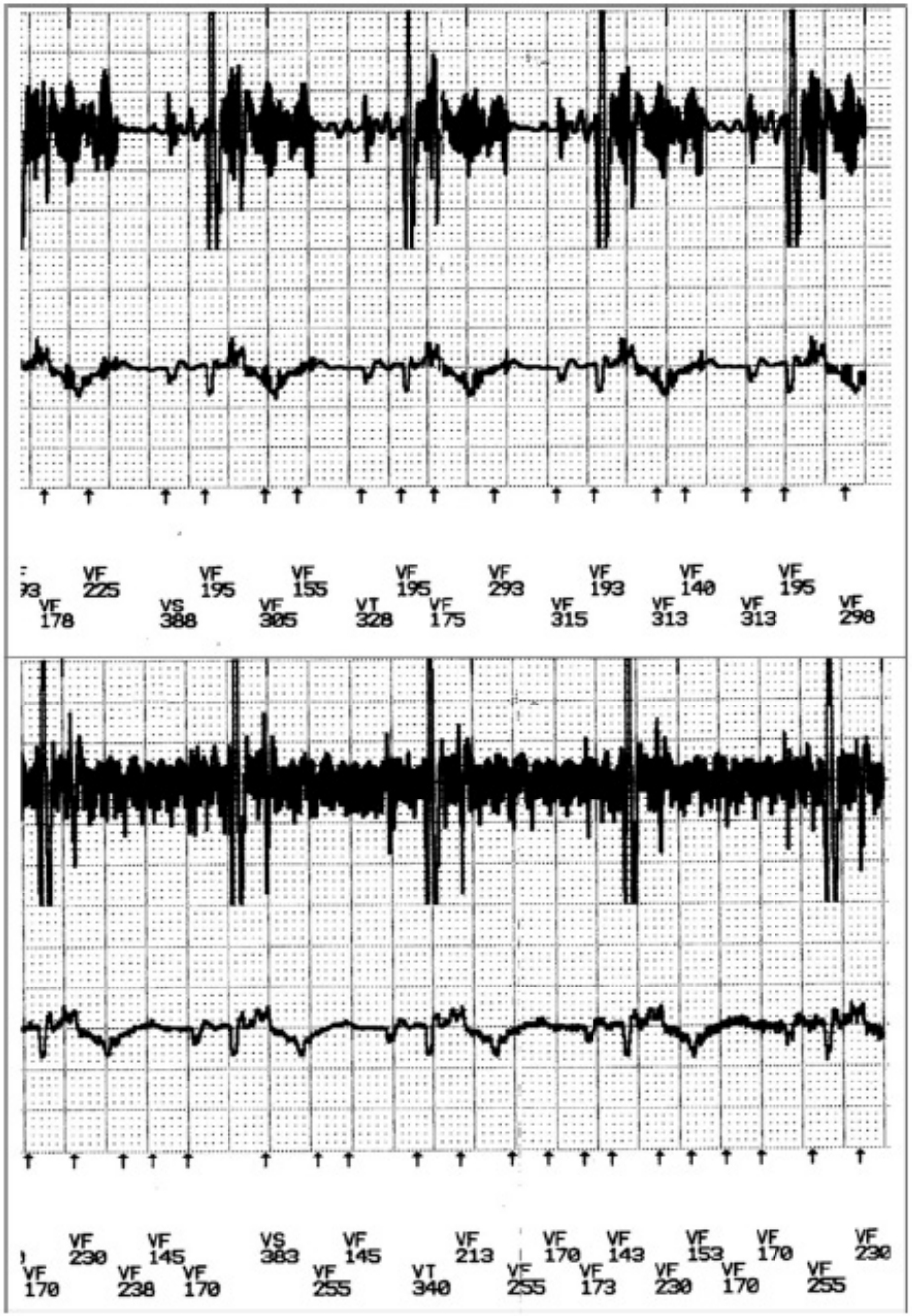


Figure 1


ICD can
Proximal coil
RV coil
Ring
Tip
Leadless ECG
Far field
(shock)
Morphology analysis
ICD can
RV coil
Near field
(sensing)
Ring
Tip
Sensed R waves
Marker channel
AS
VS

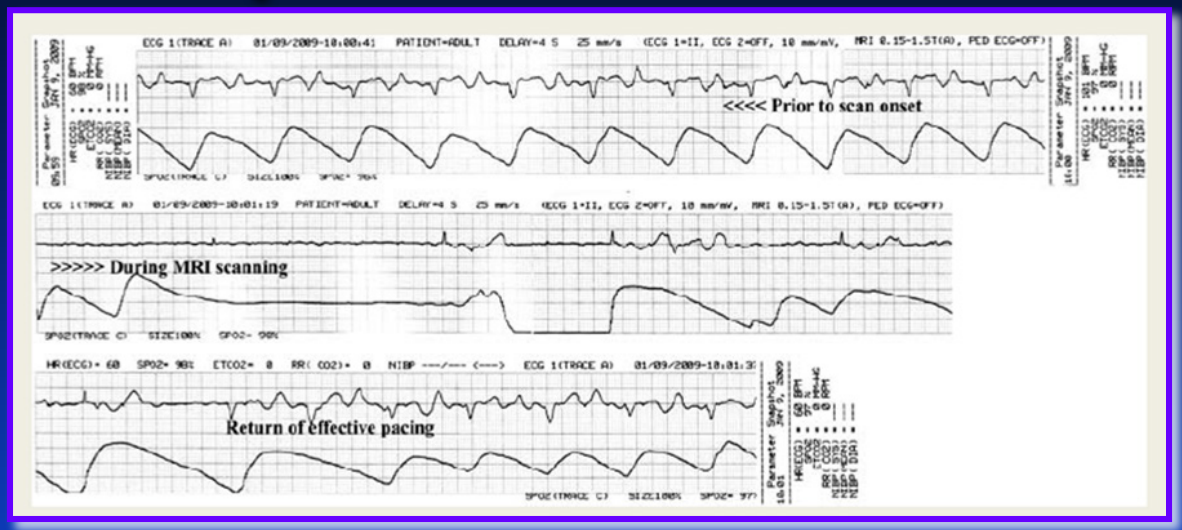


ure 2 Magnetic resonance scan noise falsely detected by an ICD as ventricular fibrillation. (*A*) Magnetic resonance pulse (ECG-gated) uence; (*B*) magnetic resonance continuous sequence.

ICD sees "noise" created by MRI as VF

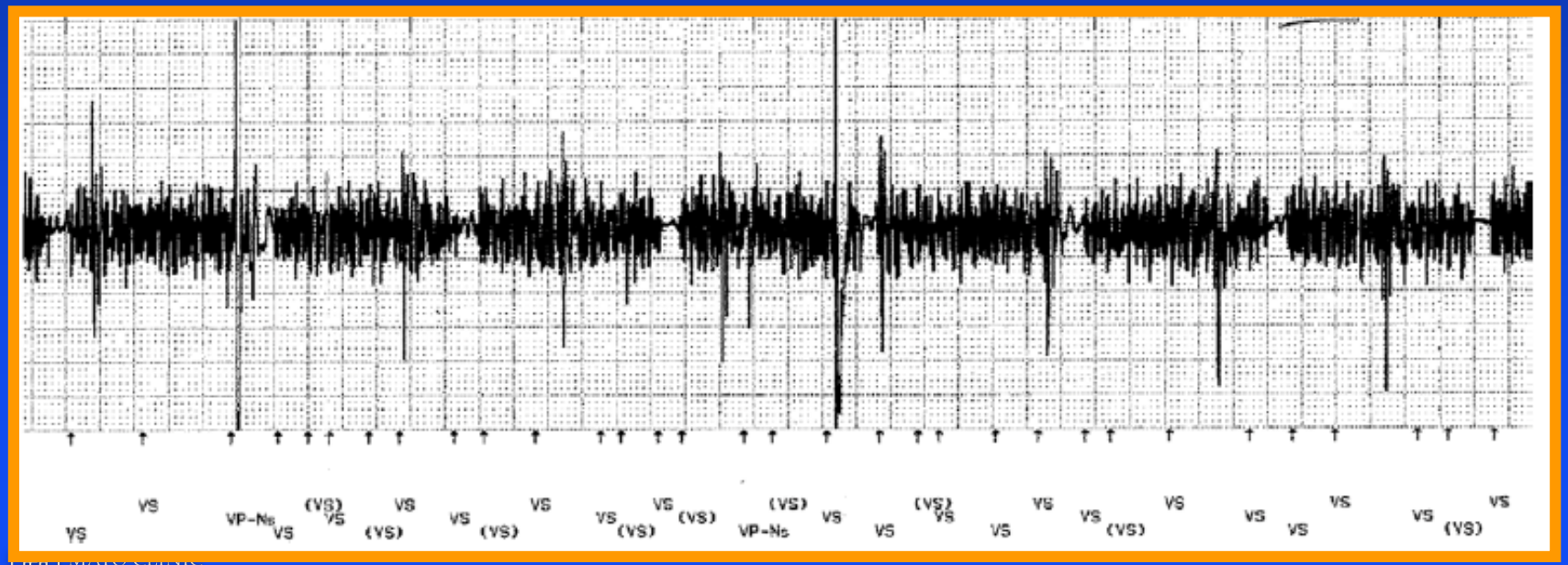
Roguin Europace 2008

Unpredictable Device Behavior in MRI



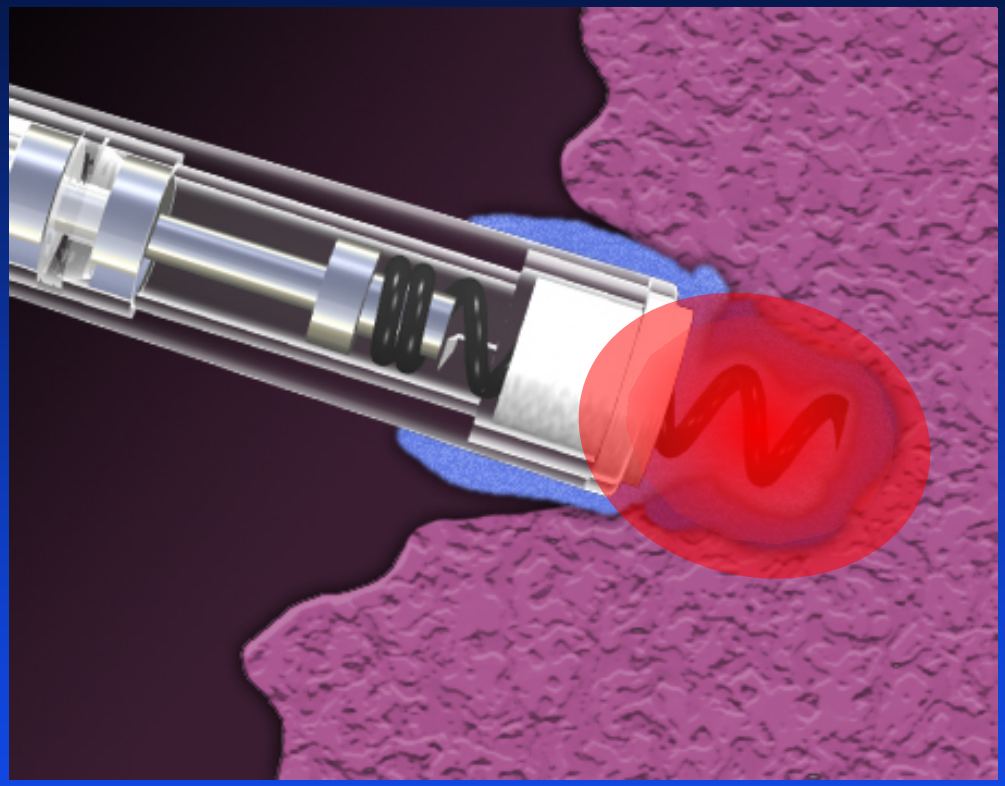
- Mechanical pull
- Rapid pacing
- Arrhythmias
- TachyRX
- Battery effects

Gimbel 2009



Beinert Circ 2013

Lead Tip Heating



- Pacing capture threshold (PCT) is lowest at implant
- Healing produces scar
- Increased distance increases PCT

- Significant heating causes tissue damage
- Increased scar volume increases PCT

MRI-Device Interaction

Major MRI-related PPM malfunctions

- Heating at the lead tip and at the lead tissue interface
- Force and torque on devices
- Image distortion
- Alteration of programming with potential damage to pacemaker circuitry
- Rapid atrial pacing
- Pacing at multiples of the radiofrequency pulse and associated rapid ventricle pacing
- Reed switch malfunction
- Asynchronous pacing
- Induction of ventricular fibrillation
- Electrical reset
- Component damage
- Death

MRI and Death

- Reported in 10 patients in 1980s
- Patients not monitored during MRI by MD
- No ECG during MRI
- Documentation is poor

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MR Conditional Labeling

ASTM Standard F2503* Defines Thre

MR Safe

MR Unsafe

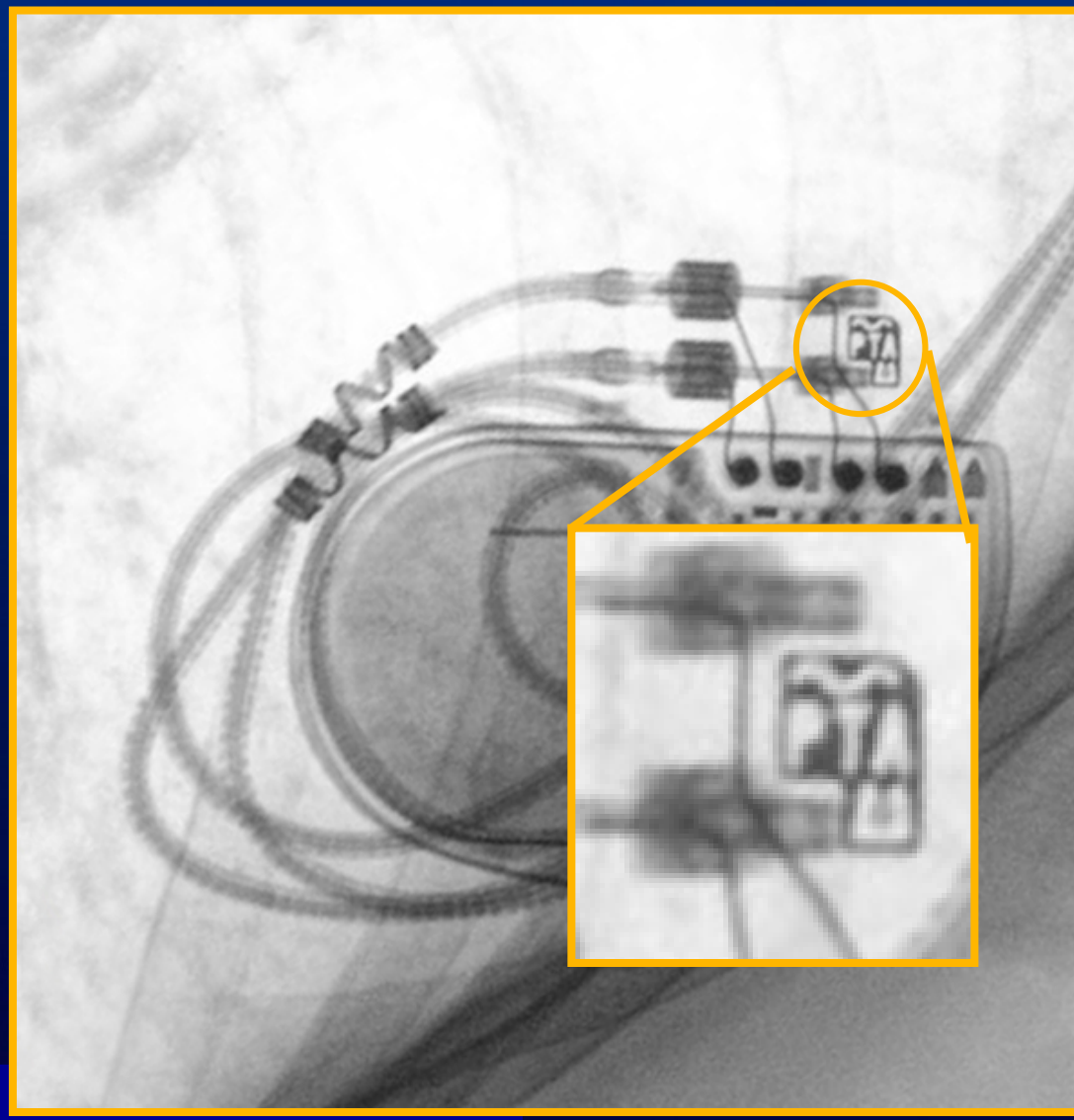
MR Conditional

*__ASTM standard F2503:__ Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

MAYO CLINIC

Mini Case: 76 y/o man needs MRI for CNS changes. You advise

1. MRI is contra-indicated
2. Proceed, but use a 1.5T magnet, limit SAR to 1.5
3. Proceed, no restrictions
4. Explant pacemaker, then perform MRI



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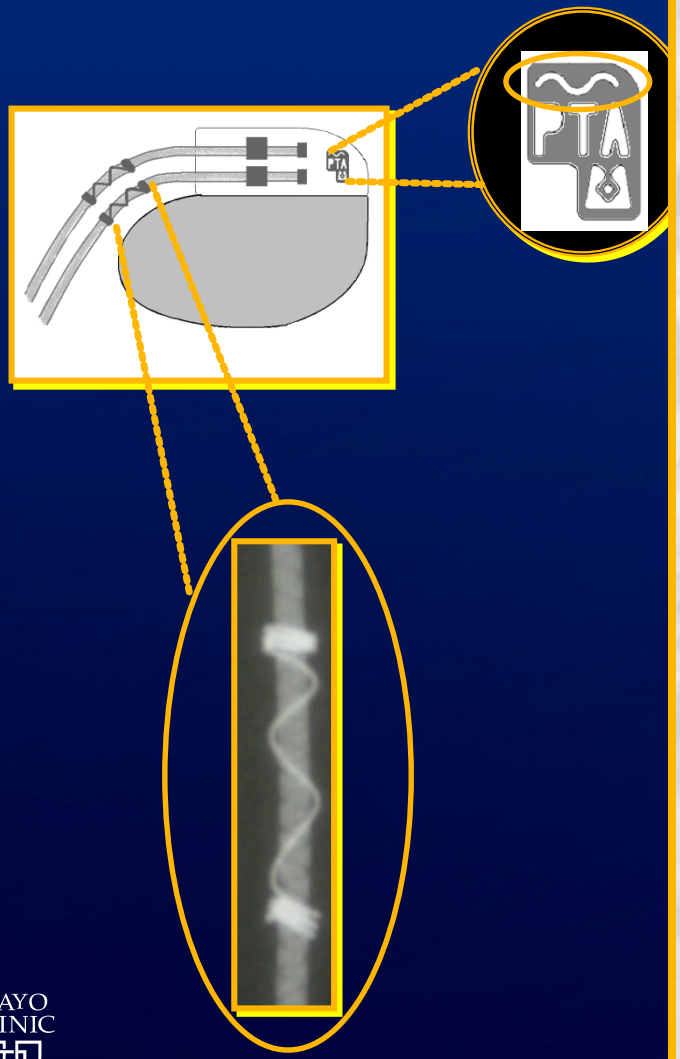
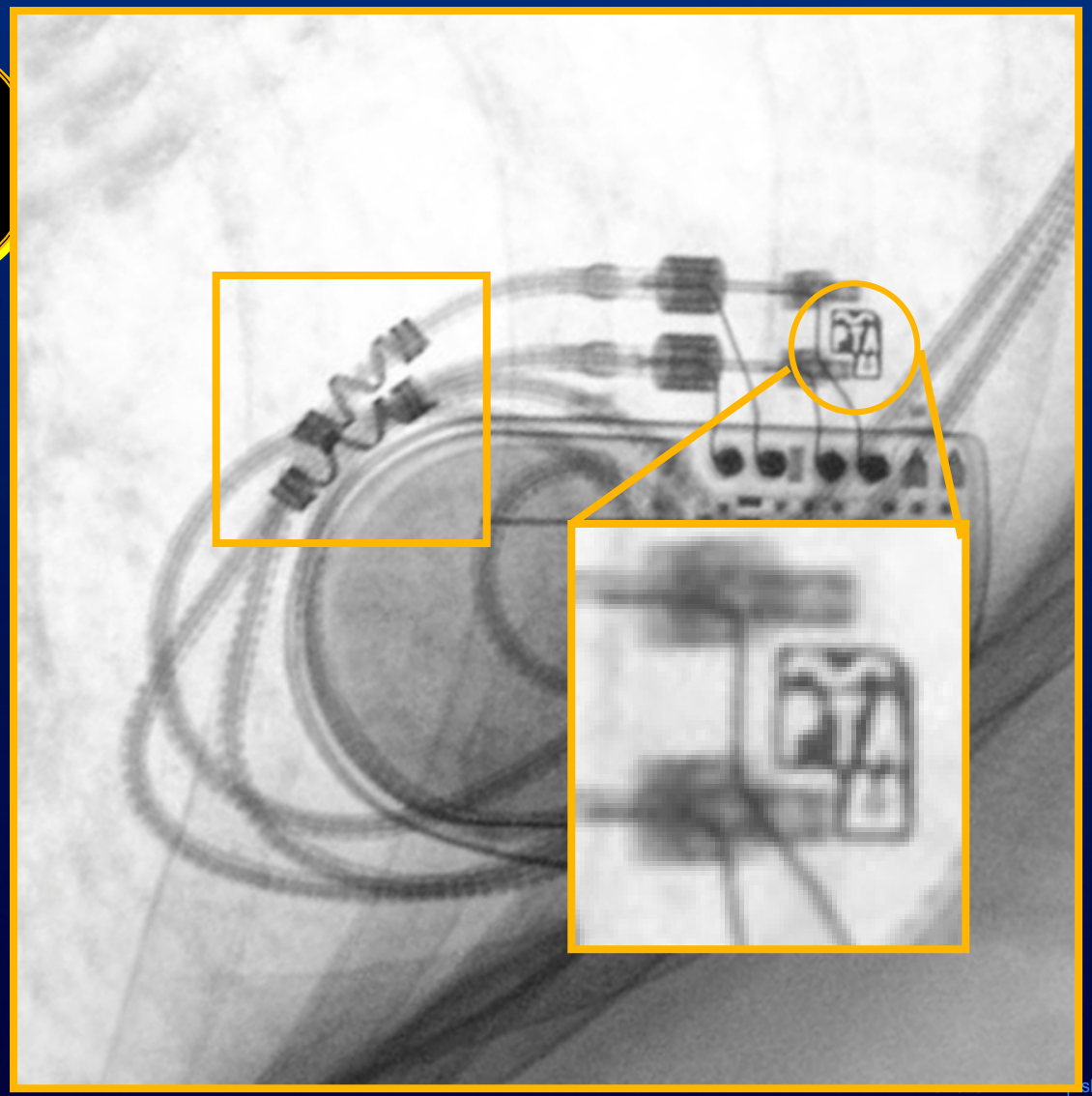
Positive System ID:
MR Conditional





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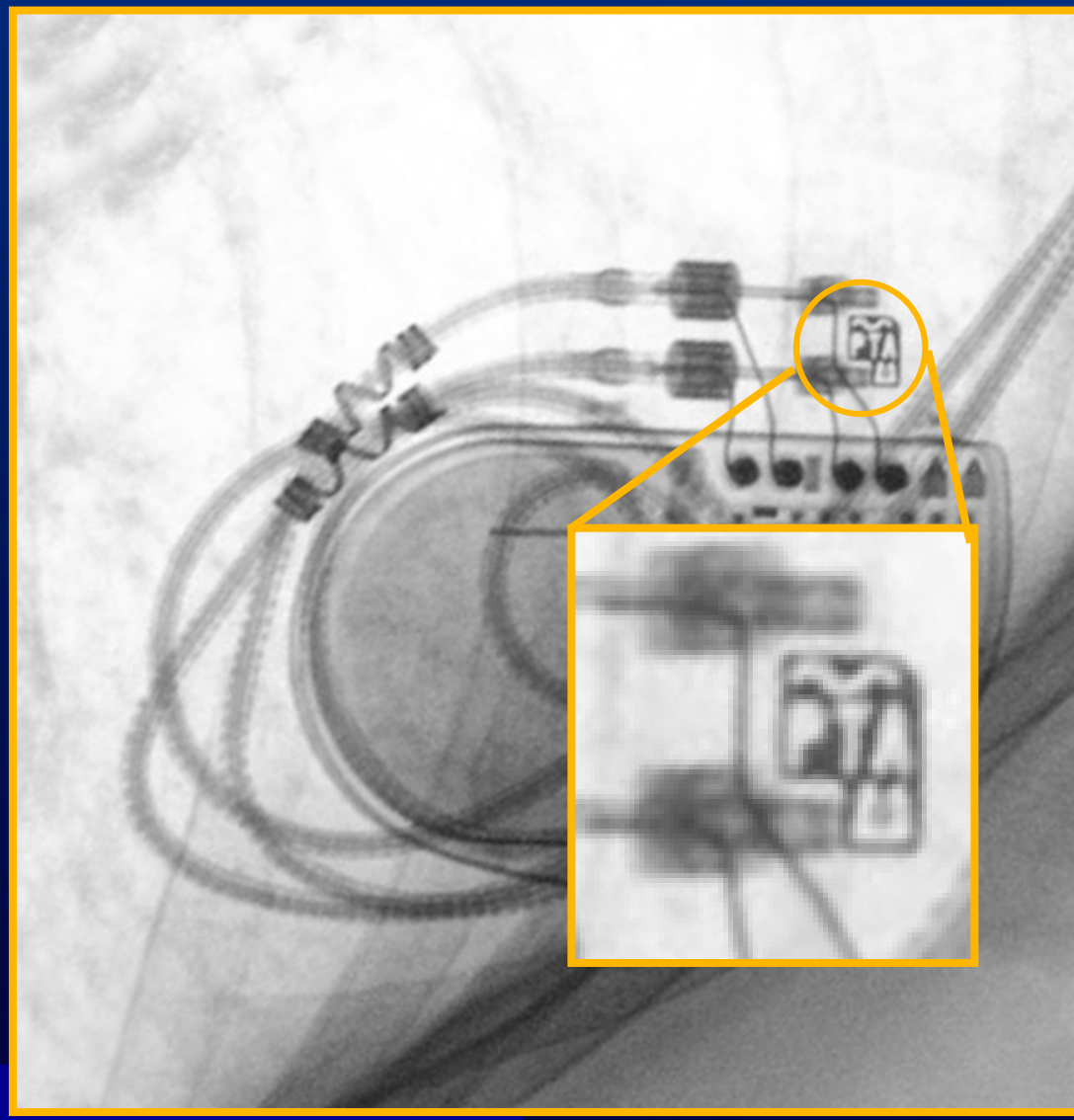

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MRI Conditional Pacemakers

- Power supply circuit protection
- Leads designed to minimize RF energy discharge at the tip
- Firmware permits MRI conditional programming and protection
- Reed Switch changed to a Hall sensor

Key Point: The ENTIRE system must be MRI conditional – not just the pulse generator

An Important Problem Remains

MRI Conditional Devices

	Medtronic*	St. Jude Medical†	Biotronik‡
Full body scan	Yes	Yes	No
MRI machine	Cylindrical bore magnet, clinical MRI systems with static magnetic field of 1.5T		
SAR limitation	≤2.0 W/kg	≤4.0 W/kg	≤2 W/kg
Max nr of scans	No	No	Yes; each scan ≤30 min maximum time for the system: 10 hours
Patient positioning	Supine or dorsal	Supine or dorsal	Only dorsal
Available leads (fixation)	Active§	Active	Active and passive
Published clinical evidence on MRI environment	Yes¶	No	No
FDA approval	Yes#	No	No
CE mark	Yes**	Yes††	Yes††

***Medtronic SureScan technical manual**
†St. Jude MRI procedure information
‡Biotronik ProMRI manual
§ Passive leads available as of January 2012
¶Heart Rhythm 7:750, 2012; Herzschrittmacherther: Elektrophysiol 22:233, 2011; Heart Rhythm 8:65, 2011
#Revo MRI and 5086 lead
****Advisa MRI and 5086 lead**
††Accent MRI and Tendril MRI lead
‡‡Evia Pro MRI and Safio and Solia leads

Santini et al: PACE, 2013

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MRI Conditional devices

Cardiology Journal 2012, Vol. 19, No. 1

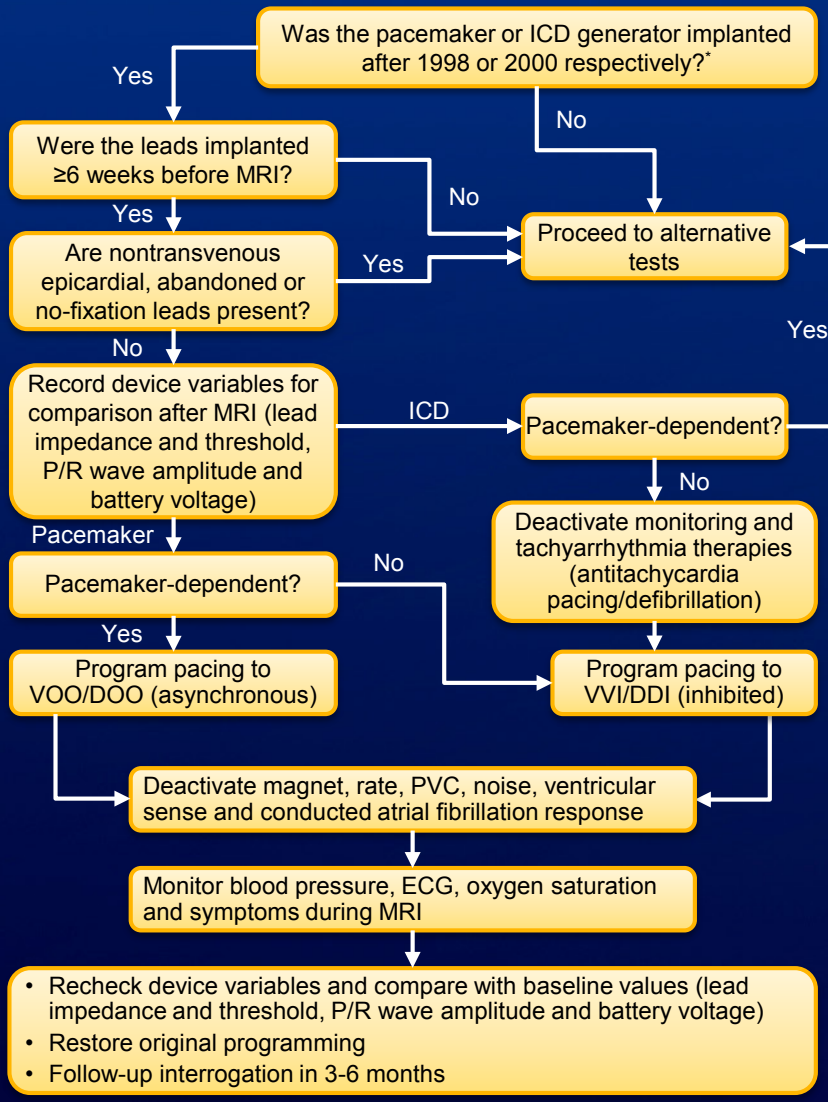
Table 1. Availability of approved magnetic resonance imaging conditional devices.

Device	Type	Availability date	Region
EnRhythm MRI SureScan (Medtronic, Inc.)	Pacemaker	2008	Europe
Accent MRI (St. Jude Medical Inc.)	Pacemaker	2010	Europe
ProMRI (Biotronik)	Pacemaker	2010	Europe
Ensura MRI SureScan (Medtronic, Inc.)	Pacemaker	2010	Europe
Advisa DR MRI SureScan (Medtronic, Inc.)	Pacemaker	2010	Europe
Revo MRI SureScan Pacemaker System (Medtronic, Inc.)	Pacemaker	2011	USA
Lumax 740 series Device (Biotronik)	ICD	2011	Europe

The vast majority of patients do not have MRI conditional devices!

Lobodzinski Cardiology Journal 2012

Safety protocol for MRI in the setting of implanted cardiac devices



- 555 1.5 T MRI scans in 438 patients (54% PMs, 46% ICDs)
- CIEDs not MRI conditional
- PM mode asynch if dependent; otherwise demand
- Monitoring: BP, ECG, Sa2 by ACLS RN with MD b/u
- 3 patients: Transient backup mode reversion
- RV sensing and imp reduced after MRI – did not require revision or reprogramming

MRI can be safely done in patients with selected devices; electrophysiologic monitoring during MRI is essential

Nazarian et al: Ann Intern Med, 2011

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How is this possible?

Advances in Technology, Preparation and Planning

- Newer generation PM/ICDs have much better isolation/filtering (pass through filters, etc) – even if not approved MRI conditional
  - Pre 1998 devices excluded
- Coordinated radiology/cardiology service
- Careful patient monitoring by ACLS trained RN during the scan
- Use of T/R coils and sequences to limit SAR

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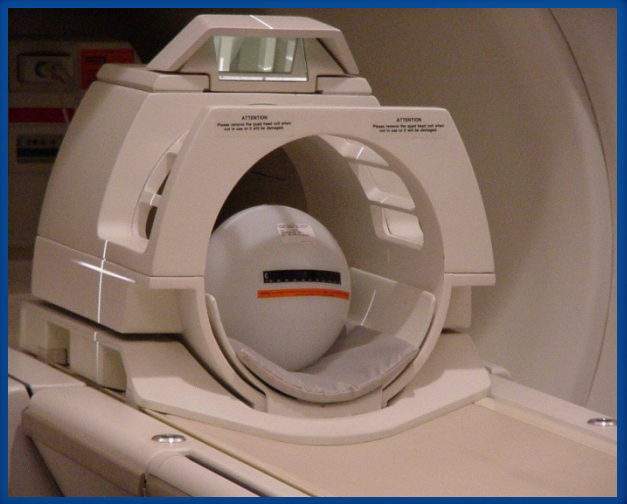
SAR (Specific Absorption rate) and T/R coils?

SAR: energy put in tissues

T/R coil: localize



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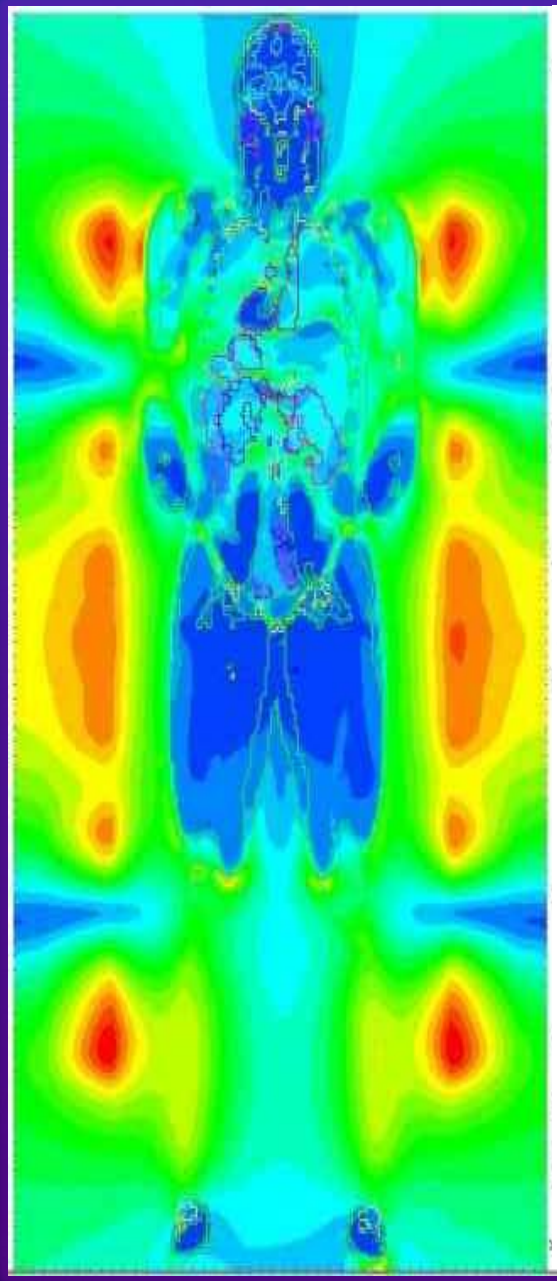
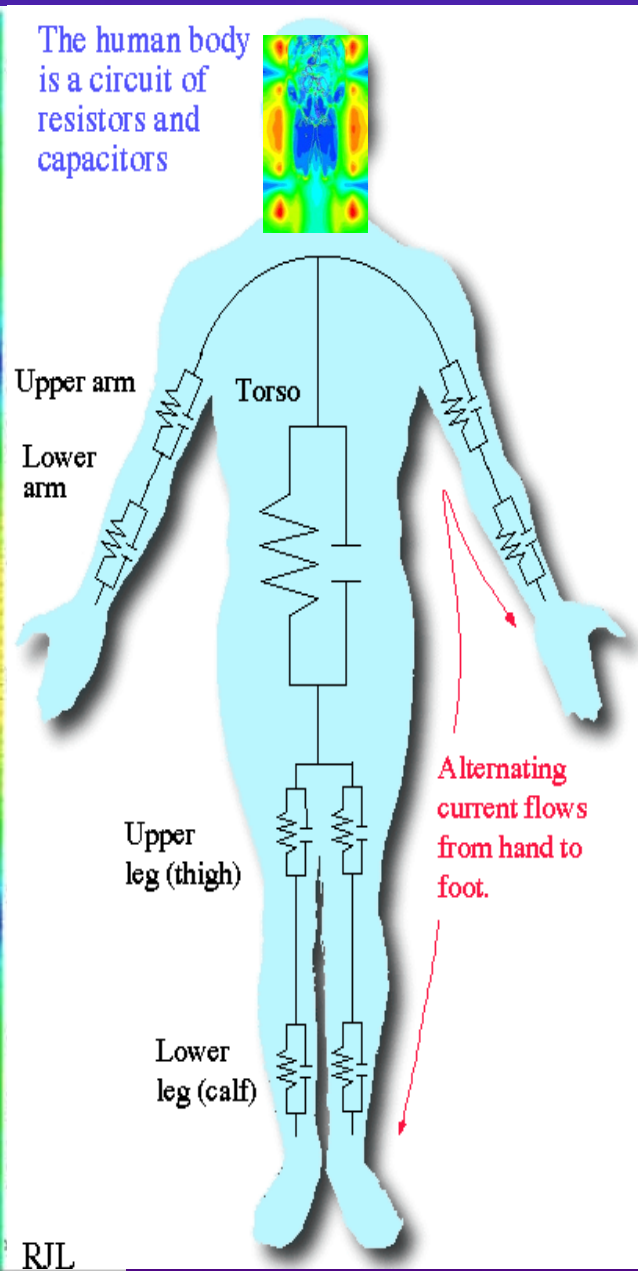
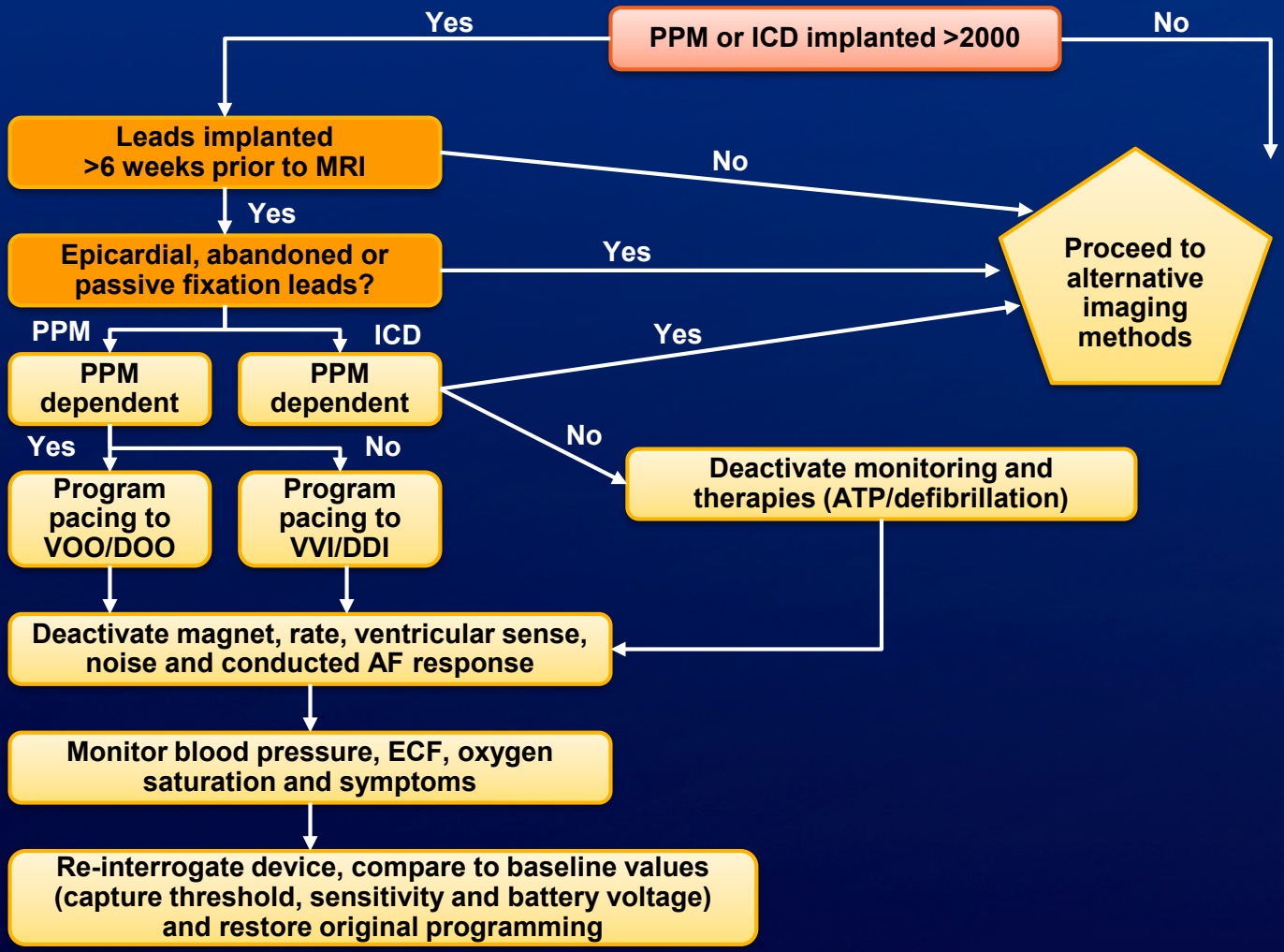




Proposed Algorithm for MRI in CIED Patients



Beinart and Nazarian: CardioSource, 2012

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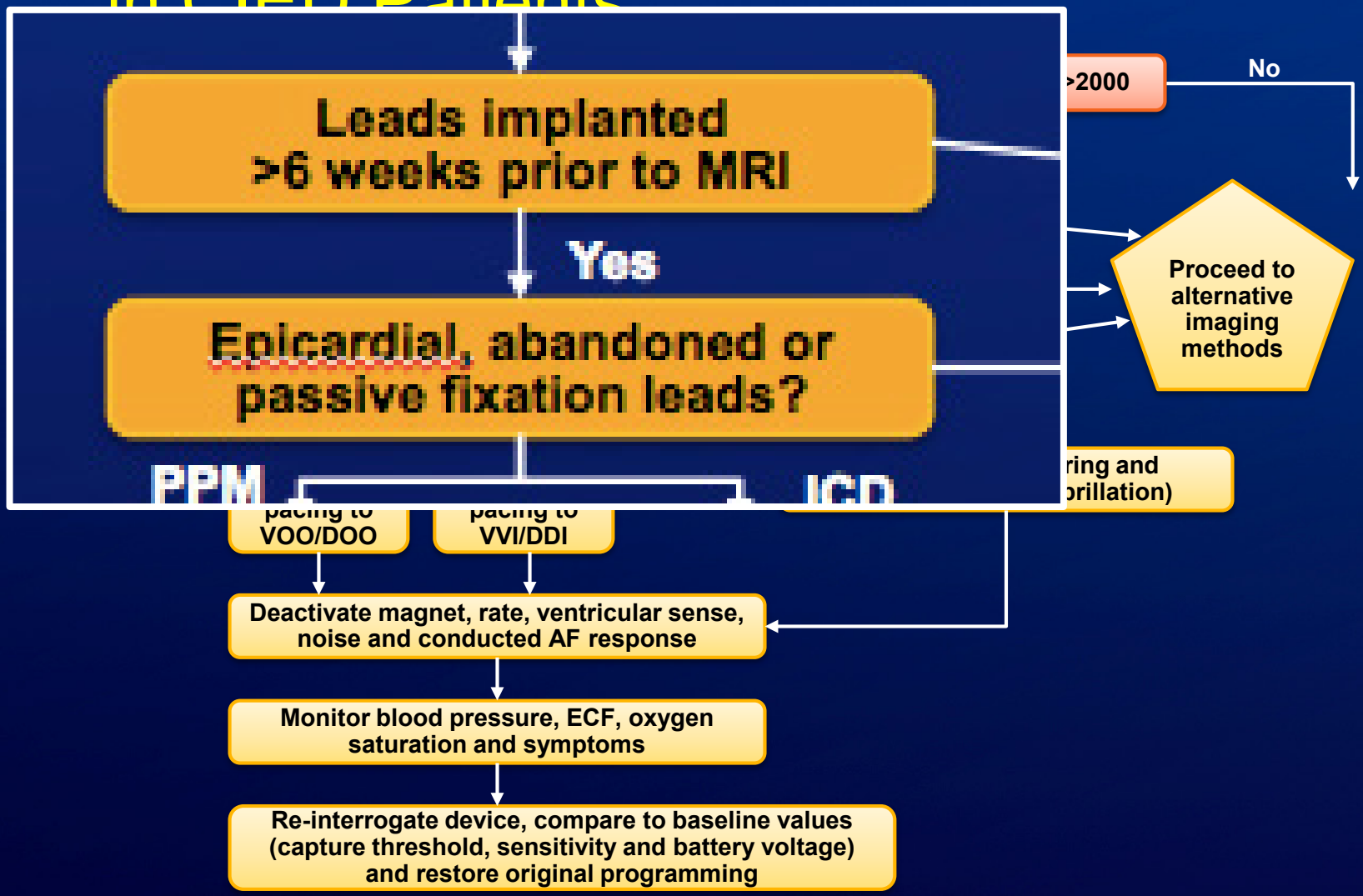
Proposed Algorithm for MRI in CIED Patients



Beinart and Nazarian: CardioSource, 2012

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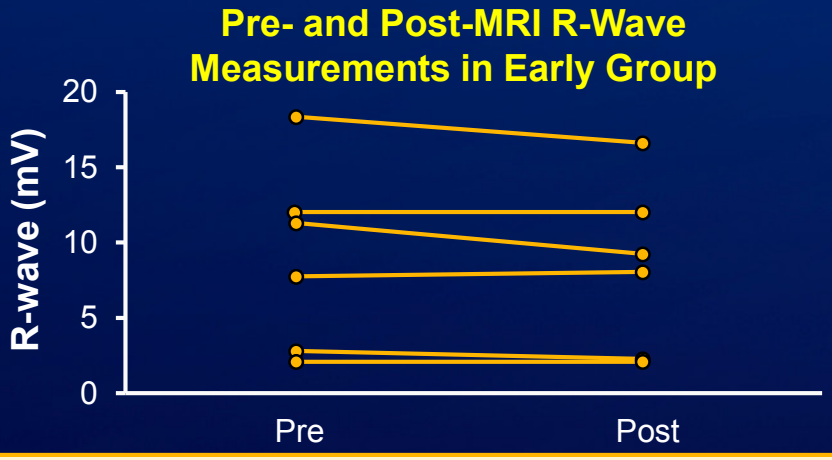
MRI in Patients With Recently Implanted Pacemakers

- Mayo MRI/CIED database
- 219 scans in 171 patients
- 8 patients had recent (<42 days) device
- 1/8: Permanent temporary

- No complications
- No pain
- No changes in device function
- No increase CK/troponin



With careful monitoring MRI imaging is feasible in patients with a recently implanted pacemaker system

Hannah Friedman et al: PACE, 2013

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Pacemaker abandoned lead CXR

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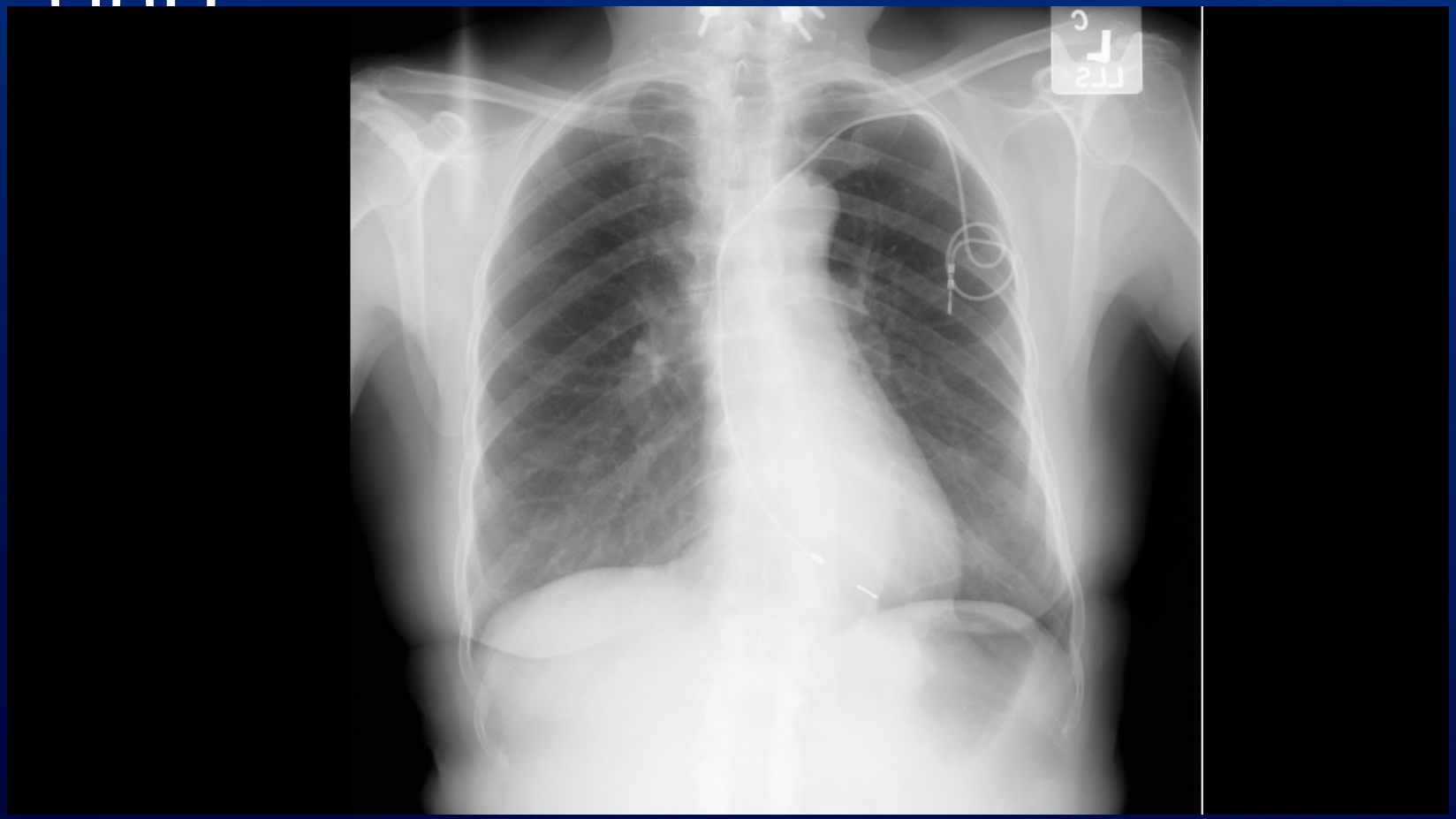

MRI in Patients With Abandoned Leads

- Abandoned leads may pose high risk by acting as antenna for RF field, leading to heating
- Between 1990-2013
  - 15 patients with PM; 3 with ICD and abandoned leads underwent 31 MRI scans
  - Mean of 1.67 abandoned leads during MRI
  - No leads were MRI conditional
- No adverse events in 7 days after scan
- 12 patients: Generators reimplanted with reuse of abandoned leads – worked appropriately

- **MRI in patients with abandoned cardiac device leads appears safe, although experience is small**
- **MRI did not affect lead function when later reused**

Higgins et al: PACE 2014 37:1284-1290

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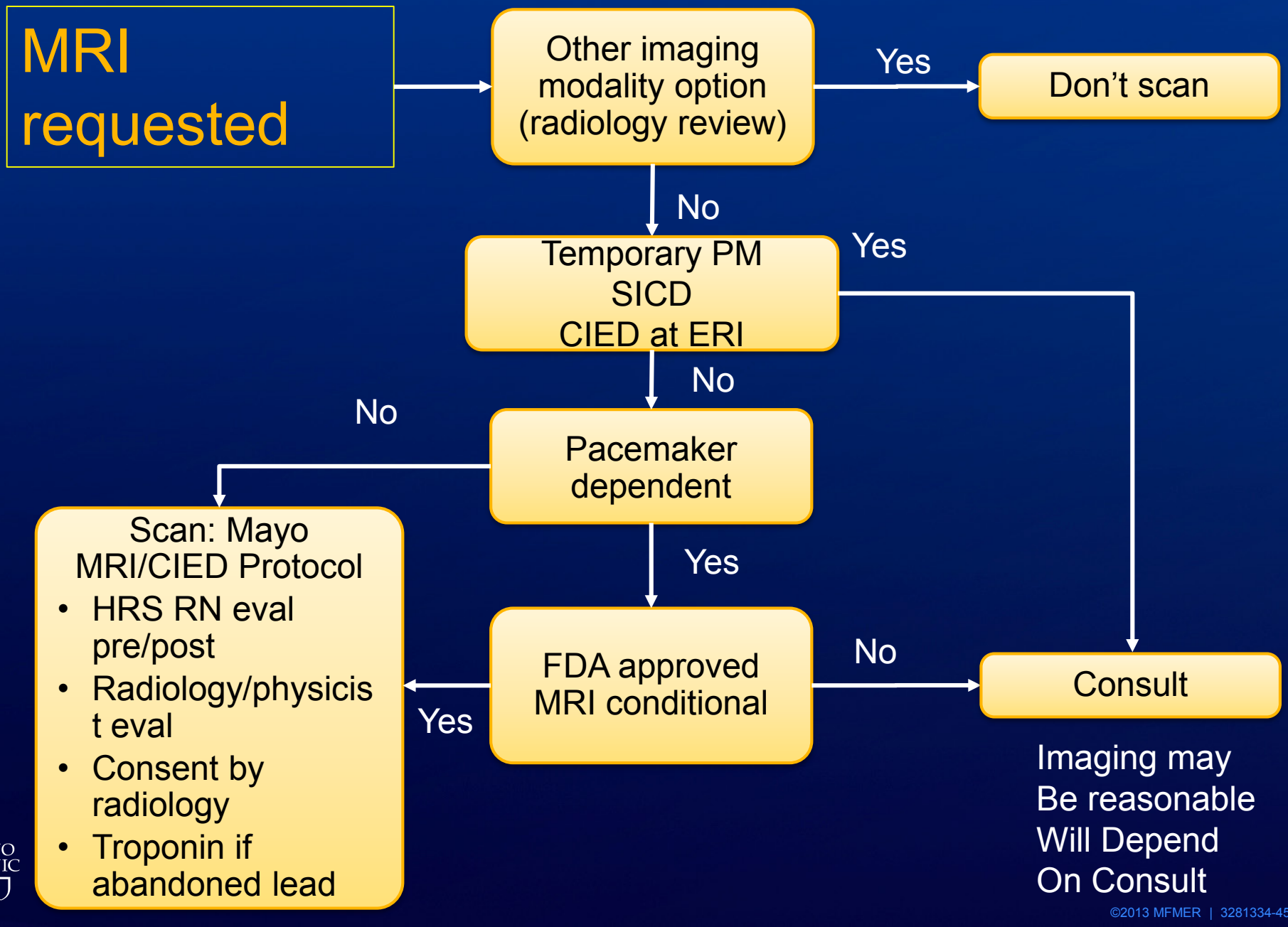
Mayo Clinic Experience

- >1000 MRIs in patients with pacemakers and ICDS
- No adverse clinical events
- Cardiology/Radiology protocols, reviewed/updated periodically
- Have included: dependent patients (but exception in non-conditional), abandoned leads, recent implants, CS leads
- Power on reset: concern in dependent patients → seen in 6% MDT implants before 2005

Hannah Friedman et al: PACE, 2013
Boilson et al J Inter Card EP 2011
Higgins PACE 2014; 37:1284-1290
Sheldon, JCE in 2014
Higgins HRJ. 2015 12(3):540-4

MRI Scanning at Mayo Clinic in CIED Patients



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MRI Scanning at Mayo Clinic in CIED Patients

Monitoring

- ACLS trained
- Awake patient
- HR, SaO2, ECG
- Arrhythmia: remove from magnets

Scan: Mayo MRI/CIED Protocol

- HRS RN eval pre/post
- Radiology/physicist eval
- Consent by radiology
- Troponin if abandoned lead

- Radiologist: consent
- Scan sequence determine by radiology physicist (SAR < 1.5)
- Device RN checks device before and after; ACLS RN monitoring
- Pre- and Post- troponin: if abandoned lead
- Patient alert
- Programming:
  - HR < 80: DOO/VOO/AOO 20 beats above (but <100) – unless single chamber (e.g. VVI ICD): intrinsic
  - If >80: ODO, OVO, OAO or subthreshold -> VVI or AAI 40
  - Rate response, capture mx, mode switch, sudden brady, etc: OFF

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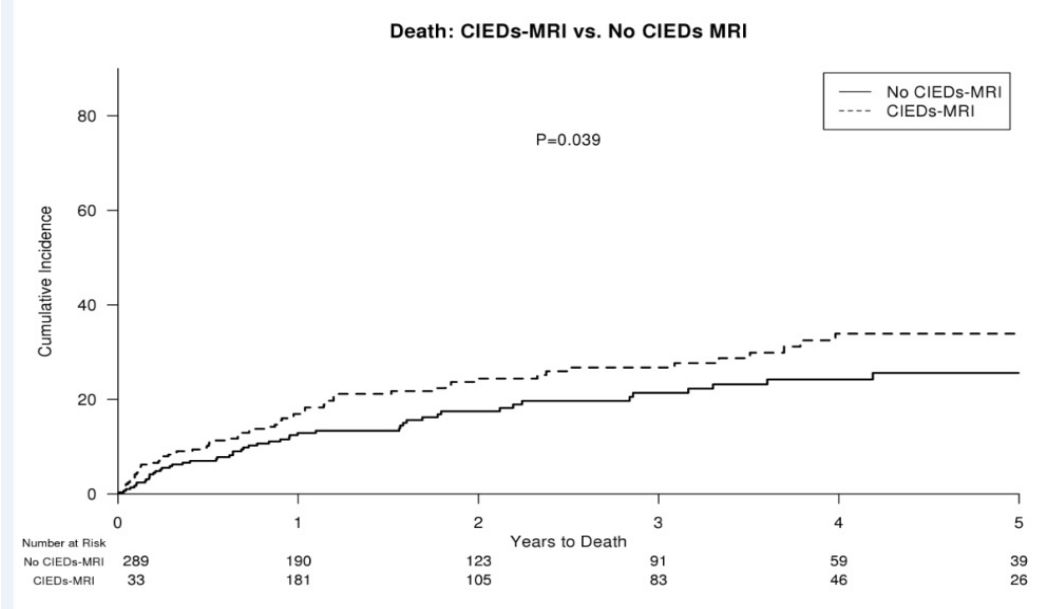
Safety: Mortality and HEAD MRI with CIED

- 873 patients with CIED and MRI 1/08-12/15
- 289 had first time head MRI – studied
- Matched
  - Age, gender, year
  - Head MRI (no CIED)
  - Head CT (with CIED)



Padmanaban et submitted

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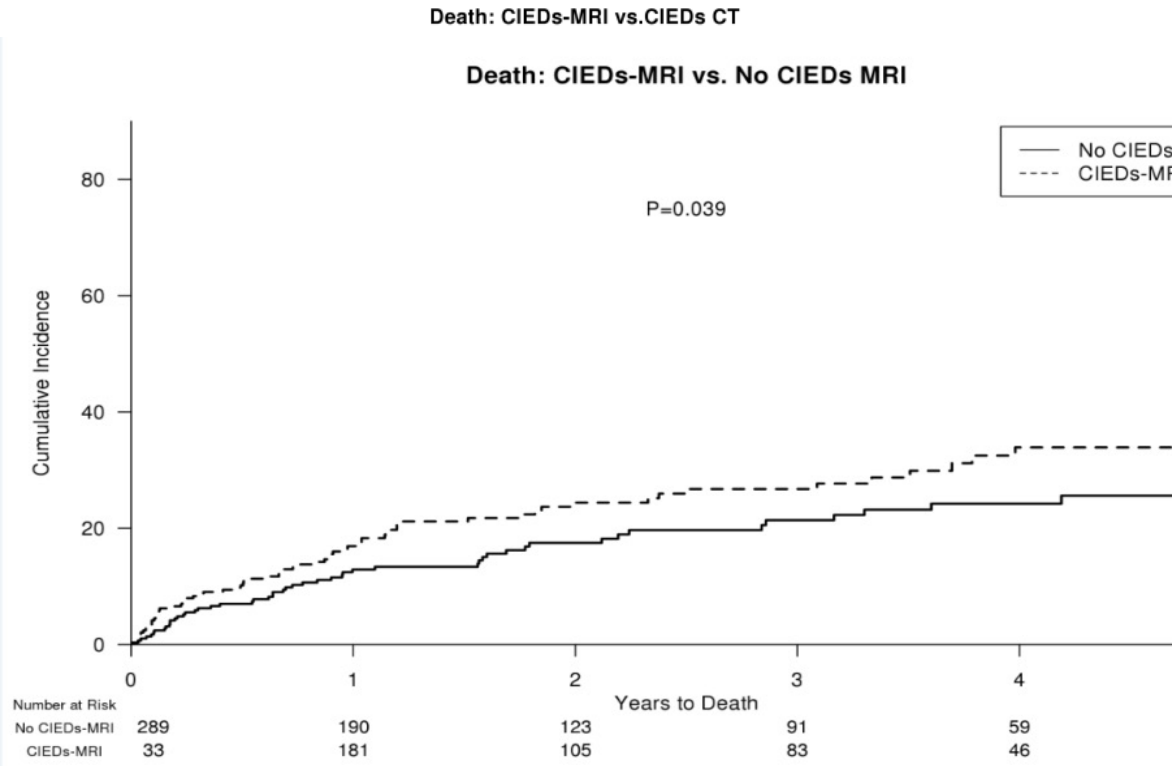

MRI of patients with pacemakers and defibrillators is safe when performed using real-time monitoring and protocols implemented by multi-specialty integrated care teams, with no difference in mortality in this population as compared to CT in patients without cardiac devices.

2017 HRS Expert Consensus Statement on MRI and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices (CIEDs)

Recommendations for Public Comment (Deadline July 14, 2016)

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Guidelines open for public comment

- Class IIa Recommendation, LOE B-NR:

It is reasonable for a patient with an MRI non-conditional CIED system to undergo MR imaging if there are no fractured, epicardial, or abandoned leads, the MR is the best test for the condition, and there is an institutional protocol, and a designated responsible MR-physician and CIED physician.

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- Class I Recommendation, LOE B-NR: It is recommended that continuous MRI-conditional ECG and pulse oximetry monitoring be utilized while the patient with an MRI non-conditional CIED is reprogrammed for imaging.
- Additional recommendations
  - Trained personnel (device and radiology)
  - Specific skills needed
  - Equipment required
  - Device programming recommnedations

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Conclusions

- Most patients with PMs and ICDs can be imaged by MRI safely – *irrespective of whether the CIED is MRI conditional*
- *Extreme caution must be used in pacemaker dependent patients, esp pre-2005 implants*
- Requires coordinated effort between radiology, cardiology, nursing, and physics
- MRI conditional devices facilitate imaging at hospitals without established programs
- Imaging in device patients will increase in future, including cardiac MR

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- Thank you
- pfriedman@mayo.edu

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Manufacturer Recommendations Regarding Safe Radiotherapy in PM/ICD Patients

Recommendation	Medtronic	St. Jude Medical
Device checks		
Before RT course	Not stated	Not stated
During RT course	Yes (if recommended safe dose is exceeded	Yes (a detailed evaluation once or twice during the RT course in PM-dependent patients)
After RT course	Yes	Yes
Maximal PM dose	5 Gy	No safe dose
Maximal ICD dose	1-5 Gy depending on model	No safe dose
Maximal beam energy	≥10 MV	Not stated
Inactivation of antitachycardia therapies	Yes	Yes
Lead shielding of the device	No (ineffective against neutrons)	Not stated (reduction in the device dose is recommended
Heart rhythm monitoring during RT	Not stated	Yes

Zaremba et al: PACE 00:1, 2015)

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Call for Public Comment

- Health Policy & Payments
- Cardiac Electrophysiology Accreditation
- MACRA Resource Center
- Clinical Guidelines & Documents
- EP Buyer's Guide
- Provider Resources

The draft **recommendations** of the *2017 HRS Expert Consensus Statement on MRI and Radiation Exposure in patients with CIEDs* are available for public comment until July 14, 2016.

This document will address safety considerations and management of the CIED patient requiring MRI imaging, indications and considerations for MRI-conditional CIEDs, and protocols and programming for MRI imaging in patients with CIEDs.

The Heart Rhythm Society is developing the document in collaboration with:

- the American College of Cardiology (ACC),
- the American College of Radiology (ACR),
- the American Heart Association (AHA),
- the American Society of Radiation Oncology (ASTRO),
- the Asia-Pacific Heart Rhythm Society (APHRS),

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Interrogation Frequency During RöRx

- Currently no consensus
- Mayo – most commonly see patient before, mid, and at completion of therapy
  - May make exceptions for pacemaker dependent patients and patients that are particularly anxious
- Remote monitoring simplifies management
- New guidelines will provide specific recommendations on this issue

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Manufacturer Recommendations Regarding Safe **Radiotherapy** in PM/ICD Patients

Recommendation	Biotronik	Boston Scientific
Device checks		
Before RT course	Yes	Specific to each patient
During RT course	Not stated	Specific to each patient
After RT course	Yes, including a supplementary follow-up shortly after RT	Yes, including subsequent close monitoring of the device function
Maximal PM dose	2 Gy	No safe dose (2 Gy as a reference)
Maximal ICD dose	2 Gy	No safe dose (2 Gy as a reference)
Maximal beam energy	<10 MV	Not stated
Inactivation of antitachycardia therapies	Yes	Yes
Lead shielding of the device	Yes	All available shielding options, including both internal shielding within the LA and external shielding of the patient
Heart rhythm monitoring during RT	Yes	As determined most appropriate by the physician team

Zaremba et al: PACE 00:1, 2015)

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