MRI imaging for patients with cardiac implantable electronic devices (CIEDs)

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Objectives

1) Review the terminology surrounding MRI labelling for medical devices.

2) Discuss the potential risks of MRI on patients with cardiac implantable electronic devices (CIEDs).

3) Review the “absolute” contra-indications for MRI amongst patients with CIEDs.

4) Discuss the workflow surrounding the process of MR scanning for patients with CIEDs.

5) Examine the data and issues surrounding MR scanning for patients with (i) MR-conditional and (ii) non-MR-conditional CIEDs.

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MRI labelling for medical devices: terminology

Terminology	*Definition*
MR safe	An item that poses no known hazards in all MR environments.
MR conditional	An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. The field conditions that define the specified MR environment include parameters such as: i) field strength, ii) spatial gradient, iii) time rate of change of the magnetic field (dB/dT), radiofrequency fields, and specific absorption rate (SAR). Additional conditions, such as specific configurations of the item, may be required.
MR unsafe	An item that is known to pose hazards in all MR environments

Adapted from: Woods T.O. Standards for medical devices in MRI: present and future. *J Magn Reson Imaging* 2007;26:1186-9.

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How can MRI affect CIEDs?

Risks associated with MR imaging arise from 3 distinct mechanisms:

1) Static magnetic field.

2) Gradient magnetic field.

3) Radiofrequency (RF) energy.

How can MRI affect CIEDs?

Static magnetic field

- In general, the magnetic field strength of 1.5 to 3.0 Tesla MRI scanners is about 30,000 to 60,000 times that of the Earth's magnetic field strength.

- Ferromagnetic objects may move, rotate, or dislodge in the presence of such powerful fields.

How can MRI affect CIEDs?

Gradient magnetic field

- During image acquisition, time-varying magnetic fields (known as *gradients, measured in dB/dt [teslas/second]*) are rapidly and repeatedly applied to the patient in an on-and-off fashion.

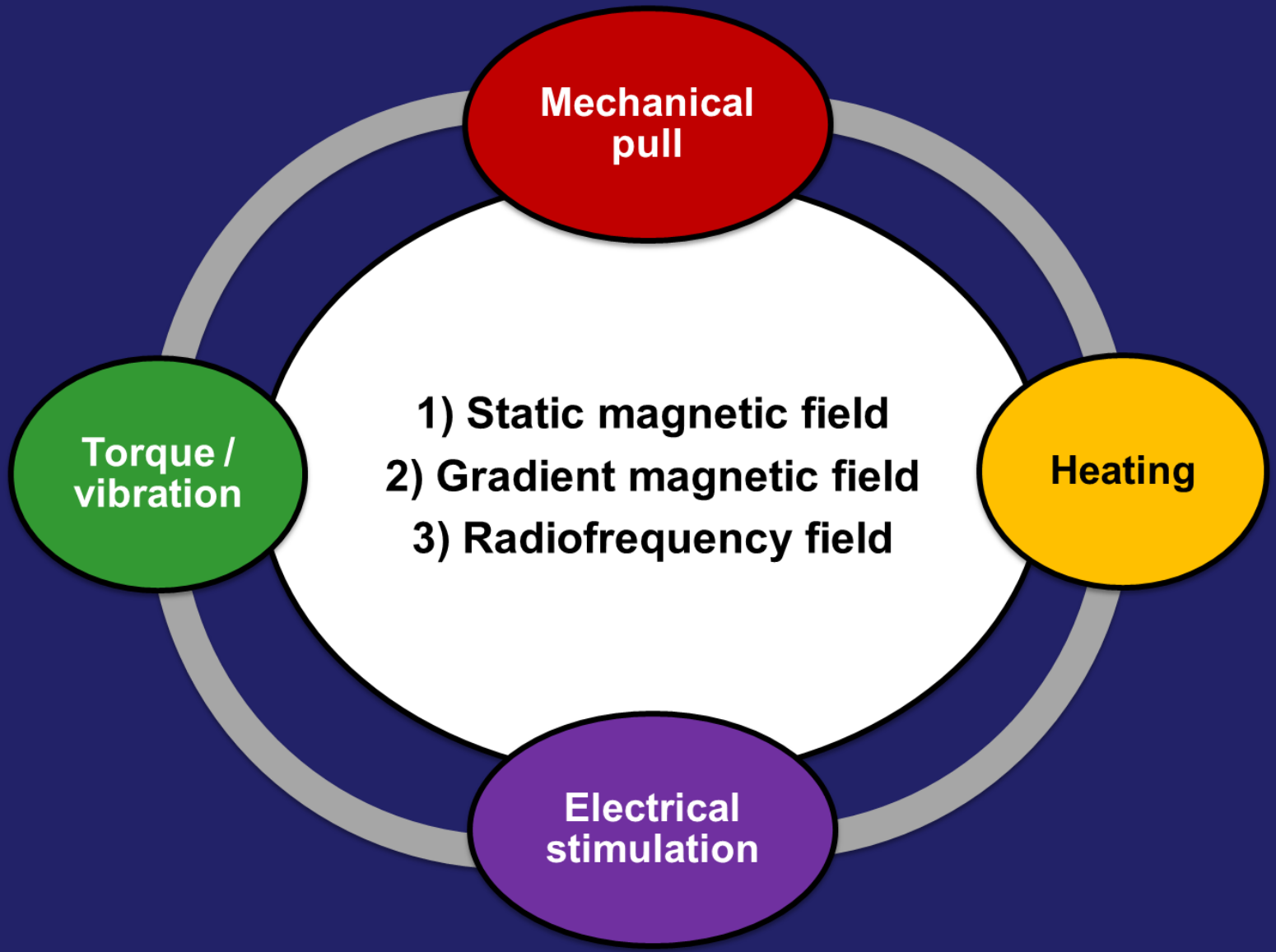
- These rapidly changing magnetic fields can generate electrical currents which can affect CIEDs in the following ways:
  - *These currents may be strong enough to be conducted within electrical wires of the CIED, potentially causing arrhythmias.*
  - *The flow of electrically conductive blood in the presence of powerful magnets may generate small voltages which can lead to electrocardiographic artifcacts.*

How can MRI affect CIEDs?

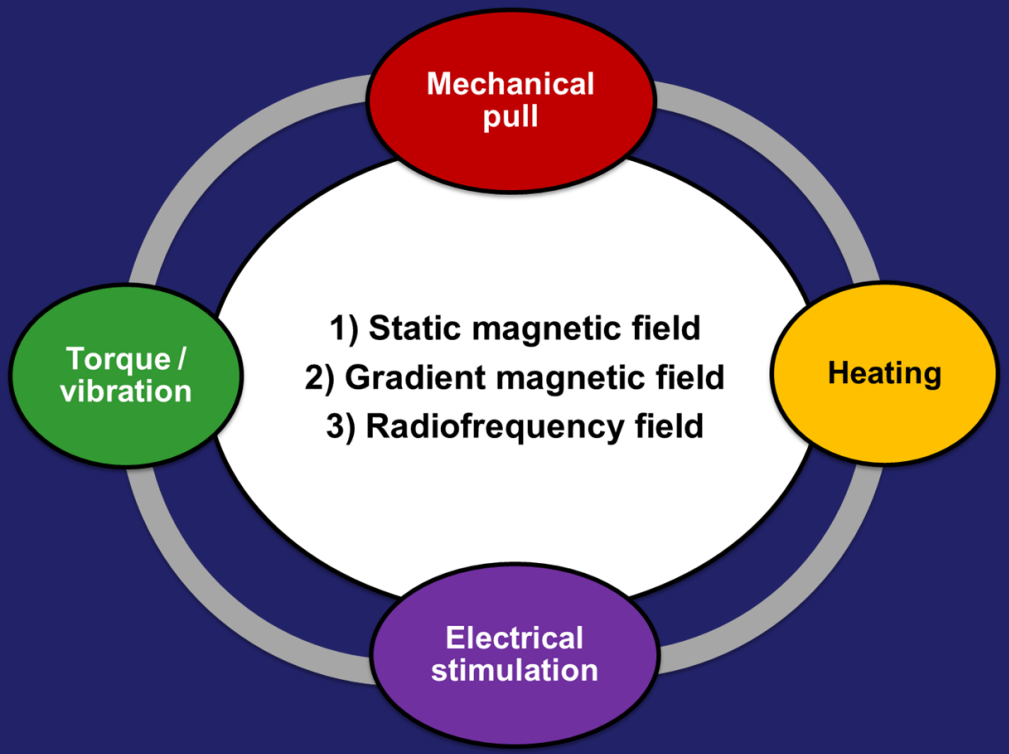
Radiofrequency (RF) energy

- RF energy is “pulsed” during MR scanning to generate the images.
- Some of this energy will be absorbed by the body, leading to heating (usually $<1^0$C).
- RF energy can generate electric currents which may be conducted within electrical wires.
- The strength of the RF energy is frequency-dependent and varies according to the field strength *(ie: a CIED system which is “safe” in a given field strength/frequency may not be so in a different setting).*

MR imaging of cardiac implantable electronic devices (CIED): Potential mechanisms of risk



MR imaging of cardiac implantable electronic devices (CIED): Potential mechanisms of risk



Lead dislodgement

Lead dislodgement

Device Heating

Tissue heating (Δ in pacing thershold)

Reprogramming or power-on-reset

Reed switch closure: Inhibition of therapy

Electrogram distortion: over-/undersensing

Arrhythmia induction

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CIED components which are considered to be contra-indicated for MR imaging

- Broken or fractured lead(s) – known or suspected.
- Abandoned (capped) or extraneous lead(s), lead extender(s), or lead adaptor(s).
- Remnants of a lead which persist in the patient's body *(e.g. pacemaker pocket, vascular space, or cardiac chamber).*
- A pacemaker-dependent patient with a non-MR-conditional ICD system.
- Permanent epicardial pacing or ICD lead(s). (*Note: the presence of temporary epicardial wire(s) inserted at the time of cardiac surgery is not considered to be an absolute contra-indication for MR scanning.**)

Verma A. et al. *Can J Cardiol*. 2014 Oct;30(10):1131-41.
*Hartnell GG et al. *Am J Roentgenol*. 1997 May;168(5):1157-9

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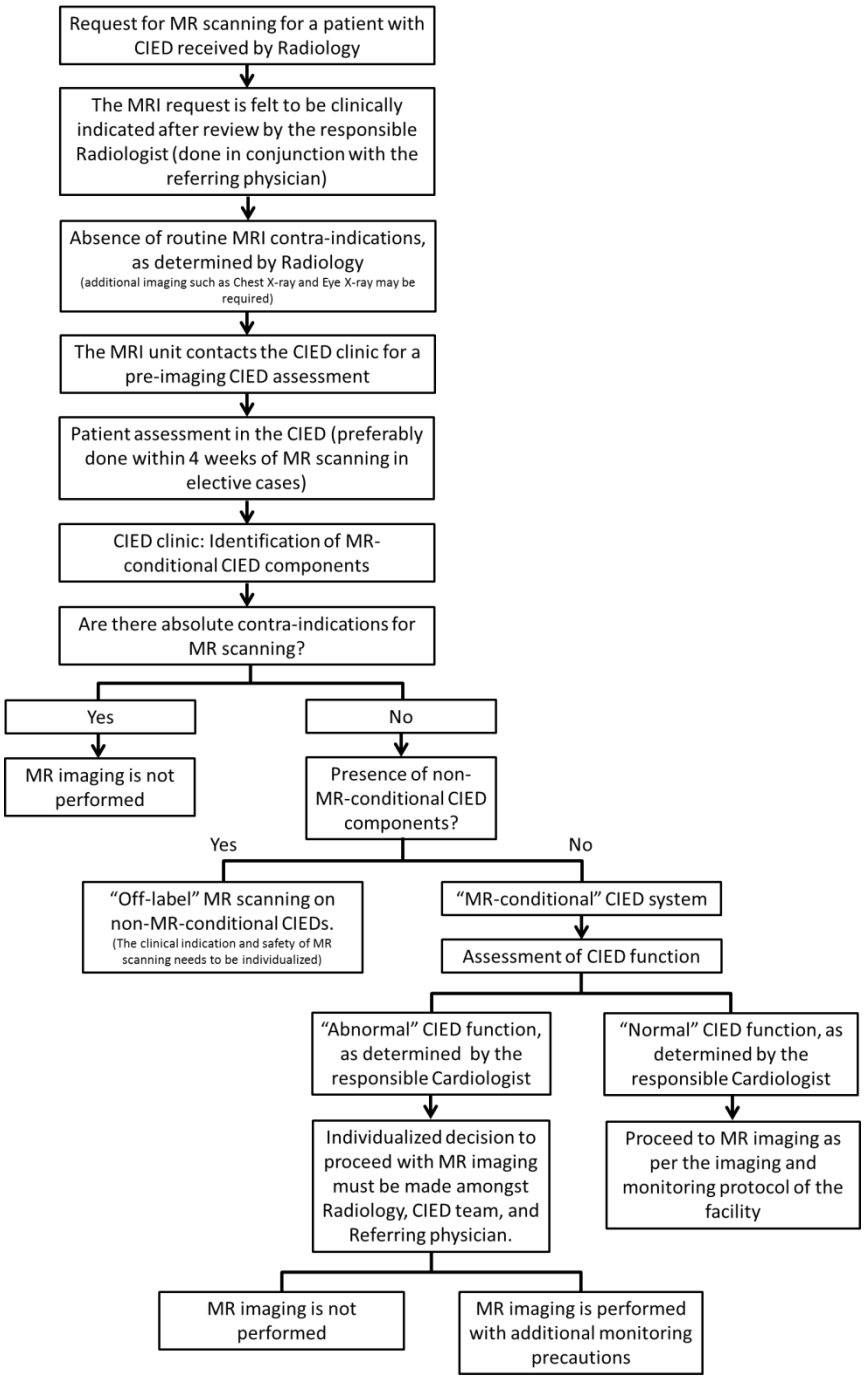

Sample workflow diagram of the triage and referral process for MR scanning of patients with CIEDs

Emphasis on a collaborative team approach:

- CIED clinic members (techs / nurses)
- MR suite members (techs / nurses)
- Cardiologist / EP specialist
- Radiologists
- Hospital administration
- Physicist *(if available)*

3 MAIN QUESTIONS:

(1) Is MRI indicated and can another imaging modality be just as useful?

(2) Are there "absolute" contra-indications for MR scanning?

(3) Can the CIED system undergo MRI without excessive risk to the patient?

Verma A. et al. *Can J Cardiol*. 2014 Oct;30(10):1131-41.

Monitoring modalities of CIED patients during MR scanning

Mode	Potential advantages	Potential limitations
ECG monitoring	Most direct way to assess the patient's heart rhythm status in a continuous manner.	1) The use of ECG monitoring equipment is subject to significant artifact which may preclude accurate assessment of the patient's rhythm. 2) Improper positioning of the ECG lead and electrodes may cause skin burns. *(e.g if the lead is inadvertently wrapped around the electrode or if the lead is in contact with skin).* 3) No information of the patient's respiratory status will be provided by this mode of monitoring.
Pulse oximetry	1) Allows for continuous monitoring of the patient's pulse, which reflects cardiac output. 2) Provides information on the patient's respiratory status (oxygen saturation). 3) Obviates the potential risks associated with ECG monitoring.	Does not provide real-time monitoring of the patient's cardiac rhythm.
Intermittent verbal communication	Allows for (i) monitoring of the patient's mental status; (ii) patients to communicate any potential discomfort to the MRI team.	Not applicable for patients who are unable to verbally communicate.

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What is a “MR-conditional” CIED system?
What is the “fine print”?

- No CIED system is “MR-safe”.
- Some CIED systems are “MR-conditional”; this means that patients may undergo MR scanning without additional known risks as long as manufacturer-specified scanning parameters are followed.
- Recommended scanning parameters vary amongst CIED manufacturers, meaning that the MR scanning protocol will vary in accordance to the patient’s CIED system.

Verma A. et al. *Can J Cardiol*. 2014 Oct;30(10):1131-41.

MRI for patients with MR-conditional pacemakers

Clinical safety of the ProMRI pacemaker system in patients subjected to thoracic spine and cardiac 1.5-T magnetic resonance imaging scanning conditions

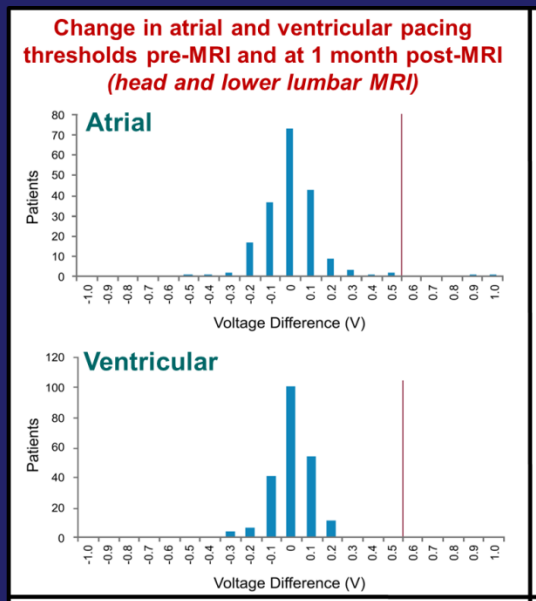
Clinical safety of the ProMRI pacemaker system in patients subjected to head and lower lumbar 1.5-T magnetic resonance imaging scanning conditions

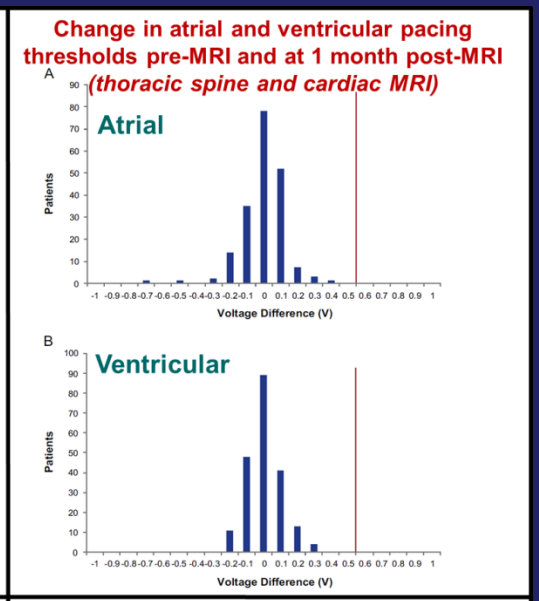
William M. Bailey, MD, FHRS,[*] Lawrence Rosenthal, MD,[†] Lameh Fananapazir, MD,[‡] Marye Gleva, MD, FHRS,[§] Alexander Mazur, MD,[‖] C.A. Rinaldi, MD,[¶] Alexander Kypta, MD,[**] Béla Merkely, MD,[††] Pamela K Woodard, MD,[§]on behalf of the ProMRI/ProMRI AFFIRM Study Investigators

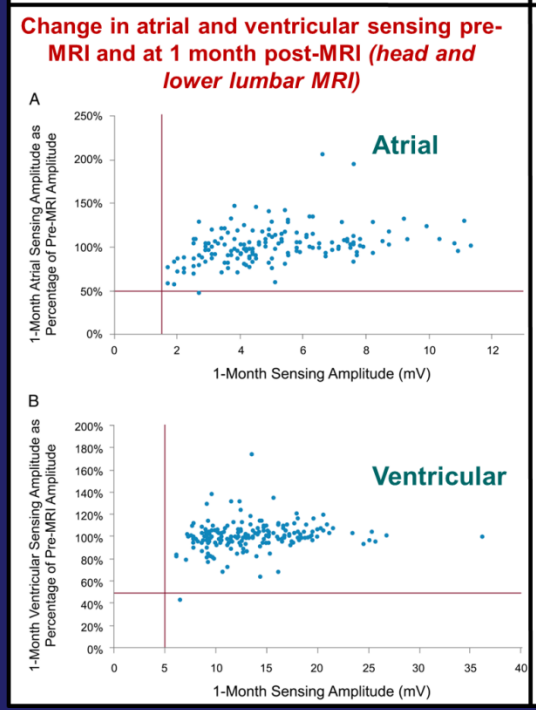
- Prospective, single-arm, non-randomized study evaluating the safety of MR scanning for patients with single or dual-chamber Biotronik Entovis pacemakers (Setrox S 53-cm and/or 60-cm leads).
- Patients undergo thoracic spine, cardiac, head, and lower lumbar MR scanning at ≥5 weeks post pacemaker implant.
- 245 patients were enrolled from 31 centres between Dec 13 2013 to July 11 2014.

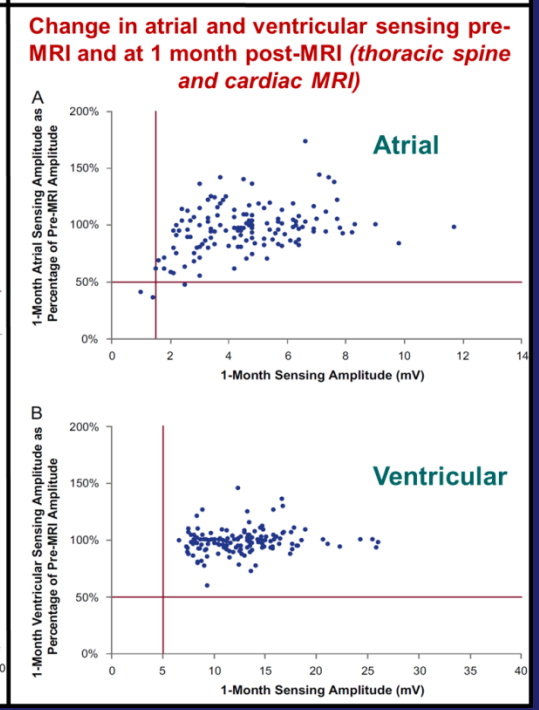
Bailey WM et al. Hearth Rhythm 2015;10:1-8 and 2015; 12:1183–1191

MRI for patients with MR-conditional pacemakers









Comments:

(1) Patients were excluded from MRI scan if they had pre-MRI threshold(s) >2.0 V @ 0.4ms; lead impedance <200 or >1500 Ω; phrenic nerve stimulation at 4.8Va @ 1.0 ms; or threshold variation exceeding 0.5 V from baseline.

(2) Otherwise, no appreciable change in atrial or ventricular pacing thresholds or sensing was noted in this study.

Bailey WM et al. Hearth Rhythm 2015;10:1-8 and 2015; 12:1183–1191

MRI for patients with MR-conditional pacemakers: adverse events

- The freedom rate of serious adverse event was 99.6% (220/221 subjects).
- One subject experienced an adverse event which was felt to be possibly related to MR scanning.
- This subject developed chest pain with pericarditis and a pericardial effusion 4 days post-MRI. There was no imaging evidence of perforation. This was eventually treated with repositioning of the ventricular lead.

Bailey WM et al. Hearth Rhythm 2015;10:1-8 and 2015; 12:1183–1191

MRI for patients with MR-conditional ICD

Full-Body MRI in Patients With an Implantable Cardioverter-Defibrillator

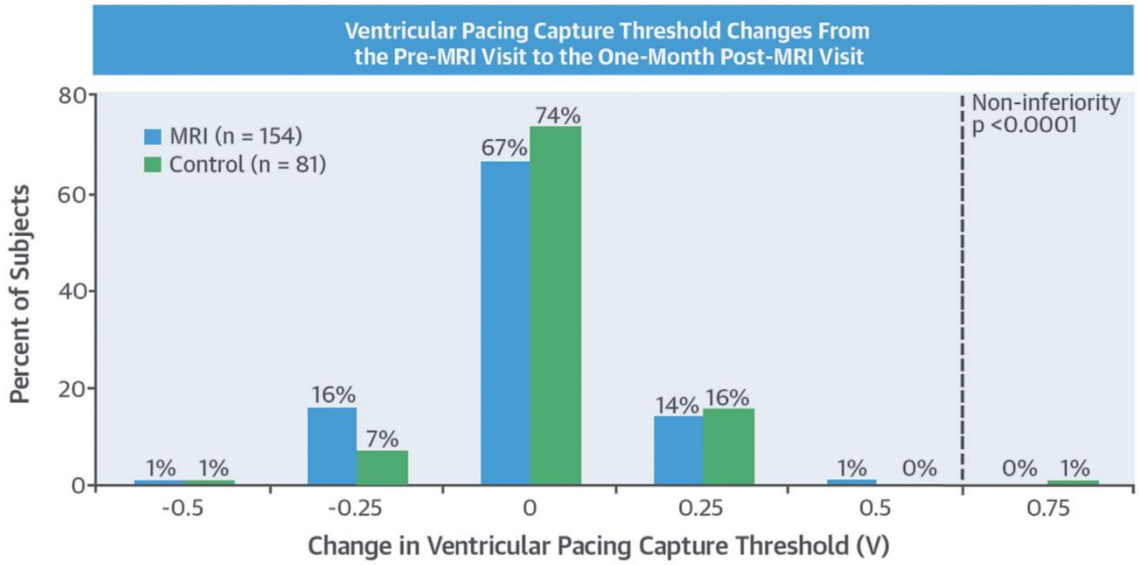
Primary Results of a Randomized Study

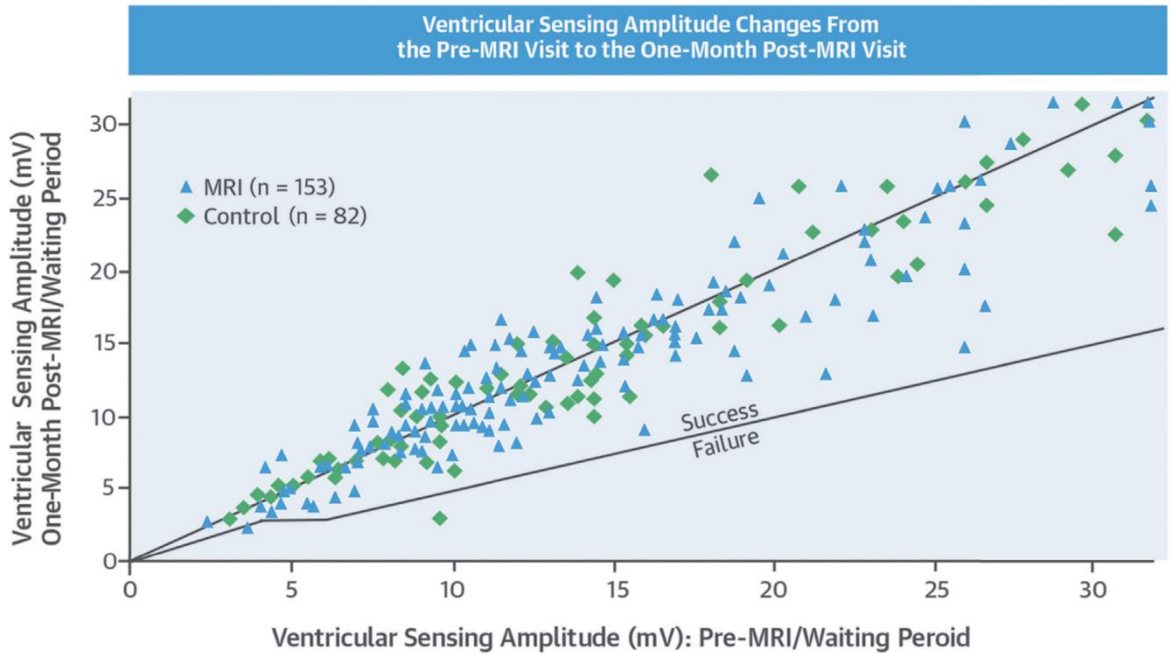
Michael R. Gold, MD, PhD,* Torsten Sommer, MD, PhD,† Juerg Schwitter, MD,‡ Ahmed Al Fagih, MD,§ Timothy Albert, MD,‖ Béla Merkely, MD, PhD, DSc,¶ Michael Peterson, MD,# Allen Ciuffo, MD,** Sung Lee, MD,†† Lynn Landborg, BA,‡‡ Jeffrey Cerkvenik, MS,‡‡ Emanuel Kanal, MD,§§ on behalf of the Evera MRI Study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

- Prospective, 2-arm, randomized study evaluating the safety of MR scanning for patients with single or dual-chamber Medtronic DF-4 Evera ICDs (6935M or 6947M 55-/62-cm ICD leads ± Medtronic 5076 atrial leads).
- If randomized to the MR scanning group (n=175), patients underwent “full-body” MRI (cardiac, thoracic spine, lumbar spine, head) at 9-12 weeks post ICD implant.
- Patients in the control group (n=88) did not undergo protocol-mandated MR scanning.
- 275 patients were enrolled from 42 centres.

Gold MR et al. *JACC* 2015;65:2581-2588.

MRI for patients with MR-conditional ICD





Comments:

(1) Overall, there was no significant change in ventricular pacing thresholds or sensing amongst subjects who underwent MR scanning with the Medtronic Evera ICD system.

(2) 24 subjects had 34 episodes of VT/VF (20 were induced for DFT) in the follow-up period after MRI. All episodes were appropriately detected by the ICD system.

(3) All subjects in this analysis had intrinsic ventricular rhythm *(i.e. no subject was pacemaker-dependent).*

Gold MR et al. *JACC* 2015;65:2581-2588.

MRI for patients with MR-conditional ICD: adverse events

- There were 5 MR-imaging-related events occurring in 5 subjects.
- 2 subjects reported site warmth and 1 reported back pain during scanning (no additional action was required).
- 1 subject reported a burning sensation in the forehead – no specific pathology was noted (X-ray ruled out presence of metallic foreign body).
- 1 subject experienced atrial tachycardia which was terminated by atrial ATP. The MR scan was suspended and was eventually completed. This patient had multiple episodes of atrial tachycardia during follow-up.
- There were 12 deaths (4 control, 8 MRI group). After adjudication by the clinical events committee, none of the deaths was felt to be related to the MR-ICD system or the MRI procedure.

Gold MR et al. *JACC* 2015;65:2581-2588.

MR scanning of patients with non-MR-conditional CIEDs

- There are a number of published reports which examined this topic.
- In general, these studies are retrospective and included relatively small numbers of patients.

MRI for patients with non-MR-conditional pacemakers

Study	# of pacemaker patients	Tesla (T)	# of pacemaker-dependent patients	Abnormal device-related findings during or after MR scanning
Gimbel et al.	5	0.5T	1	Asymptomatic 2-second pause in a pacemaker-dependent patient with unipolar leads whose device was programmed in DOO mode.
Sommer et al.	18	0.5T	NA	Reed switch activation and continuous pacing at a fixed rate. (n=18)
Sommer et al.	44	0.5T	0	None.
Vahlhaus et al.	32	0.5T	0	Temporary Reed switch deactivation (n=12); Diminished battery voltage was observed immediately post-scan but recovered 3 months later.
Martin et al.	54	1.5T	0	Changes in lead parameters occurred at 9.4%; of which 1.9% required a change in programmed output.
Del Ojo et al.	13	2.0T	0	None.
Gimbel et al.	10	1.5T	10	Change of pacing threshold by ± 0.5 V at 3 months. (n=7)
Sommer et al.	82	1.5T	0	Electrical reset. (n=7); ↑ pacing threshold noted after MR scanning; none resulted in changes in the programmed output.
Nazarian et al.	31	1.5T	12	None.
Naehle et al.	44	3.0T	0	None.
Mollerus et al.	32	1.5T	0	None.
Naehle et al.	47	1.5T	NA	Decreased pacing thresholds and battery voltage with repetitive MR scanning (171 scans in 47 patients). These changes did not lead to changes in programmed output.
Mollerus et al.	46	1.5T	0	Asymptomatic ventricular ectopy during MR scanning; some was secondary to the noise reversion function of the device. (n=4)
Pulver et al.	8	1.5T	0	None.
Mollerus et al.	105	1.5T	0	None.
Halshtok et al.	9	1.5T	6	Power-on-reset. (n=2)
Strach et al.	114	0.2T	Yes (exact number unknown)	None.
Burke et al.	24	1.5T	6 in total (unclear how many patients had pacemakers)	None.
Buendia et al.	28	1.5T	4 in total (unclear how many patients had pacemakers)	Temporary communication failure. (n=2); Oversensing due to EMI. (n=1); Safety signal. (n=1)
Nazarian et al.	237	1.5T	53	Power-on-reset (n=2).
Cohen et al.	69	1.5T	29 in total (unclear how many patients had pacemakers)	Changes in various lead parameters were noted (2-12%) that were not statistically different than a historical control group.
Boilson et al.	32	1.5T	0	Power-on-reset. (n=5) Magnet mode asynchronous pacing. (n=3)

Verma A. et al. *Can J Cardiol*. 2014 Oct;30(10):1131-41.

MR scanning of patients with non-MR-conditional ICD systems

Study	# of MRI patients	Tesla (T)	Abnormal device-related findings during or after MR scanning
Gimbel et al.	7	1.5T	Power-on-reset. (n=1)
Nazarian et al.	24	1.5T	None.
Mollerus et al.	5	1.5T	None.
Naehle at al.	18	1.5T	Decrease in battery voltage. (n=2); Oversensing of EMI as ventricular fibrillation; no ICD therapy was delivered. (n=2)
Mollerus et al.	6	1.5T	Asymptomatic ventricular ectopy during MR scanning; some was secondary to the noise reversion function of the device (n=3).
Mollerus et al.	22	1.5T	Decreased sensing amplitudes and pace impedances.
Halshtok et al.	9	1.5T	None.
Burke et al.	14	1.5T	None.
Buendia et al.	5	1.5T	Oversensing of EMI as ventricular fibrillation; no ICD therapy was delivered. (n=1)
Nazarian et al.	201	1.5T	Power-on-reset. (n=1); Changes in lead parameters were observed; none of which led to device revision or reprogramming.
Cohen et al.	40	1.5T	Changes in various lead parameters were noted (2-12%) that were not statistically different than a historical control group.

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MR scanning of patients with non-MR-conditional CIEDs: Comments

- Considered to be “off-label” and not “standard of care” in many institutions.
- Potentially serious complications may occur as a consequence of MR scanning in this patient population (e.g. death, system malfunction or damage, arrhythmia induction).
- If this is to be done, we suggest: (i) development of an institutional-specific standardized protocol; (ii) clear discussion of risks and benefits amongst patient and physicians; (iii) written informed consent.

Verma A. et al. *Can J Cardiol*. 2014 Oct;30(10):1131-41.

MR scanning of patients with CIEDs: Conclusions

(1) No CIED system is “MRI-safe”.

(2) There are a number of CIED systems which are MR-conditional. This means that patients with these systems may undergo MR scanning without additional/excessive risk, provided that:
   (i) manufacturer-specified MR scanning parameters are followed.
   (ii) the CIED is checked pre-MRI and its function is deemed satisfactory.
   (iii) the CIED is reprogrammed to the “MR scanning” mode during MRI.

(3) Published studies of MR scanning of patients with MR-conditional CIEDs included very few, if any, patients who are pacemaker-dependent.

(4) MR scanning of non-MR-conditional CIEDs is considered “off-label” and not part of “standard of care” in most institutions. They may be performed but a rigorous system of checks and balances is needed.