Magnetic Resonance Imaging and Implantable Devices

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In recent years, there has been a remarkable increase in the number of patients who benefit from cardiovascular implantable devices. On the other hand, magnetic resonance imaging (MRI) compared with other imaging techniques undoubtedly has many advantages regarding its discrimination ability without radiation exposure. The risks of scanning device patients that have non "MR Safe" or "MRConditional" devices (Table 1), due to field effects, are well known as are the risk mitigation strategies.

Hazards and safety concerns

There are three distinct mechanisms associated with MRI that can give rise to potential risks related to cardiovascular devices: (1) the static magnetic field, (2) radiofrequency (RF) energy, (3) gradient magnetic fields or any combination of them. Static main magnetic field exposes ferromagnetic components to mechanical forces and torque and causes unpredictable magnetic sensor activation, reed switch closure and electrocardiograms distortions on electronic implantable pulse generators (IPGs), implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices. Modulated RF field interacts with pacemaker devices and leads causing heating of cardiac tissue adjacent to electrodes, reset and sensing problems of the device. ICDs can falsely detect RF field as ventricular tachycardia (VT) and start the sequence of defibrillation. Gradient magnetic field can induce currents in electrically conductive wires and leads that could cause over-/under-sensing and induce arrhythmias. Combined field effects can cause alteration of device function, vibrations, electronic reset and device or lead damage. Electrical reset is a safety emergency mode that limits pacemaker functionality to minimal in case of battery depletion or dip due to MR field interference. Factory default settings and usually a VVI mode are set while ICD therapies are deactivated. Because ICD's parts, such as capacitors and batteries, are much larger than those of pacemakers and the technology used is more complicated they tend to pose greater conflicts, electromagnetic and mechanical forces (10 times higher than pacemaker), under MRI conditions. Generally pacemakers are switched to asynchronous magnet or interference mode and ICD therapy is switched off after MR field exposure. On the other hand, pacemaker leads left in place after device removal are "antennas" causing heating even if isolated by silicon cup and in some cases heat generated is higher than normally connected leads. Temporary epicardial pacing stainless steel leads after cardiac surgery seem to post no threads during non cardiac MRI.[39, 40] Another aspect that should be considered is image artifacts due to implanted devices near the imaging field of view producing static fields causing image distortion.

Table 1. Terminology

Older	
MR Safe	When used in the MR environment presents no additional risk to the patient or other individual but may affect the quality of the image obtained. The MR conditions in which the device was tested should be specified in conjuction with the term "MR Safe" because it may not be safe under other MR conditions.
MR Compatible	MR safe and when used under MR field does not affect image quality or its functioning properties. Again the MR conditions must be specified.
Newer	
MR Safe	Item with no known hazards in any MR field. Nonconducting, nonmetallic, nonmagnetic.
MR Conditional	Item with no known hazards in a *specific MR environment and conditions of use* eg. static field strength, spatial magnetic gradient, dB/dt (time varying magnetic fields), RF fields and SAR. Additional conditions specifying configuration of the item may be required.
MR Unsafe	Item with known hazards in all MR environments.

Studies covering the consequences of MRI in pacemakers and defibrillators

Several ex vivo and animal studies concerning pacemaker and ICD interactions with magnetic fields of MR examination have been set off by advances in device technology. Devices in use today pose greater resistance to changes in function while in MRI conditions [4] and measurements of lead temperature in vivo demonstrated no considerable alterations in stimulation thresholds or heat related lesions. [2-4] Recent reports [2,5,7] demonstrate a relative safety during MRI examination for newer devices under 0.5-3.0 Tesla magnetic field exposure and only few and minor alterations in threshold values or cases requiring reprogramming of the device or battery depletion.

In vitro and animal subjects

Pavlicek et al in 1983 showed that RF energy fields could inhibit demand pacemakers and that gradient magnetic fields could produce currents mimicking cardiac electrical activity with a 17 Gauss threshold to asynchronous mode initiation. Fetter et al in 1984 postulated that under 0.15T magnetic field a reversion from demand to asynchronous mode happened without reed switch sticking or magnetizing or damage to other components of the electrical circuit. Erlebacher et al in 1986 showed total inhibition of atrial and ventricular

output or rapid atrial pacing of various DDD pacemakers under 0.5T field due to RF interference. Lauck et al in 1995 tested the behavior of VVI, VVIR, VOO, DDD, DDDR, DOO modes under 0.5T and observed a reversible reed switch activation with asynchronous stimulation in all pacemakers. Devices with auto mode switch to demand pacing or programmed reed switch inactivation were triggered in dual chamber and inhibited in single chamber mode while devices in asynchronous mode showed no conflicts concerning rate and capture during MRI. Thus, they suggested turning into asynchronous mode before 0.5T MRI or device inactivation in non pacemaker depended patients. Hayes et al in 1987 investigated in vivo various single and dual chamber devices under 1.5T MR scanners. Except reversion to asynchronous mode and reed switch activation, RF signal exposure caused rapid pacing at a cycle length of 200ms (the frequency of RF emition) resulting in blood pressure precipitation as a result of an "antenna" effect of the device output circuits on 7 of the 8 investigated pulse generators. Achenbach et al in 1997 showed that no interference was observed in asynchronous mode either VOO or DOO, while VVI and DDD devices posed inhibition and rapid pacing during spin echo imaging due to above sensing threshold in atrial leads currents that triggered ventricular response. Lead heat is of great importance in MR environment and technically difficult to measure a fact coupled with results fluctuation. Achenbach et al in the same study used an optical temperature sensor to record pacing lead tip temperature. A 63.1^0C maximal temperature increase after 90 sec of scanning was observed while in 7 electrodes the temperature increase exceeded 15^0C. Sommer et al in 2000 connected specific absorption rate (SAR) with the maximum temperature increase that was 8.9^0C at 0.6 W/Kg and 23.5^0C at 1.3W/Kg. Roguin et al in2004 report a maximal heating of 7^0C under 3.7 W/Kg SAR, while in vivo in the same study there was no significant rise of the temperature when leads were into the right ventricle of a canine model due to heat diffusion through blood. In addition 15 dogs with ICD leads were scanned under prolonged and high SAR protocols (3-4W/Kg / 3-4 hours) and no heat induced injury was observed. Schmiedel et al in 2005 also reported no heat induced tissue damage. Luechinger et al in 2005 stated that cell damage during lead implantation cannot be distinguished from that of heat and in vivo only minor changes in stimulation thresholds (<0.5V), while no heat induced damage were observed despite the increasing temperature up to 20^0C, using leads with additional thermocouple wires as temperature sensors. Roguin et al one year earlier used optic fibre measurements and no heat rise was observed but they also found no significant heat damage or threshold changes. Of course both studies took place under in vivo blood flow cooling environment of animal hearts. Force and torque in vivo and in vitro was minimal in a series of studies [27,28,30] with no tissue damage, no permanent lose of capture and no function problems concerning newer devices.

Human studies

Most studies until late 1990s (Table 2) reveal no lethal consequences on pacemaker patients underwent MRI. Only few reports of unexpected deaths were posted. [13-15] Vahlahaus et al in 2001 used a 0.5 T MR system on 32 pacemaker patients combining this with a just after and 3 months later PM interrogation. Decreased battery voltage was observed immediately after MRI which recovered 3 months later. Lead impedance, sense and thresholds were not affected. Reed switch activation by static field was not predictable. Martin et al in 2004 tested 54 non pacemaker depended patients at 1.5 T MRI. Statistically significant threshold changes were up to 9.4% but patients' symptoms were mild and ECG changes did not pose a threat to stop the examination. Schmiedel et al in 2005 tested (brain MRI) 45 pacemeker patients (63 MRIs) at 1.5 T of a maximum SAR of 1.2 W/Kg and under continuous ECG and oximetry monitoring. Devices were reprogrammed to asynchronous mode prior to the examination. An increase $<2.98^0$C max to the temperature observed is not of great concern. No changes concerning programmed parameters or damage of device (in vitro n=0/24) and in vivo n=0/63) and no significant (<1V) changes of thresholds immediately after MR or in 3 months follow up were observed. Sommer et al tested 82 patients with Medtronic pacemaker devices implanted under 1.5 T MR (pacemaker depended patients and those required thorax MRI were excluded). SAR was at 1.5W/Kg. Parameters investigated were troponin I levels and PM function (capture threshold before and three months after). Reprogramming to asynchronous mode of patients with heart rates <60 bpm and sense only mode to those with heart rates >60 bpm was used to avoid MR induced inhibition and arrhythmias respectively. Capture threshold increased (p=0.017) and so did troponin I levels. In 2 of 195 leads capture threshold increased at 1V/ 0.4 ms and in one case this was followed by an increase of troponin I levels from 0.02 baseline to 0.16 post MR. Nazarian et al in 2006 investigated 55 patients with clinical need of MR examination having devices (31 PM/24 ICD) that have been tested by in vitro phantom and in vivo animal testing and shown to be MRI safe. [27] They posted that MRI examination (cardiac and non cardiac) in patients with selected devices can be safe if all technical aspects and precautions are under consideration. Asynchronous mode for PM dependent patients and demand for the rest has been selected while magnet

response and tachyarrhythmia function were set to off. No considerable changes in lead impedances, capture thresholds, sensing amplitudes were observed in a median 99 days follow up and no abnormal activation or inhibition of pacing were observed during MRIs while diagnosis have been set in 100% of non thoracic and in 93% of thoracic studies. Gimbel et al in 2005 tested 10 PM depended patients under MRIs of neck and head of a whole body SAR < 2 W/Kg end reprogrammed devices to VOO or DOO 60 ppm. No arrhythmias or other events were noted during or post MRI and no battery depletion observed. Thresholds post MRI and 3 months later had no significant changes. Nazarian et al and Goldsher et al in2006 posted similar results on PM dependent patients. To draw a conclusion of these studies, PM dependent patients may undergo MRI safely if special parameters are arranged including reprogramming of the device, use of MR sequences with low magnetic field power, careful monitoring and use of transmit-receive coil in cranial scans.

With regard to ICDs, laboratory testing seems to pose that modern systems can undergo MR scanning without harm vs older systems that were irreversibly damaged (4). Naehle et al in 2009 tested 18 ICD non pacemaker dependent patients under MRI conditions concerning all body parts examinations. No thermal injury or significant changes in pacing parameters was observed. All devices could be interrogated normally post MRI while no torque or heat sensations were reported by the patients during the examination. Mean battery voltage had dipped from pre MRI 3.86 ± 1.48 V, to post MRI 3.83 ± 1.48 V with reversion to 3.9 ± 1.52 at follow up. Gimbel et al in 2005 (10) tested 7 ICD patients underwent 8 MRI scans at 1.5 T and no adverse effects clinical or electrical were reported. Nazarian et al in 2006 (7) on the largest MR scanned ICD patients reported series posed no issues in all 24 patients and devices. Roguin et al in 2008 showed similar results (2). However, careful evaluation of all physical/technical and clinical/patient aspects must be performed before any MR scanning to avoid adverse effects.

Technical aspects and clinical safety concerns in MRI of patients with implanted devices

Given the wide range of available MRI systems and conditions, pacemakers, ICDs, leads and a variety of diseases with MRI indication it is difficult to post specific recommendations for routine use. None MR scanning should be considered safe despite the several studies posing the opposite. Today's devices seem to be more safe but they are neither MR safe nor MR conditional labeled. However, Medtronic developed and tested EnRhyhm-MRI SureScan pacing system to be used safely under MRI conditions (8). Anyway, indications have to be carefully evaluated and the risks should be discussed with the patient and informed consent must be obtained. The whole examination must be done under strict observation by MR and electrophysiology expert personel. Monitoring and full resuscitation facilities must be present and both thoughtful pre-MR reprogramming and thorough follow up must be performed. As posted by Roguin et al in 2008 position paper three groups of patients with risk correspondence are recognized and related recommendations were given (Table 3).

Conclusion

Although MRI has become an increasingly attractive imaging modality over the past decades many caveats and contraindications were posted regarding MR scans in patients with implanted devices. Despite the considerable number of studies and the amount of patients with implanted devices underwent MR scan safely, special safety issues must always be considered regarding heating, arrhythmogenesis, and device function that demand measures to mitigate them related to both the device and the MR scanner. MRI may be done after thorough evaluation of the indication and in the absence of an alternative imaging modality. In any case informed consent must be obtained after discussing the risks with the patient. Pre-reprogramming the device, patient monitoring during MR and thorough follow up must always be performed. New devices MR-conditional labeled are under investigation and others will be developed in the future paving the way to safe MRI scans in the growing population of patients who benefit from implanted pacemakers and defibrillators.

Table 3. MRI and pacemakers: safety concerns & guidelines.

(1) Pacemaker-dependent patients (very high risk)	If underlying rhythm is too slow—reconsider indication. The threshold for imaging and the safety requirements are higher, but no absolute contraindication
(2) ICD patient (non-dependent)[a] (high risk)	The patient must have a documented extremely serious, life threatening or severely quality-of-life limiting condition
(3) Pacemaker patient (non-dependent) (low risk)	The patient must have a documented very serious, life threatening or severely quality-of-life limiting condition.

Table 2. Published reports (1989–1998) describing the non-lethal consequences of magnetic resonance imaging in pacemaker patients

Author	*Indication for MR imaging*	*Pacemaker model*	*Dual-/single-chamber*	*Lead polarity*	*PM mode*	*Field strength (T)*	*Outcome after MR imaging*
Alagona (1989)	Brain tumor	AFP	Dual	Unipolar	OOO	1.5	Normal
Inbar (1993)	Cerbellopontine syndrome	Paragon II	Dual	Bipolar	OOO	1.5	Normal
Gimbel (1996)	Heart valve	AFP	Single	Unipolar	OOO	1.5	Image artifact
	Brain tumor	Genesis	Dual	Unipolar	DOO	0.5	Pause (2s)
	CIA	Paragon II	Dual	Bipolar	OOO	0.35	Normal
	Pituitary tumor	Synchrony	Dual	Bipolar	DOO	1.5	Normal
	Cervical disc	Synchrony II	Dual	Bipolar	DDD	1.0	Normal
Fontaine (1998)	Dizziness	Thera DR	Dual	Bipolar	VVI	1.5	Rapid vent pacing
Garcia Bolao (1998)	Cranial nerve palsy	Meta	Dual	Bipolar	AOO	1.0	Asynchronous pacing
Sommer (1998)	CNS	Elite	Dual	NA	DOO	0.5	Asynchronous pacing
	Cardiac tumor	Elite	Dual	NA	DOO	0.5	Asynchronous pacing
	Periprosthetic (asc.aorta)	Elite	Dual	NA	DOO	0.5	Asynchronous pacing
	Pseudoaneurysm	Relay	Dual	NA	VOO	0.5	Normal
	Paravalvar Prosth	Vista	Dual	NA	DDD	0.5	Asynchronous pacing
	Constrictive pericarditis	Dialog	Single	NA	VVI	0.5	Asynchronous pacing

CIA = ; CNS = ; NA = not available; PM = pacemaker

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