Pacemakers and Magnetic Resonance Imaging: No Longer an Absolute Contraindication When Scanned Correctly

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ABSTRACT: **Background:** Until recently, cardiac pacemakers and implantable cardioverter defibrillators were considered an absolute contraindication for magnetic resonance imaging. Given the significant increase in implanting such devices, these contraindications will preclude MRI scanning in a large patient population. Several recent reports have addressed the safety and feasibility of MRI in the presence of cardiac implantable devices.

Objectives: To summarize our experience with MRI scanning in the presence of pacemakers and implantable cardioverter defibrillators.

Methods: Eighteen patients (15 males and 3 females, median age 59) were scanned using a 1.5 T MRI scanner. A clinical discussion was held to verify the absolute medical necessity of the study before performing the scan. Scan supervision included device interrogation and programming beforehand, patient monitoring during, and device interrogation and reprogramming after the scan. Full resuscitation equipment was available outside the MRI suite.

Results: Thirty-four scans were performed, and all but one were of diagnostic quality. Anatomic regions included the brain (N=26), cervical spine (N=2), lumbar spine (N=1), cardiac (N=2), abdomen (N=1), abdomen and pelvis (N=1) and pelvis (N=1). None of the patients reported any side effects and no life-threatening events occurred during or following the scans. Five cases of device spontaneous reversion to backup mode were recorded (four in the same patient). Device replacement was not required in any patient.

Conclusions: In this small cohort of patients MRI scanning in the presence of cardiac implantable devices was safe. MRI in these patients is feasible although not recommended for routine scans. Scans should be considered on a case-to-case basis and performed in a dedicated specialized setup.

IMAJ 2010; 12: 391–395

KEY WORDS: magnetic resonance imaging, implantable pacemaker, defibrillators, safety

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Magnetic resonance imaging has evolved in the past two decades into an essential component of the radiologic imaging arsenal, offering multisystem high-end imaging. MRI is considered the modality of choice for neuroimaging, musculoskeletal imaging and innumerable clinical indications. Additional advantages include the lack of ionizing radiation exposure and the use of gadolinium (as the contrast agent), which is significantly less nephrotoxic and allergenic than iodinated contrast.

MRI scanners use powerful static magnetic forces and pulsing radiofrequency energy. In these conditions the electrodes of pacemakers and implantable cardioverter defibrillators may act as "antennas" predisposing them to device malfunction. These potentially include rapid atrial pacing, pacing at rapid ventricular pace with a rare potential to induce ventricular fibrillation, reed switch malfunction, asynchronous pacing that may be arrhythmogenic, pacing output inhibition, programming alteration, potential damage to the pacemaker circuitry, device movement, and the potential of thermal injury at the lead tip resulting in high pacing thresholds or loss of capture [1-3].

Reports have documented life-threatening events and even death of patients with pacemakers and ICDs who underwent non-monitored MRI scanning [4]. Thus, intracardiac devices were considered an absolute contraindication for MRI scanning, and despite the unique role of MRI in imaging, this modality was considered unavailable in most medical institutions for the large and growing population of patients with such implantable devices.

As pacemakers and ICDs become smaller and contain fewer magnetic components, the devices are better protected from the external magnetic environment. Monitored MRI scanning is being reevaluated and the absolute contraindication for MRI in the presence of pacemakers and ICDs was recently reconsidered [5,6]. Examining the feasibility and safety of MRI in the presence of a pacemaker or ICD, several reports [7-11] recently demonstrated the ability to perform

ICD = implantable cardioverter defibrillator

safe MRI scanning at 1.5 Tesla environment scanners in subjects with pacemakers within a professionally supervised setting [8,12,13]. This setup includes limiting the radiofrequency exposure, pre-procedural device reprogramming, continuous pulse and pulse oximetry monitoring, continuous verbal communication, availability of an electrophysiologist, full resuscitation facilities, and post-study pacemaker interrogation and reprogramming when necessary. So far, only a few reports have examined MRI scanning of patients with pacemaker or ICD in a 3 Tesla environment [14-16].

Although new "MRI conditional" pacemakers (a device approved for MR imaging with certain restrictions) are currently being introduced [4,17], the vast majority of devices are still "non-MRI safe." In this study we review our preliminary experience with MRI scanning of patients with pacemakers and ICDs.

PATIENTS AND METHODS

Thirty-four sequential MRI studies were obtained in 18 patients with pacemakers or ICDs in a single university medical center between 2004 and 2009. The patient cohort included 15 males and 3 females with 11 pacemakers and 7 ICDs. Median patient age was 59 years (range 11–94).

Table 1. Patient characteristics

Patient	M/F	Age (yrs)	MR	Reason for the scan	ICD/ PM	Time	PMd	Malf
1	M	59	Brain	Neurologic deficit with normal CT	PM	7 yr *	Yes	
1	M	59	Brain	Post-biopsy, gemistocytic astrocytoma	PM	7 yr *	Yes	No
2	M	46	Brain	Frontoparietal SOL on CT	ICD	3 yr 11 mo	–	No
2	M	46	Brain	Frontoparietal SOL, post-op	ICD	4 yr 1 mo	–	No
2	M	46	Brain	Anaplastic astrocytoma FU	ICD	4 yr 6 mo	–	No
2	M	46	Brain	Post-SOL resection	ICD	5 yr 2 mo	–	No
3	M	62	Brain	Rt hemiparesis	PM	1 yr 7.5 mo	Yes	No
4	M	80	Brain	SOL in rt lateral ventricle	PM	9.5 mo	No	No
5	M	67	Brain	Known melanoma, FU	PM	3 yr 8 mo	Yes	No
6	M	70	Brain	Lt mastoidectomy due to BCC, FU	ICD	3 yr 8 mo	–	No
6	M	71	Brain	Lt mastoidectomy due to BCC, FU	ICD	4 yr 7 mo	–	No
7	M	88	Brain	Susp. of SOL on CT	PM	5 yr	Yes	No
8	M	75	Brain	S/P left parietal meningioma resection	PM	10 yr	No	Reset
8	M	75	Brain	S/P left parietal meningioma resection	PM	11 yr	No	No
9	M	75	Brain	Hemiplegia and focal convulsions	ICD	1 yr 7 mo	–	No
10	M	59	c-spine	Rt arm paresis	ICD	7 yr	–	No
11	M	35	Cardiac	CM or RVD	ICD	8 mo	–	No
12	M	11	Cardiac	Pre-op HOCM	PM	3 mo	No	No
13	M	84	Brain	Brain SOL seen on CT	CRTP	1 yr 1 mo	Yes	No
14	M	70	Abdomen and pelvis MRA	Claudication	ICD	1 yr 9 mo	No	No
15	F	94	Pelvis	Rectal carcinoma, malignancy	PM	5 yr 7 mo	Yes	No
16	F	56	Lumbar spine	Low back pain	ICD	NA**	–	No
17	F	35	Brain	Incomplete resection of astrocytoma, FU	PM		No	Reset
17	F	35	Brain	Incomplete resection of astrocytoma, FU	PM		No	No
17	F	35	Brain	Incomplete resection of astrocytoma, FU	PM	10 yr 3 mo	No	Reset
17	F	35	Brain	Incomplete resection of astrocytoma, FU	PM	9 yr 10 mo	No	Reset
17	F	33	Brain	Incomplete resection of astrocytoma, FU	PM	8 yr 2 mo	No	No
17	F	31	Brain	Incomplete resection of astrocytoma, FU	PM	6 yr 8 mo	No	No
17	F	31	Brain	Incomplete resection of astrocytoma, FU	PM	5 yr 11 mo	No	No
17	F	30	Brain	Post-op evaluation of posterior fossa astrocytoma	PM	5 yr 8 mo	No	No
17	F	30	Brain	Pre-op evaluation of posterior fossa astrocytoma	PM	5 yr 6.5 mo	No	Reset
17	F	30	Brain	Neck pain and anisocorea	PM	5 yr 6 mo	No	No
17	F	30	c-spine	Neck pain and anisocorea	PM	5 yr 6 mo	No	No
18	M	84	MRCP	S/P Klatskin tumor, question of relapse	PM	2 mo	**	No

* ICD implanted in another institution, implantation time may be longer than 7 years.

**NA = Not applicable. Outpatient records were not found.

BCC = basal cell carcinoma, CM = cardiomyopathy, CRTP = cardiac resyncronization therapy pacemaker, CT = computed tomography, F = female, FU = follow-up, ICD = intracardiac defibrillator, Indc = indication, Lt = left, M = male, Malf = malfunction, op = operation, PM = pacemaker, PMd = pacemaker dependency, R/O = rule out, rt = right, RVD = right ventricular dysplasia, S/P - status post, SOL = space-occupying lesion, susp. = suspicion, Time = time from date of implantation to MR scan

Anatomic scanned regions included brain (N=18), cervical spine (N=2), cardiac (N=2), abdomen (N=1, magnetic resonance cholangiopancreatography), lumbar spine (N=1) and pelvis (N=1). All patients were scanned using a 1.5 Tesla MRI scanner (Signa Excite Ver. 11 or 14, General Electric, Milwaukee, WI, USA). The gradient performance (1.5T Signa EchoSpeed HDxt) was maximum gradient amplitude of 33 mT/m and a maximum gradient slew rate of 120 T/m/s. The coils used were receiver coils.

MRI scanning was performed according to accepted clinical indications [6]. A detailed clinical discussion verified the absolute medical requirement for the MRI scan in all patients. Patients who had newly implanted systems or floating abandoned electrodes were not cleared for MRI scanning. Clinical indications for the scans included malignancy evaluation (N=24), neurologic symptoms (N=6), backache (N=1) and claudication (N=1). Cardiac MRI was performed to differentiate arrhythmogenic right ventricular dysplasia from other cardiomyopathy and for the preoperative evaluation of hypertrophic obstructive cardiomyopathy. The patients' characteristics are presented in Table 1. Pacemaker and ICD type and indication for device implantation are summarized in Table 2.

Immediately before the scan the devices were interrogated by a dedicated team comprising an electrophysiologist and device technicians in order to verify normal function and battery status and to determine pacing and sensing thresholds. Pacemaker dependency was determined in each patient before the scan, and pacing was reprogrammed to asynchronous mode with high output in pacer-dependent patients. Some non-dependent patients were reprogrammed to non-pacing or very low output pacing. All ICDs were programmed to detection and/or therapy off-mode. Patients' heart rate and oxygen saturation were continuously monitored during the study. Verbal contact was maintained throughout the study. Full resuscitation equipment ("crash cart") was readily available outside the MRI scanner. After the scan the devices were reevaluated, and any changes in device performance or thresholds were recorded. Pacer-dependent patients had devices set to high thresholds for at least one month after the scan. The records of one outpatient were not available for evaluation.

RESULTS

Thirty-four scans were performed in 18 patients. No life-threatening events occurred during any of these scans. None of the patients complained of any discomfort including heating or torque sensations. Changes in pacemaker programming causing a return to reset mode in which the pacemaker paces at a constant rate occurred in five brain scans (one in a male patient and four in a female patient), Devices were reprogrammed successfully to normal function in all cases. There were no other changes in device function and no significant changes in device thresholds.

Power on reset is not an uncommon phenomenon when strong electromagnetic interference occurs. However, different examinations may involve a variable intensity of electromagnetic interference to the pacemaker area and therefore it cannot be known whether power on reset will or will not occur during a specific examination. On this point, worthy of particular mention is the case of a young female who was scanned repeatedly due to incomplete resection of a posterior fossa astrocytoma. Altogether 11 MRI scans were performed (10 brain scans, 1 c-spine) with pacemaker reset occurring on the second, seventh, eighth and ninth brain scans. There were no device changes in any of the other studies.

Studies were of good diagnostic quality in 33 of the 34 scans [Figure 1]. The non-diagnostic scan was a cardiac MRI performed in an 11 year old boy with hypertrophic cardiomyopathy prior to surgery. The ICD caused significant susceptibility artifacts projected over the entire thorax, rendering the scan non-diagnostic. The ICD artifacts were particularly prominent due to the relatively small thorax size and the proximity of the device to the heart itself [Figure 2]. Another cardiac MRI (in a 35 year old man) demonstrated

Table 2. Device type and indication for device implantation

Patient	Manufacturer	Device type	No. of leads	Indications for ICD/PM
1	SJM	TRILOGY SR	1	Ablation and pacing
2	Biotronic	LEXOS VR-T	1	1° prevention
3	Medtronic	KAPPA KDR901	2	Complete AV block
4	Medtronic	KAPPA KDR901	2	Intermittent AV block
5	Medtronic	KAPPA KDR703	2	Complete AV block
6	Medtronic	InSync Sentry 729	3	CHF, 1° prevention
7	Medtronic	SIGMA SDR303	1	Complete AV block
8	Medtronic	THERA DR 7962i	2	Syncope
8	Medtronic	THERA DR 7962i	2	Syncope
9	SJM	ATLAS II VR V 168	1	Dilated CM, 1° prevention
10	Boston Scientific	VENTAK PRIZM 2 DR	2	Dilated CM, 2° prevention
11	Guidant	VITALITY 2 EL DR	2	Idiopathic VT
12	Medtronic	VIRTUSO DR D164AWG	2	HOCM
13	Medtronic	InSync III 8042	3	Dilated CM, 1° prevention
14	Boston Scientific	CONTAK RENEWAL 4 HE	2	Ischemic CM, 2° prevention
15	Medtronic	KAPPA KDR703	2	Sick sinus syndrome
16	Guidant	VITALITY 2 EL DR	2	2° prevention
17	Medtronic	THERA DR 7962i	2	Sick sinus syndrome

AV = atrioventricular, 1° prevention = primary prevention from sudden cardiac death, 2° prevention = secondary prevention following either ventricular tachycardia or ventricular fibrillation, CHF = congestive heart failure, CM = cardiomyopathy, HOCM = hypertrophic obstructive cardiomyopathy, VT = ventricular tachycardia

Figure 1. Male patient, aged 84, with history of Klatskin tumor. MR cholangiopancreatography was performed for relapse evaluation. In this T2 coronal plane image of the abdomen note the lack of artifacts in the upper abdomen, despite the close proximity of the cardiac leads.

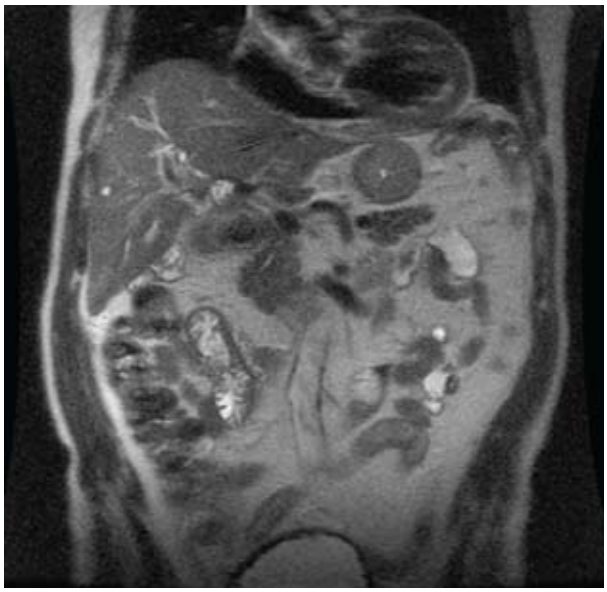
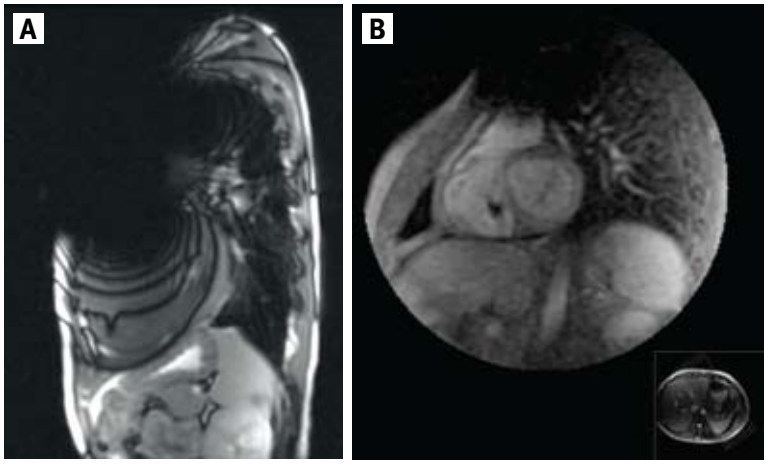


Figure 2. [A] Cardiac MRI (non-gated localizers) in sagital plane in an 11 year old boy. Significant susceptibility artifacts project from the chest wall obscuring the heart, rendering this study non-diagnostic (the scan was stopped). **[B]** Cardiac MRI in oblique plane in a 35 year old man is of acceptable diagnostic quality, and susceptibility artifacts projected from the chest wall obscure only the upper most part of the heart.



significant susceptibility artifacts adjacent to the pacemaker device; nevertheless, the study itself was diagnostic.

DISCUSSION

Pacemakers and ICDs are neither MR safe nor MR compatible according to the manufacturers' instructions. A single MR-conditional FDA-approved pacemaker is currently available (Medtronic – EnRhythm MRI™ EMDR01) that does not necessitate monitoring during the scan but requires modification to "MR-safe" mode. Nevertheless, the C1-C7 region is still excluded even for this "MR-conditional" device. This device is relatively new and due to economic considerations is being used in a small and selected patient population.

The decision to perform an MRI scan in the presence of a pacemaker or an ICD should be considered only after all other imaging modalities were rendered insufficient for the diagnosis of a specific clinical question. Benefit versus risk needs to be weighed carefully. Our experience shows that 1.5 Tesla MRI scanning is feasible and safe. This is in accordance with previous reports showing the safety and feasibility of MRI studies in patients with pacemakers or ICDs in a 1.5 Tesla environment [7,8,10,12,13]. A recent single report addressed the feasibility of MR scanning, in the presence of a pacemaker, at a scanner field strength of 3 Tesla [14].

A monitored dedicated setup is the key for scan safety, preferably performed in experienced dedicated specialized centers. The pacemaker or ICD should be evaluated by an electrophysiologist before and after the scan. Mandatory continuous monitoring during the study includes pulse oximetry and heart rate control as well as verbal communication with the patient. A dedicated team comprising an electrophysiology technician and a physician should be present during the scan, with resuscitation equipment as well as crash cart at hand, and an electrophysiologist readily available for emergencies.

This study has several limitations: troponin blood levels were not measured and the physiologic effects were concluded based on the subjective feeling of the patients. The study cohort was relatively small and the follow-up time relatively short; conclusions should therefore be drawn with caution. The safe uneventful completion of a previous MRI scan in the presence of a pacemaker or ICD does not exclude the possibility of future adverse events in the MR environment. Each study should be regarded as unique, reconsidered if truly needed, and supervised according to the strict recommendations mentioned previously [8,12].

MRI scans in patients with pacemaker or ICD are usually of good diagnostic quality, with few artifacts unless the device is included in the scanned body region. When the thorax or cardiac regions are included, significant susceptibility artifacts are caused by the device apparatus, while device wires cause only minimal artifacts. We conclude that MRI scans, when justified, can be performed safely at 1.5 Tesla scanners in patients with pacemaker or ICD.

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