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Safety of magnetic resonance imaging in patients with permanent pacemakers: a collaborative clinical approach

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Abstract
Objective This study aimed to characterize the interactions of pacemakers with magnetic resonance imaging (MRI) and to identify device characteristics that could predict adverse interactions.
Background The safety of MRI in patients with indwelling pacemaker systems remains uncertain. Previous studies demonstrated safety in most patients, but unpredictable, potentially concerning changes in pacemaker behavior have occurred.
Methods We prospectively studied patients with pacemaker devices *in situ* who were not pacemaker dependent and in whom MRI was essential for adequate diagnosis and treatment. All patients were monitored by electrocardiography and pulse oximetry during scanning; devices were interrogated and cardiac enzymes were measured before and after scanning.
Results Of 32 patients studied (46 MRI examinations), 28 patients had a dual-chamber system and one had a biventricular device. Regions scanned were the head and spine. Devices were reprogrammed to asynchronous pacing or sense-only mode in all except six patients before MRI. During six scanning episodes (five patients), "power-on" resetting of the device was noted. Magnet-mode pacing was noted during four episodes (three patients). Occasional premature ventricular contractions were noted in one patient. No significant changes in battery voltage, sensed P wave and R wave, pacing thresholds, lead impedance, or cardiac enzymes were noted immediately after MRI or at 1-month follow-up.
Conclusions Overall, no significant changes were seen in pacemaker device function, and no adverse clinical events were observed. A minority of patients with older devices had unpredictable changes in device behavior, which stresses the need for close monitoring during and careful device interrogation after scanning.

Keywords Arrhythmias · Device interactions · Magnetic resonance imaging · Permanent pacemakers · Power-on resetting

Abbreviations

CIED	Cardiac implantable electronic device
FDA	US Food and Drug Administration
ICD	Implantable cardioverter defibrillator
MRI	Magnetic resonance imaging
POR	Power-on resetting

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1 Introduction

Magnetic resonance imaging (MRI) is an important diagnostic imaging modality that has had increasing utility in the field of cardiology [1]. The safety of MRI in patients with permanent

pacemaker systems remains uncertain and continues to provoke controversy [2–5]. Because of the increasing prevalence of cardiac implantable electronic devices (CIEDs) and the increased demand for MRI, it has been estimated that up to 75% of patients who currently have a CIED are likely to require an MRI scan during their lifetime [6].

The current guidelines issued by the American Heart Association regarding use of MRI in patients with CIEDs discourage performing MRI in patients with a pacemaker who are not pacemaker dependent ("non-pacemaker-dependent patients") and recommend that it should only be considered if there is a strong clinical indication and if the benefits clearly outweigh the risks [7]. They further recommend that MRI examinations not be performed on pacemaker-dependent patients and those with implantable cardioverter defibrillators (ICDs) [7]. Indeed, all of the major CIED manufacturers have stated that they do not support or recommend the use of devices currently available in the USA with MRI [8–10]. A similar position has also been taken by the US Food and Drug Administration (FDA) [11].

The concerns in relation to CIEDs exposed to the strong magnetic fields during MRI scanning principally extend to changes in programmed parameters and inappropriate sensing and pacing and the potential effect of lead tip heating on myocardial tissue. Although recent studies have demonstrated the safety of MRI in most patients with pacemakers included in specific protocols [12, 13], abnormalities in pacemaker function during pacing continue to be reported [13–16], some of which are potentially concerning, even with the current generation of available devices [17, 18]. Nonetheless, the increasing demand for use of MRI in patients with CIEDs has motivated clinicians and engineers to continue to research pacemaker and MRI interactions to permit the development of MRI-safe devices [13, 19, 20].

In this prospective study, we aimed to characterize pacemaker–MRI interactions in the present era at a single center and to identify device characteristics (generator model and brand, lead model and brand, programming mode during scanning, and implant site) that could predict any adverse interactions. We hypothesized that MRI can be safely conducted in non-pacemaker-dependent patients in an environment with beat-to-beat heart rhythm monitoring and a medical team consisting of members with expertise in radiology and cardiac devices.

2 Methods

2.1 Patient selection

2.1.1 Inclusion criteria

Patients seen at Mayo Clinic, Rochester, MN, USA, between January 2008 and December 2009 and in whom MRI examination was indicated and who had permanent pacemakers *in situ* were eligible for inclusion. In consultation with the referring physician, the radiologist discussed whether alternative imaging choices could provide similar information at less risk to the patient. If it was determined that MRI was the preferred imaging modality for a given patient, the referring clinician requested a pacemaker clinic consultation, including a device interrogation/examination (by nursing staff) and a clinical consultation (by a staff cardiologist). The main aim of the pacemaker clinic consultation was to determine whether the patient was pacemaker dependent and to determine the relative need for pacing (percentage of pacing) with the baseline device setting. Only non-pacemaker-dependent patients were considered for MRI. Furthermore, the lead system was required to be mature (implanted for more than 90 days). During the initial phase of this study, efforts were made to limit cases to head MRI and to scanners for which MRI-compatible monitoring equipment was available. In consultation with MRI physicists, scanning protocols and parameters were planned.

The patient and referring physician were informed that the imaging examination may affect some pacemakers and possibly discharge the battery [21]. After assessing the patient's pacer function and reviewing the goals and risks of the procedure, the cardiologist obtained written consent from each patient that was scanned into the patient's electronic medical record. The study was approved by the Mayo Clinic Institutional Review Board.

2.1.2 Exclusion criteria

Patients who were pacemaker dependent, as evidenced by absence of a stable escape rhythm of more than 30 beats per minute (bpm) or the presence of a potentially life-threatening arrhythmia or hemodynamic instability while the pacemaker was turned down to noncapture or subthreshold pacing, were excluded. Other exclusion criteria for this study were age younger than 18 years, presence of more than one implanted pulse generator, abnormal values for troponin I (>0.03 ng/mL) or creatine kinase-MB (>6.2 ng/mL), presence of any type of ICD device, and patients requiring sedation, anesthesia, or continuous intravenous medication, especially for cardiovascular support. In addition, patients were excluded if they had evidence of inadequate pacemaker function, as evidenced by one of the following: (1) high pacing threshold—capture at 0.5-ms pulse width at more than 3.0 V, (2) pacing lead impedance greater than 2,000 Ω, (3) battery voltage less than 2.7 V, or (4) battery longevity prediction of less than 6 months or at the elective replacement indicator.

2.2 Device programming before MRI examination

On the day of examination, at the MRI site, device interrogation and thresholds were documented and the patient's intrinsic heart rate determined. The pacemaker was programmed to asynchronous pacing at the intrinsic heart rate plus 20 bpm (not exceeding 110 bpm) in AOO, VOO, or DOO mode. If the intrinsic heart rate was greater than 90 bpm, the device was programmed to monitor only (OAO, OVO, or ODO). If the monitor-only feature was not available, the device was programmed to a subthreshold output (AAI, VVI, or DDD). All other diagnostic and therapeutic features were programmed off (rate response, capture management, and mode switch).

2.3 MRI protocol

Mayo Clinic recently developed a pilot clinical protocol for body and head MRI in patients with cardiac devices (Fig. 1). This protocol incorporated common elements from protocols in the published literature [13, 17, 22, 23]. Development of the protocol was a collaboration between the Department of Radiology and the Electrophysiology group in the Division of Cardiovascular Diseases. The Safety and PM Monitoring Committee included two radiologists, one physicist, three electrophysiologists, and two pacemaker nurses. During each MRI examination, particularly early in the study, at least one radiologist and one physicist member of the Safety and PM Monitoring Committee were present to assess any potential clinical or device adverse events. Later in the study, other radiologists and physicists, who could be in immediate contact with members of the Safety and PM Monitoring Committee, participated in some of the studies once they were properly trained in the protocol.

2.4 Monitoring

The patient was monitored by a cardiologist or pacemaker nurse throughout the MRI procedure by

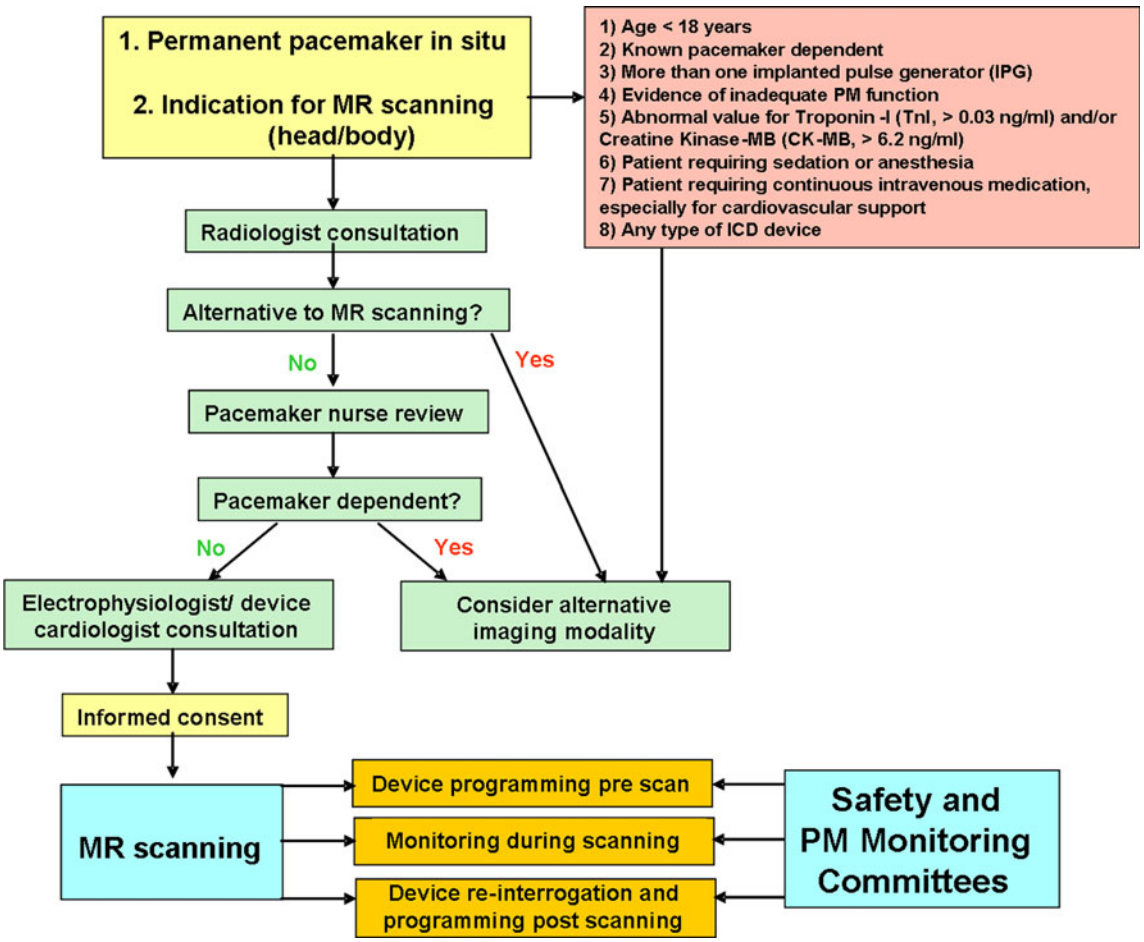

Fig. 1 Algorithm for magnetic resonance scanning in patients with permanent pacemaker devices *in situ*. *ICD* implantable cardioverter defibrillator, *PM* pacemaker

pulse oximetry, CO_2 measurement, electrocardiography (3-lead), and blood pressure measurement at 2-min intervals. In order to assess for the effects of lead tip heating, cardiac enzyme levels (creatine kinase and troponin I) were measured before and after each study as normal levels of these parameters after scanning are a helpful indicator of the absence of significant myocardial injury [16, 24]. Heart rate was monitored continually during the examination, with pulse oximetry and appropriate electrocardiographic monitoring. The MRI acquisition would be halted immediately whenever the cardiologist supporting the examination deemed necessary. The cardiologist or, for later studies, pacemaker nurse reviewed all physiologic data before and after the patient was moved into the center of the magnet bore to be familiar with normal signal artifacts. The examination was stopped if adequate monitoring could not be achieved. Patients were not anesthetized and were instructed to inform the MRI technologist and monitoring cardiologist if pain or discomfort occurred during the examination.

2.5 MRI settings

The MRI pulse sequences used were tailored by the radiologist and physicist supporting the examination. Magnetization transfer pulses were not used, and the specific absorption rate was limited to the minimum needed to acquire adequate imaging. The recommended specific absorption rate limit was 1.5 W/kg for up to 30 min of acquisition time, as described by Sommer et al. [13].

When possible, before imaging, the automatic and manual prescan sequences were used to assess the patient's sensitivity to radiofrequency: If the patient's heart rate synchronized to the transmission–receive interval of the radiofrequency coil, the scan would be discontinued.

2.6 Post-MRI patient assessment

The cardiologist examined the patient after imaging was completed. A pacemaker interrogation was performed and data collected before returning the pacemaker to the patient's original settings.

2.7 Statistical analysis

Fisher exact tests and Pearson χ^2 tests were performed for bivariate analysis of categorical variables. The effect of time on continuous variables was analyzed by one-way ANOVA analysis. $P<0.05$ was accepted as statistically significant. All continuous numerical data are represented as mean (SD), except where otherwise indicated.

3 Results

3.1 Patients and examinations

A total of 32 patients with pacemaker devices *in situ* met all the inclusion criteria for the study; 17 (53%) were men. The mean (SD) patient age was 67 (14) years. The clinical indications for MRI examination are shown in Table 1. Most studies were MRI scans of the head ($n=35$), and the remainder were spine studies (12 cervical, 7 thoracic, 5 lumbar) and one pelvic examination. All MRI examinations performed were diagnostic, and in none of the studies was artifact from the device sufficient to interfere with interpretation.

Forty-six MRI scanning episodes were studied in the 32 patients. Twenty scanning episodes were of more than one region. The devices and leads used and specific indications for MRI are shown for each patient in Table 2. One patient had a biventricular device, and the rest had a single right ventricular lead. Twenty-six patients also had a functioning right atrial lead. In the case of one patient, the generator was in an abdominal location with a ventricular epicardial lead, but this was a nonfunctioning device.

3.2 Device–MRI interaction during MRI

In the study group, 11 occurrences of abnormal pacemaker function were observed in nine patients (Table 3). Occasional premature ventricular contractions were noted during one scanning episode. During six scanning episodes in five patients, the device underwent "power-on" resetting (POR). The device reverted to magnet-mode pacing (Fig. 2) during four further scanning episodes (three patients), but normal function resumed after the scan. The patient with a nonfunctioning abdominally placed device had abdominal pain during the scan, but this was not believed to be related to

Table 1 Indications for MRI

Indication for MRI	No. of scanning episodes
Neurobehavioral changes	6
Spinal cord compression	6
Seizure	4
CNS lymphoma	4
Astrocytoma	3
Bacteremia/endocarditis	3
Intracranial mass, non-specified	2
Acoustic neuroma/sensorineural hearing loss	2
Movement disorder	2
Pituitary adenoma	1
Intractable hiccups	1

CNS central nervous system, *MRI* magnetic resonance imaging

Table 2 Patients and devices

Patient #	Generator	Leads	Implant site	Programmed mode	Indication for MRI
1	Medtronic Kappa KDR 703	RA 5524M/RV 5024M	Prepectoral	DDD 50/120	Seizure disorder
2	St. Jude Identity XL DR	RA 1488T/RV 1488T	Prepectoral	VVIR 60–105	Left hemispheric lesion
3	Medtronic EnPulse E2DR01	RA 4076/RV 4076	Prepectoral	DDDR 60–140	Right frontal mass
4	Guidant Insignia I 1294	RA 5568/RV 5076	Prepectoral	VVIR 60–130	Neurobehavorial changes
5	St Jude Affinity DR	RA 5592/RV 5024	Prepectoral	DDDR 60–170	Astrocytoma
6	Guidant Altrua 60	RA 4135/RV 4136	Prepectoral	DDDR 70–125	CNS lymphoma
7	Medtronic Activitrax 8403	RV Epi 6917AT	Abdominal	Non-functioning Device	Previous pituitary tumor
8	Medtronic Adapta DR	RA 5568/RV 4076	Prepectoral	AAIR<=>DDDR 50–130	Spinal cord compression
9	Medtronic EnRhythm DR	RA 5076/RV 5076	Prepectoral	DDD 60–120	Mental status changes and encephalopathy
10	Medtronic Sigma 303 DR	RA 5545/RV 5076	Prepectoral	VDD 45/120	Persistent intractable hiccups
11	St. Jude Identity Adx DR 5380	RA 1388T/RV 1236T	Prepectoral	VVI 30	Memory impairment
12	Medtronic Kappa 701 DR	RA 1388T/RV 1388T	Prepectoral	DDD 50/140	Recurrent left-sided weakness
13	Medtronic Kappa 701 DR	RA 5568/RV 5024	Prepectoral	DDDR 60–120	Asymmetric sensorineural hearing loss
14	St. Jude Identity DR 5370	RA 1342T/RV 1346T	Prepectoral	DDD 60/120	Acoustic neuroma
15	Medtronic Kappa 401	RA 5568/RV 5068	Prepectoral	DDD 60/130	Trigeminal postherpetic neuralgia
16	Medtronic Kappa 901	RA 5076/5076 BTN	Prepectoral	DDDR 60–130	Neurobehavorial changes with seizures
17	Medtronic Kappa KDR901	RA 5568/RV 5076	Prepectoral	DDDR 70–130	Deep brain stimulator for tremors
18	Medtronic Sigma 303 DR	RA 5076/RV 4092	Prepectoral	DDDR 55–165	Seizure
19	Medtronic Kappa 901DR	RA 5076/RV 5076 BTN	Prepectoral	DDDR 60–130	Myeloneuropathy
20	St. Jude Affinity DR 5330	RA 1342T/RV 1346T	Prepectoral	DDDR 60–130	Epilepsy
21	St. Jude Zephyr 5826	RA 1688TC/RV 1646T	Prepectoral	DDI 75/120	Cervical myelopathy
22	Medtronic Sensia SEDR01	RA 4076/RV 4076	Prepectoral	DDD 50/150	Cauda equina syndrome
23	St. Jude Entity DR 5326	RA 1388TC/RV 1346T	Prepectoral	DDDR 60–120	Peripheral neuropathy
24	Medtronic Sensia DR	RA 5524M/RV 5068	Prepectoral	DDDR 60–130	Recurrent intracranial bleed
25	Medtronic Kappa 701 DR	RA 5592/RV 5092	Prepectoral	DDDR 60–130	Spastic paraparesis
26	Medtronic Adapta DR	RA 4076/RV 4076	Prepectoral	DDD 60/130	MRSA bacteremia spinal epidural abscesses
27	Medtronic EnPulse E2DR01	RA 4469/RV 5076	Prepectoral	DDD 60/120	Visual deficit and left-sided symptoms
28	Medtronic EnPulse E2DR01	RA 3830/RV 3830	Prepectoral	DDDR 70–130	Peripheral neuropathy, right-sided weakness
29	Medtronic Prodigy SR	RV 6972	Prepectoral	VVI 30	Sensory changes
30	Biotronik Philos II DR	RA Setrox S/RV Setrox S	Prepectoral	DDD 60/120	Brainstem stroke
31	Medtonic EnPulse E2DR01	RA 5076/RV 5076	Prepectoral	DDDR 60–130	Hematemesis and lytic lesions
32	Guidant Contak Renewal H120	RA 4086/RV 4087/LV 4548	Prepectoral	VVIR 65–120	Staphylococcal endocarditis with periaortic abscess

change in position of the pacemaker generator or lead. Otherwise, no other device function abnormalities were noted. No significant clinical adverse events were observed during the MRI examinations, and all patients completed the study.

The occurrence of premature ventricular contractions during scanning was only noted with the single Biotronik device studied in this series (P=0.02). POR appeared to occur more frequently with the Medtronic Kappa devices during MRI (Table 4). This observation was on the borderline of statistical significance (P=0.05). This finding held regardless of whether a synchronous or asynchronous mode of pacing was selected before MRI (P=0.69).

Lead model did not predict any of the observations of abnormal pacemaker function noted in this series, nor did

Table 3 Notable observations of pacemaker function during MRI

Patient	Device/site	Leads	Baseline mode	Scanning mode	Observation	Region scanned
#10	Medtronic Sigma 303 DR	RA 5545/RV 5076	VDD 45/120	VDD 45	Power-on reset	Head
#12	Medtronic Kappa 701 DR	RA 1388T/RV 1388T	DDD 50/140	DOO 100	Power-on reset	Head
#12	Medtronic Kappa 701 DR	RA 1388T/RV 1388T	DDD 50/140	ODO 80	Power-on reset	Head
#13	Medtronic Kappa 701 DR	RA 5568/RV 5024	DDDR 60–120	ODO 80	Power-on reset	Head
#15	Medtronic Kappa 401	RA 5568/RV 5068	DDD 60/130	DOO 95	Power-on reset	Head
#29	Medtronic Prodigy SR	RV 6972	VVI 30	VVI 30	Power-on reset	Head
#5	St Jude Affinity DR	RA 5592/RV 5024	DDDR 60–170	DOO 80	Pacing at magnet rate throughout	Head
#5	St. Jude Affinity DR	RA 5592/RV 5024	DDDR 60–170	DOO 80	Pacing at magnet rate throughout	Head
#32	Guidant Contak Renewal H120	RA 4086/RV 4087/LV 4548	VVIR 65–120	VVI 80	Pacing at magnet rate throughout	Head
#11	St. Jude Identity Adx DR	RA 1388T/RV 1236T	VVI 30	VVI 30	Occasional pacing at magnet rate	Head
#30	Biotronik Philos II DR	RA Setrox S/RV Setrox S	DDD 60/120	DDD 60/120	Occasional PVCs	Head

region scanned. Because only one patient had a left ventricular lead, the effect of this was not analyzed statistically.

3.3 Device function after MRI

No effect on generator voltage was noted in the immediate period after MRI or at 1 month post-MRI. Similarly, no significant effect was noted on lead function as assessed by P wave and R wave detection, measurement pacing threshold, or lead impedance at the time intervals above (Table 5).

3.4 Cardiac muscle enzymes

No patient had an increase in cardiac muscle enzymes observed when these were checked before and 24 h after MRI scanning (mean [SD] creatine kinase-MB, 3.2 [1.7] ng/mL; mean [SD] cardiac troponin I, 0.01 [0.01]ng/mL) (n=22).

4 Discussion

The current study demonstrates the safety of MRI scanning of the head and body in our population of non-pacemaker-dependent patients. Our data add to similar data from other centers. Pacemaker–MRI interactions in this cohort were not infrequent; POR (n=6), magnet-mode pacing (n=4), and frequent premature ventricular contractions (n=1) were all presumed to occur because of this interaction. However, all interactions were transient and reversible and resulted in no adverse consequences for the patient or for device function. We observed some relationships between pacemaker–MRI interactions and specific pacemaker models, but the relatively small numbers of each device model studied advocates caution in the interpretation of these results.

A very important component of the practice approach described in this paper is the collaborative protocol between cardiology and radiology, which ensured optimal patient safety with real-time continuous monitoring, while maintaining the diagnostic quality of the studies performed. Other centers have described the presence of an electrophysiologist and radiologist during the MRI procedure, along with continuous monitoring [13, 22, 23]. This has been incorporated into our current clinical practice with the establishment of a Safety and PM Monitoring Committee, which included representation from the departments of radiology, medical physics, and cardiology and pacemaker nursing staff. We believe that this collaborative clinical model is relevant to most institutions in which radiology and cardiology/electrophysiology are distinct and separate clinical practices.

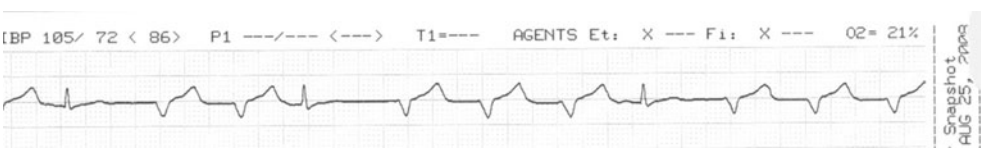

Fig. 2 Example of magnet-mode pacing during magnetic resonance imaging

Table 4 Bivariate analysis of factors affecting device function

	Pacing at magnet rate	"Power-on" reset	PVCs
Region scanned			
Cervical spine	0.21	0.12	0.55
Thoracic spine	0.38	0.27	0.67
Lumbar spine	0.38	0.27	0.67
Pelvis	0.76	0.70	0.88
Device brand	0.02	0.30	0.02[a]
Device model	0.16	0.05[a]	0.94
RA lead model	0.12	0.19	0.92
RV lead model	0.50	0.32	0.98
Synchronous/asynchronous pacing	0.30	0.69	0.10

[a] Statistically significant factor

In the current study, several pacemaker–MRI interactions were observed that have been previously documented by other groups. The most frequent of these was POR in six patients. POR occurs when the pacemaker generator battery voltage drops below a critical preset level determined by the manufacturer because below this voltage, the operation of the device is believed to be unpredictable. Thus, after the onset of POR, all device functions are disabled until the battery voltage exceeds this preset level, known as the *POR trip voltage*. Typically, the device then "resets" all pacing and sensing parameters to nominal settings determined by the manufacturer. Usually, the pacing mode is VVI, with nominal manufacturer-determined pacing rates, amplitudes, pulse width settings, sensitivities, and refractory periods. Occasionally, these parameter changes may be permanent. In pacemaker-dependent patients, POR can have potentially disastrous consequences if MRI interference inhibits VVI pacing, as was reported recently in a pacemaker-dependent patient in whom asystole developed for this reason. A review of 115 patients with Medtronic implants by Sommer et al. [13] demonstrated POR in seven patients' devices (all Sigma and Thera models). However, other reviews of pacemaker and MRI interactions demonstrated no incidence of POR at 1.5 T [22]. Our experience with POR seems similar to that reported recently in a study of pacemakers and ICDs in the magnetic field of a remote magnetic navigation system, in which a preponderance of POR was noted in Medtronic Kappa model pacemakers [25].

Table 5 Changes in battery voltage, sensing, pacing thresholds, and lead impedance before, immediately after, and 1 month after magnetic resonance imaging

	Pre-MRI	Immediately after MRI	1 month after MRI	*P*
Battery voltage	2.76±0.08	2.75±0.09	2.80±0.14	0.44
P wave (mV)	2.77±1.44	3.20±1.87	3.01±1.43	0.52
R wave (mV)	10.72±5.35	9.73±4.51	9.39±4.83	0.52
RA threshold (V)	0.70±0.42	0.74±0.41	0.75±0.27	0.88
RV threshold (V)	0.75±0.36	0.78±0.37	0.73±0.30	0.86
RA impedance	545±106	553±109	587±90	0.35
RV impedance	579±179	578±178	582±202	0.99

The next most common form of pacemaker–MRI interaction seen was asynchronous pacing at the magnet rate in four patients, resulting from reed-switch activation in the MRI magnetic field. This incidence is somewhat lower than the experience of Sommer et al. [13] (26 of 47 patients) and Nazarian (10 of 55 devices, including ICDs) [22]. Furthermore, some devices may revert to magnet-mode pacing even after switching them to an asynchronous mode, as was our experience. In many cases in which programming is set to asynchronous for the scan, reversion to magnet-mode pacing simply results in a change in rate. However, in patients with higher heart rates in which the device is set to sense-only mode, the change in setting to asynchronous pacing could be clinically significant. Some experts in the field have suggested switching the magnet mode off when possible and then programming the device as desired [26]. Furthermore, it has been suggested that it would be ideal for electrocardiographic gating during MRI to take place only during the ventricular refractory period, but that, in practical terms, this would most likely increase the duration of the scan unacceptably.

In our study, we saw no evidence of device malfunction immediately after MRI or at the time of repeat testing 1 month after scanning. Furthermore, in contrast to the findings of previous authors, we noted no abnormality in cardiac enzymes after MRI [13]. These findings agree with the collective experience to date that scanning at 1.5 T and higher has been generally safe, with only minimal threshold changes [12, 13] and, in one study, a minor change in cardiac troponin levels [13]. In other studies, no significant changes in pacing thresholds, cardiac enzyme levels, or device function were noted [22, 27]. This is in accordance with previous work which has demonstrated the absence of significant heating at the lead tips in animal and *ex vivo* studies [26, 28, 29]. These encouraging collective clinical and laboratory findings have led to a proposed protocol for MRI in patients with CIEDs [22] and safety recommendations [7, 30].

In Europe, MRI-conditional pacemakers already have a CE mark and are thus approved for implantation. In the USA, FDA approval is awaited for these devices but is likely to occur in the next year or so. However, even if MRI-conditional pacing systems achieve widespread availability, patients with existing pacing systems will continue to need MRI for some time. Furthermore, with the exception of new implants (i.e., MRI-conditional pulse

generator and leads, after FDA approval), simply upgrading patients to MRI-safe generators and continued use of the existing lead(s) or abandoning and capping the existing lead (s) will not resolve concerns related to MRI. Such concerns would be alleviated only if all existing hardware were removed, which is associated with additional morbidity and mortality related to lead extraction.

5 Conclusions

The current study reports the findings of a collaborative approach to MRI in patients with implanted permanent pacemakers at a single institution. We demonstrate that in non-pacemaker-dependent patients, with a closely monitored MRI environment, patient safety is achieved. In devices that are available currently, some pacemaker–MRI interactions were observed but did not result in any clinically significant adverse events or device dysfunction. Despite pending approval of MRI-conditional devices, the current study provides a clinical model for patients with pacemakers *in situ* who require MRI examination.

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