

Magnetic Resonance Imaging for Patients with Permanent Pacemakers: Initial Clinical Experience

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Abstract

Background: Magnetic resonance imaging is a diagnostic tool of growing importance. Since its introduction, certain medical implants, e.g., pacemakers, were considered an absolute contraindication, mainly due to the presence of ferromagnetic components and the potential for electromagnetic interference. Patients with such implants were therefore prevented from entering MRI systems and not studied by this modality. These devices are now smaller and have improved electromechanical interference protection. Recently *in vitro* and *in vivo* data showed that these devices may be scanned safely by MRI.

Objectives: To report our initial experience with three patients with pacemakers who underwent cerebral MRI studies.

Methods: The study included patients with clear clinical indications for MRI examination and who had implanted devices shown to be safe by *in vitro* and *in vivo* animal testing. In each patient the pacemaker was programmed to pacing-off. During the scan, continuous electrocardiographic telemetry, breathing rate, pulse oximetry and symptoms were monitored. Specific absorption rate was limited to 4.0 W/kg for all sequences. Device parameters were assessed before, immediately after MRI, and 1 week later.

Results: None of the patients was pacemaker dependent. During the MRI study, no device movement was felt by the patients and no episodes of inappropriate inhibition or rapid activation of pacing were observed. At device interrogation there were no significant differences in device parameters pre-, post-, and 1 week after MRI. Image quality was unremarkable in all imaging sequences used and was not influenced by the presence of the pacemaker.

Conclusion: Given appropriate precautions, MRI can be safely performed in patients with a selected permanent pacemaker. This may have significant implications for current MRI contraindications.

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Magnetic resonance imaging has the unique ability to discriminate soft tissue without using contrast material and radiation. MRI is now the image modality most frequently used in several disciplines in medicine, and is the first modality choice for imaging many of the pathologies in the brain, spine, musculo-skeletal system, head and neck, and other soft tissue structures [1,2].

Over 2,000,000 patients in the United States had a permanent pacemaker as of the year 2002 [3], and one year later an additional 3,000,000 patients met the criteria for implantable

cardioverter defibrillator implantation [4]. Due to the advancing age of the population and expanding indications for pacing and ICD implantation, the number of patients with implantable cardiac devices will continue to increase [5-9].

The presence of a permanent pacemaker or ICD is currently considered a contraindication to MRI [10,11]. Traditional concerns about MRI of patients with implantable cardiac devices include: possible movement of the device [12], programming changes, and induced lead currents leading to heating, cell injury and cardiac stimulation [13]. Strong electromagnetic fields may theoretically also cause asynchronous pacing, activate anti-tachyarrhythmia therapies, or inhibit a pacemaker impulse [14]. Selected modern permanent pacemaker and ICD systems have less magnetic material and superior electromagnetic interference protection. Recent *in vivo* and *in vitro* studies found that selected modern permanent pacemaker and ICD systems have an improved safety profile for MRI [15-18] and may be scanned safely by MRI.

We report here our initial experience in scanning patients with pacemakers who were referred for clinically indicated MRI examination.

Methods

Patient selection

Candidates with a clinical indication for MRI and no acceptable imaging alternative and an implantable cardiac device were considered. They had no contraindication for MRI study other than their pacemakers. Patients were enrolled in the study if the pacemaker was found to be safe by previous *in vitro* and *in vivo* animal testing [18]. Patients with a device implanted less than 6 weeks prior to MRI and those with non-transvenous (epicardial) or abandoned leads were excluded. No restrictions were imposed on different transvenous lead models. Pacemaker-dependent patients were excluded. All participants gave written informed consent after demonstrating an understanding of the potential risks, such as irreversible damage to the device, thermal injury, and device malfunction leading to arrhythmia.

Device interrogation and programming

The devices were interrogated prior to and immediately after MRI. A follow-up device interrogation was performed 1 week later during a routine follow-up visit in the electrophysiology

ICD = implantable cardioverter defibrillator

device clinic. Device parameters including battery voltage, lead capture thresholds, lead impedances and sensing signal amplitudes were recorded at each interrogation.

MRI scan

Standard precautions were taken and the patients were equipped with ear protection. After baseline interrogation and before the MRI scan, pacemakers were programmed to pacing-off, OVO or ODO. A radiologist and a cardiologist were present during all scans. During the scan, continuous ECG telemetry, breathing rate, pulse oximetry and symptoms were monitored. After completion of the MRI, devices were reprogrammed to the original settings.

MRI

Imaging was performed using a 1.5 Tesla scanner (Signa, General Electric Healthcare Technologies, Waukesha, WI, USA). MRI studies were performed according to the clinical indications using the standard protocol for the examined region of interest. The specific absorption rate was limited to 4.0 W/kg for all sequences.

Statistical analysis

Continuous variables are summarized as mean and standard deviation, and discrete variables are summarized as absolute numbers and percentages. Acute and chronic lead parameters were compared using the paired student's *t*-test. $P < 0.05$ was considered significant.

Results

Patients

Three MRI examinations in patients with pacemakers were performed during the period January–April 2005. All had brain MRI studies. The clinical characteristics of the patients are summarized in Table 1. None was pacemaker dependent. The maximal SAR was 3.7 W/kg.

Safety and device function

No symptoms consistent with device movement, torque or heating were reported during MRI examinations. All devices were functioning appropriately after MRI and no changes in device programming were observed. Comparison of device interrogation results obtained prior to and immediately after MRI revealed no significant individual or mean changes in acute or chronic battery voltage, lead thresholds, lead impedances or sensing signal amplitudes.

Comparison of device interrogation results obtained prior to MRI and at 1 week follow-up revealed no significant individual or mean changes in acute or chronic battery voltage, lead thresholds, lead impedances or sensing signal amplitudes [Table 2].

Image quality

Image quality was not affected when the pacemaker was located outside the field of view. Images obtained in all were of stan-

Table 1. Patients' characteristics

Patient no.	Age (yrs)	Gender	Device	Leads	Indication for pacemaker	Time from pacemaker implant to MRI scan
1	56	M	Medtronic Sigma 303DR	A-Med. 5592 V- Biotronic APOX60BP	Symptomatic bradycardia	9 months
2	70	M	St Jude Verity SR 5156	V- St Jude 1646T (58 cm)	Hypertrophic cardiomyopathy	3 months
3	59	M	Medtronic Prodigy D 7865	A- Med RA 4523 V- Med RV 4023	Syncope with documented asystole	25 months

Table 2. Comparison of acute and chronic device parameters to baseline values prior to MRI*

	Acute mean difference	<i>P</i>	1 week mean difference	<i>P</i>
Atrial capture (V)	+0.07 ± 0.15	0.44	0.07 ± 0.87	0.97
Ventricular capture (V)	+0.08 ± 0.12	0.70	+0.07 ± 0.25	0.45
Atrial lead impedance (Ω)	+1.1 ± 9.6	0.79	-9.7 ± 29.7	0.31
Ventricular lead impedance (Ω)	+2.1 ± 12.8	0.31	-12.5 ± 26.4	0.56
R wave amplitude (mV)	+0.005 ± 1.1	0.88	-0.11 ± 0.78	0.70
Battery voltage (V)	-0.005 ± 0.02	0.21	-0.06 ± 0.18	0.18

* Values are reported as mean difference between acute or chronic and baseline parameter ± standard deviation.

dard quality. Diagnostic clinical questions were answered in all cases.

Discussion

Due to its superior spatial and tissue contrast resolution, multi-planar imaging capability and lack of ionizing radiation, MRI is an invaluable clinical tool and has become the imaging modality of choice in many clinical situations. Unfortunately, MRI is currently unavailable for an increasing proportion of the population due to the presence of permanent pacemaker and ICD systems.

In this study no adverse effects on pacemaker function were observed in the three patients undergoing MRI scan. MRI was performed using a protocol that incorporates device selection based on previous *in vitro* and *in vivo* animal testing, device programming to minimize inappropriate activation, and limitation of the SAR of MRI sequences. There is now increasing preliminary evidence that MRI can indeed be safely performed at 0.5 [15–17] and at 1.5 Tesla [3] in patients who have a modern permanent pacemaker. However, these studies reported only acute changes in battery voltage and lead thresholds, but no follow-up data. Of note, there are reports of device malfunction with the use of particular models [19–21], usually an older generation technology.

SAR = specific absorption rate

Safety MRI protocol

We used a protocol that consists of a list of devices previously tested under worst-case scenario MRI conditions (SAR up to 3.9 W/kg) [18]. It precludes patients with leads that are more prone to movement, for example, patients who received their implant less than 6 weeks previously. This interval allows for healing of the pocket where the device is implanted and fixation of leads. The protocol also precludes device leads that are prone to heating due to lack of cooling by blood flow in the case of non-transvenous epicardial leads, or not being connected to a generator that acts as a power sink in the case of abandoned leads. Given previous findings during *in vitro* and *in vivo* animal studies, no restrictions were placed on different transvenous lead models or conformations such as electrically incomplete (intact insulation) lead loops [18]. To reduce the risk of asynchronous pacing or rapid pacing, the protocol indicates device programming to the off-pacing mode. Finally, to reduce the risk of thermal injury and changes in lead threshold and impedance, SAR was limited to less than 4.0 W/kg for all sequences. With this protocol, all MRI examinations were performed without adverse events.

ECG telemetry

No MRI-pacing interactions were observed. One of the feared complications of MRI is the potential for rapid pacing [22,23]. The lack of any rapid pacing observations in our study and that of Martin et al. [3] is consistent with the assumption that the frequency of induced lead voltages from the radio frequency field is too high for direct cardiac stimulation [24].

Device and lead parameters

Previous MRI case reports and series have noted temporary acute drops in battery voltage that are not unexpected due to capacitance by the leads or telemetry coils as a result of a brief power interruption following electromagnetic interference [17,20]. More worrisome, however, are reports of changes in acute lead thresholds after MRI in patients with permanent pacemakers [3]. Such threshold changes have been attributed to heating at the lead-tissue interface [24]. In the present study there were no significant changes in acute or chronic device or lead parameters, or in the battery. This lack of any change in device parameters may be related to avoidance of non-transvenous epicardial leads, limitation of SAR and/or improved electromagnetic interference protection in the modern devices approved for the study.

MRI artifacts

The presence of ferromagnetic materials can cause variations in the surrounding magnetic field, resulting in image distortion, signal voids or bright areas, and poor fat suppression [25]. We scanned about 20 cm from the pacemaker – and no image distortion was noted.

Clinical implications

The patient population of this study was selected according to the premise of who would benefit most from MRI, given the

risks of imaging in the setting of a permanent pacemaker or ICD. Even in this small series of patients, the findings yielded by MRI highlight its importance as an invaluable diagnostic modality. MRI had an important role in the treatment decision making for each of our patients.

Extrapolation from the proportion of important diagnoses made in this small sample to the large and growing population of patients with permanent pacemaker and ICD systems underscores the importance of developing a safe methodology for MRI in such patients. Given the public health importance of this issue, it is crucial that device manufacturers design and test permanent pacemaker and ICD systems so that all such marketed devices are MRI compatible.

Limitations

Owing to strict entry criteria and the absolute clinical need for MRI and rigorous selection of safe device systems, the sample size is small. It is possible that with a larger sample size changes in device parameters or function not identified in this study would be observed.

Conclusions

Using a protocol based on device selection and programming, and limitation of SAR of sequences, MRI can be safely performed in patients with certain permanent pacemaker systems. This ability may significantly impact on clinical decision making in appropriate patients.

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