Safety and Outcomes of Magnetic Resonance Imaging in Patients with Abandoned Pacemaker and Defibrillator Leads

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Introduction: *Abandoned cardiovascular implantable electronic device (CIED) leads remain a contraindication to magnetic resonance imaging (MRI) studies, largely due to in vitro data showing endocardial heating secondary to the radiofrequency field. We tested the hypothesis that abandoned CIED leads do not pose an increased risk of clinical harm for patients undergoing MRI.*

Methods: *This single-center retrospective study examined the outcomes of patients who had device generators removed before MRI, rendering the device leads abandoned. Information was gathered through chart review. Data collected included lead model, pacing threshold before MRI, anatomic region examined, threshold data after generator reimplantation, and clinical patient outcome.*

Results: *Patients (n = 19, 11 men and eight women) ranged in age from 19 to 85 at the time of MRI. There was a mean of 1.63 abandoned leads at the time of imaging; none of the leads were MRI conditional. Of the three implantable cardioverter defibrillator (ICD) leads, two of three were dual coil. Most (31/35) of the scans performed were of the central nervous system, including head and spinal imaging. There were no adverse events associated with MRI in any of these patients with abandoned leads within 7 days of the scan. No lead malfunctions or clinically significant change in pacing thresholds were noted with generator reimplantation.*

Conclusion: *The use of MRI in patients with abandoned cardiac device leads appears feasible when performed under careful monitoring, with no adverse events, although the experience is small. MRI did not affect the function of leads that were subsequently reconnected to a cardiac device. (PACE 2014; 37:1284–1290)*

magnetic resonance imaging, cardiac pacemaker, implantable cardioverter defibrillator

Introduction

Cardiovascular implantable electronic devices (CIEDs) are widely prevalent, and their use is likely to expand with the continued aging of the U.S. population, broader indications for use, and device innovations.[1] Magnetic resonance imaging (MRI) is now the modality of choice for many neurologic, cardiac, and musculoskeletal disorders.[2] As a result of these trends, it is estimated that 50–75% of patients with a CIED will require an MRI during their lifetime.[3]

Until recently, MRI imaging was contraindicated in patients with a CIED. The effects of MRI technology on CIEDs includes the potential to inhibit pacing, induce unstable tachyarrhythmias, provoke inappropriate defibrillation, damage the generator, and alter pacing or sensing thresholds.[4–7] Fortunately, in patients who are not pacemaker dependent, it now appears that tailoring of the MRI imaging protocol, device reprogramming during scanning, and careful patient monitoring allow imaging to be completed safely in most cases.[8–10] So called "MRI-conditional" devices and leads, designed to permit safe MRI under specified imaging specifications, will increasingly become available, and further enhance the flexibility to perform MR examinations in CIED recipients.[11,12]

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Abandoned leads are leads that are disconnected from the CIED generator. They are typically abandoned due to malfunction or device upgrade. They may pose a particularly elevated risk during MRI scanning due to their susceptibility to induced currents, resulting in tissue heating and arrhythmias. Previous clinical studies demonstrating safety of MRI in patients with CIEDs excluded patients with abandoned leads.[9,10] Extraction of abandoned leads may introduce significant procedural risk or may not be feasible. Thus many are left in place, leaving a subset of patients with CIEDs ineligible for MRI scans by current protocol.

The application of radiofrequency energy has the potential to cause myocardial heating at the lead tip, which explains the concern for potential threshold alteration in leads that are in active use.[13,14] For abandoned leads, the magnitude of tip heating is potentially more substantial, which could theoretically produce serious arrhythmias or myocardial scar.[14] However, this concern reflects *in vitro* modeling and theoretical considerations, and has not been validated *in vivo*. In order to determine if this theory was observable in a clinical setting, we performed a retrospective analysis to view outcomes of patients who had previously undergone MRI scan with abandoned device leads.

Methods

In 2008, Mayo Clinic Heart Rhythm Services and the Department of Radiology service introduced a joint clinical protocol to permit MRI scanning of patients with CIEDs who were not pacemaker dependent and had a medically indicated need for MRI of the central nervous system or extremities.[15] Before that date, these patients underwent pulse generator removal for the MRI scan, followed thereafter by reimplantation if clinically appropriate. At that time, it was presumed that the scan could be completed more safely if the lead circuit was interrupted by generator removal, which also prevented damage to the electrical components of the device. Patients selected for this were nonpacemaker dependent, and underwent scanning with specific absorption rate (SAR) limited to 1.5 W/kg. We identified patients managed in this fashion and reviewed the consequences to device function and patient safety. Insulating caps were placed on retained leads before MRI during generator explantation. If it was believed there was a continued indication for the cardiac device, the pulse generator was reimplanted following the study. One patient underwent scanning off protocol for one MRI as it was not recognized that an abandoned lead was present (patient 10, scan three). All others were scanned as part of a clinical protocol that entailed Advanced Cardiovascular Life Support (ACLS) device nurses, heart rhythm physician input, radiologist input, and radiology physicist input.

We performed a single center, retrospective analysis to assess clinical outcomes in patients with abandoned leads who underwent MRI scans. We defined abandoned leads as those not attached to a pulse generator. All patients who were recorded to have device explantation in between 1990 and 2013 at our institution, including 4,087 pacemaker explantations and 2,782 implantable cardioverter defibrillator (ICD) explantations, were cross-referenced with MRI scans. This assessment yielded 1,239 unique scans. The dates of the explantation procedure and MRI scan were obtained and analyzed, seeking those studies that took place following generator removal, with abandoned leads in place. We identified 16 pacemaker and three ICD patients for analysis who met these criteria.

All MRIs were performed using a 1.5T magnet. Data on SAR limitations was available for seven patients undergoing a total of nine studies. Anatomic regions scanned by MRI and patient outcomes within 7 days of the scan were recorded. Generator and lead model numbers, number of abandoned leads at the time of scan, and number of ICD coils were recorded. If pulse generators were reimplanted, lead threshold data before and after MRI were recorded, and for patients followed at Mayo Clinic long-term device function was also recorded.

Results

A total of 19 patients, including 11 men and eight women, underwent 35 MRI with abandoned cardiac device leads. Generator explantations to permit MRI imaging with retained leads took place between 1999 and 2010, with a majority occurring between 2000 and 2006. Fifteen of the 35 MRI studies imaged the head, including one magnetic resonance angiography of the head and neck, 16 imaged the spinal cord, and four scanned the musculoskeletal system (pelvis, left wrist and hand, and knees; Table I). For studies where SAR data was available, the SAR was never greater than 1.5 W/kg. Additionally, of these studies, six were done with a transmit-receive (TR) head coil (that focuses the RF energy on the head), and two were completed using body coil transmission.

No complications occurred during the scan and no study required early termination. Within 7 days following the MRI examination, there were no observed adverse clinical events. Of the nine patients who received long-term follow-up with the Heart Rhythm Services (average 82 months

Table I.

Patient and MRI Characteristics in Patients with Abandoned Leads

Patient Number	Age at Time of Study/Studies	Patient Gender	Anatomic Area of Study (Numbered in Chronologic Order)	Coil used if Known with Maximum SAR (with Scan Number)
1	62	M	MRI head, with and without contrast	TR head coil, maximum SAR = 0.04356 W/kg
2	40	M	MRI head, with and without contrast	TR head coil .0984 W/kg
3	38	F	MRI head, with and without contrast	TR head coil .0512 W/kg
4	85	F	MRI/MRA thoracic and lumbar spine, with and without contrast	
5	70	M	MRI cervical and thoracic spine, with and without contrast	
6	69	M	1. MRI cervical, thoracic, and lumbar spine with MRA spinal canal, 2. MRI/MRA head with and without contrast	
7	52	M	MRI head, with and without contrast	TR head coil .0466 W/kg
8	73, 74, 75	F	1. MRI cervical spine with and without contrast, 2. MRI cervical and lumbar spine with and without contrast, 3. MRI cervical spine with and without contrast	
9	71	M	MRI head with and without contrast	TR head coil .0488 W/kg
10	71, 72, 73, 75, 77	M	1. MRI cervical and thoracic spine with and without contrast, 2–5. MRI thoracic spine with and without contrast	
11	65, 67	M	1. MRI head with and without contrast, 2. MRI pelvis with contrast	
12	35	F	MRI head with and without contrast	
13	62	M	MRI head with and without contrast	
14	64	F	MRI right wrist and hand with and without contrast	Body coil transmit, arm 1.294 W/kg
15	27	F	MRI Head with and without contrast	
16	41	F	1. MRI head with and without contrast, 2. MRI lumbar spine with and without contrast, 3. MRA head and neck with and without contrast	1. TR head coil .058 W/kg, 2. Body coil transmit 1.294 W/kg, 3. Limit of 1.5 W/kg observed
17	66	M	1. MRI head with and without contrast; 2. MRI cervical, thoracic, and lumbar spine with and without contrast	
18	19	M	1. MRI head with and without contrast; 2. MRI cervical, thoracic and lumbar spine with and without contrast; 3. MRI right knee without contrast; 4. MRI left knee without contrast; 5. MRI cervical, thoracic, and lumbar spine with and without contrast	
19	67	F	1. MRI head with and without contrast; 2. MRI cervical, thoracic, and lumbar spine with and without contrast	

MRA = magnetic resonance angiography; MRI = magnetic resonance imaging; SAR = specific absorption rate; TR = transmit-receive.

± 39 months after scan), no negative sequelae were observed that could be attributed to MRI in the presence of abandoned device leads.

There were an average of 1.63 ± 0.49 abandoned leads per MRI study, none of which were MRI conditional. Two of three ICD leads were dual coil, the other single coil (Table II).

Abandoned leads were reconnected to the device in 12 of 19 patients; all ICD patients underwent reimplantation. Voltage and pulse width thresholds before generator removal and following the MRI scan and generator reimplantation were available for 10 patients (Table III). The largest discrepancy pre- and postscan was a ventricular lead in which the threshold went from 1.9 volts at 0.5-ms prescan to 2.6 volts at 0.5-ms postscan. One of the 12 patients had what was described as "normal pacing thresholds" following reimplantation, and another did not have an assessment of thresholds before device removal. The latter patient had a clinically acceptable threshold following reimplantation. In all patients in whom leads remained in use, no clinically significant alteration in pacing or sensing threshold was reported. Additionally, five patients with reimplanted devices had long-term follow-up available, all with stable thresholds several years following MRI (Table III).

Discussion

In this study, we evaluated the safety of MRI imaging in patients with abandoned cardiac device leads and found no significant complications or adverse events. In patients who had these chronic device leads reused, there was no clinically significant change in function.

Potential complications of MRI in patients with CIEDs include structural damage to or functional impairment of pulse generators or leads, and damage to surrounding tissue leading to arrhythmia. The mechanism for these changes is introduced by the static magnetic field, gradient magnetic field, and modulated radiofrequency field (RF) of the magnet.[4–7] In current practice, these risks have been mitigated by reducing the amount of ferromagnetic material within newly manufactured devices, close monitoring of patients during MRI, and modulation of the RF to reduce the SAR in patients during scans.[9]

In animal studies, myocardial heating of up to 20°C has been associated with MRI when leads have been connected to the generator. However, there were no shown histologic changes in the myocardium noted in these experiments.[13] In addition, a SAR of 3.8 W/kg was used which is much higher than what current protocol dictates. *In vitro* studies in leads of 40–60-cm length have showed greater heating with abandoned leads than with leads attached to generators at a constant RF signal.[14] Even for the newest generation of devices, RF field-mediated heating of the myocardial tissue by lead tips remain a substantial risk.[14] Currently, there is no literature reporting *in vivo* or clinical data on the potential complications of abandoned leads in MRI. Although there are many theoretical risks associated with performing MRI in patients with abandoned CIED leads, our limited experience did not demonstrate any significant adverse consequences.

MRI was previously contraindicated in patients with pacemakers. In recent years, protocols have been put in place for patients with CIEDs to undergo MRI demonstrating patient safety, leading to increasing use of MRI in select patients that are not pacemaker dependent.[9] These protocols involved careful monitoring and routinely exclude patients with abandoned leads. Although our experience is small, the absence of adverse events is encouraging. Most importantly, there were no acute events that took place during these studies requiring termination of the exam or acute intervention, or resulting in adverse clinical outcomes. Specifically, there was no postimaging pain or new arrhythmia. We did observe an increase in pacing threshold in patients who had abandoned leads reused; however, they were not significant enough to warrant lead replacement or render them nonfunctional. Additionally, in patients who continued to be followed at Mayo Clinic, the chronic leads that were in place at the time of MRI continued to function with clinically acceptable thresholds. Our data could support prospective protocols evaluating the safety of MRI examinations in patients with abandoned leads.

Several previous studies have demonstrated safety of MRI scanning in patients with pacemakers and ICDs that are not MRI conditional when imaging is performed under monitored conditions.[16] Our findings extend these previous findings to include patients with abandoned device leads, which as far as we can determine have never been analyzed *in vivo* in humans. Since most of the exams we have analyzed took place in the early part of the last decade, patients did not have devices specifically designed to undergo MRI, and there were no MRI conditional leads. Although previous work has demonstrated additional lead tip heating for abandoned leads versus leads attached to a generator in an *in vitro* setting and changes in impedance in an animal model, we did not see significant *in vivo* clinical consequences of lead tip heating.[13,14] We believe our study provides a basis for future prospective evaluation of MRI scanning protocols in patients with abandoned CIED leads, as we

Table II.

Device and Lead Characteristics

Patient Number	Generator Model	Atrial Lead	Ventricular Lead	Type of Device
1	Pacesetter Synchrony 2022 T	Medtronic 4058M, bipolar, active fixation	Medtronic, CapSure 4004M, bipolar, tines fixation	Pacemaker
2	Intermedics Cosmos 283–03	Medtronic 4057M, unipolar, active fixation	Medtronic 4057, unipolar, active fixation	Pacemaker
3	Medtronic Kappa 700	Medtronic 5076, CapSure fix novus, bipolar, active fixation	Medtronic 5076, CapSure fix novus, bipolar, active fixation	Pacemaker
4	Kappa KSR 901	Pacesetter 1222T, bipolar, J + tines fixation	AAI system, no ventricular lead	Pacemaker
5	Vitatron Topaz II model T0520ECUS	VVI system, no atrial lead	Vitatron PIROUET + IMU 49B, bipolar, active fixation	Pacemaker
6	Pacesetter 2360 L	Pacesetter 1388T, bipolar, active fixation	Pacesetter 1388T, bipolar, active fixation	Pacemaker
7	St. Jude Medical Affinity SR 5130	Pacesetter 1188T, bipolar, active fixation	AAIR system, no ventricular lead	Pacemaker
8	Medtronic Minix ST8330	VVI system, No atrial lead	Medtronic CapSure SP 5024M, bipolar, tines fixation	Pacemaker
9	Medtronic Kappa 700	Medtronic CapSure SP novus 4592, bipolar, J + tines	Medtronic CapSure SP novus 4092, bipolar, tines fixation	Pacemaker
10	Medtronic Kappa KSR706	No atrial lead	Pacesetter 1015M, unipolar, small fins	Pacemaker
11	Pacesetter Synchrony II model 2022	Oscor ZY-52-PJBV, bipolar, J + active fixation	Pacesetter 1226T, bipolar, tines fixation	Pacemaker
12	Medtronic Kappa KDR 901	Medtronic 4058, bipolar, active fixation	Medtronic CapSure SP, 5024, bipolar, tines fixation	Pacemaker
13	Medtronic Kappa KDR 701	Medtronic CapSure SP 4524, bipolar, J + tines fixation	Medtronic CapSure SP 4024, bipolar, tines fixation	Pacemaker
14	Medtronic EnRhythm P1501 DR	Medtronic CapSure fix novus 5076, bipolar, active fixation	Medtronic CapSure fix novus 5076, bipolar, active fixation	Pacemaker
15	Medtronic 7960	Medtronic CapSure SP 4524, bipolar, J + tines fixation	Medtronic CapSure Z 5034, bipolar, tined	Pacemaker
16	Medtronic Kappa KDR701	Medtronic CapSure SP 5524, bipolar, J + tines	Medtronic CapSure SP 5024, bipolar, tines fixation	Pacemaker
17	Medtronic Gem III DR 7275 ICD	Medtronic CapSure fix novus 5076, bipolar, active fixation	Medtronic Sprint, 6943, tripolar, endocardial, active fixation	ICD: Right ventricular coil
18	St. Jude Medical Atlas VR V-199	None	Medtronic 6947 Sprint Quattro secure, quadripolar active fixation	ICD: Superior vena cava and right ventricular coils
19	CPI 1831	Medtronic CapSure SP 5524M, bipolar, J + tines fixation	CPI Endotach endurance RX 0145, tripolar, tines fixation	ICD: Superior vena cava and right ventricular coils

ICD = implantable cardioverter-defibrillator.

Table III.

Threshold, Impedance, and Follow-Up Characteristics

Patient number	Prescan lead threshold (ms/V) and impedance (ohms)	Postscan lead threshold (ms/V) and impedance (ohms)	Long-term follow-up capture threshold (ms/V)
1	Atrial (A) – 0.6 /1.5, ventricular (V) – 0.4 /1.5, A – 435, V – 599	A – 0.5/1.0, V – 0.5/1.1, A – 569, V – 595	7 years postscan, A – 0.4/1.2, V – 0.6/1.1, 137 months postscan, A – 0.8/1.4 V – 0.6/1.1
2	A – 0.6/0.4, V – 0.6/0.8, A – 360, V – 420, 11 years before MRI	A – 0.5/1.4, V – 0.5/1.5, A – 531, V – 674	119 month follow-up, A – 0.4/1.25, V – 0.4/1.25
3	n/a	n/a	Abandoned leads not reused, but follow-up with continued 129 months postscan
4	A – 0.5/0.7, A – 538	A – 0.5/0.9, A – 463	25 month follow-up, A – 0.4/0.75
5	V – 0.5/1.9, V – 850	V – 0.5/2.6, V – 657	n/a
6	A – 0.5/0.6, V – 0.5/1.3, A – 346, V – 340	Postscan – "normal pacing"	n/a
7	A – 0.5/0.8, A – 530	A – 0.5./9, A – 619	n/a
10	V – 0.5/0.9, V – 475	V – 0.5/0.9, V – 425	3-month follow-up, V – 0.4/1.0, generator not reimplanted following second MRI. EP follow 42 months following initial scan
11	n/a	n/a	EP follow-up continued 86 months following initial scan
13	A – 0.4 /1.5, V – 0.4/1.25, A – 693, V – 275	A – 0.5 /0.5, V – 0.5/1.3, A – 571, V – 268	n/a
14	A – 0.5/0.4, V – 0.5/0.5, A – 530, V – 619	A – 0.2/1, V – 0.3/1, A – 418, V – 560	71-month follow-up A – 0.4/0.75, V – 0.5/0.375
17	A – not tested, pacemaker set on VVI, V – 0.5/1.6, V – 729	A – n/a, V – 0.5/1.5, V – 714	N/A
18	V 1st – 0.5/1.2, 2nd – 0.5/1.3, 1st – 447, 2nd – 440	V 1st – 0.5/1.4, 2nd – 0.5/1.3, 1st – 458, 2nd – 448	65-month follow-up V – 0.5/1.3
19	A – 0.5/0.4, V – 0.5/0.4, A – 470 F V – 643	A – 0.5/0.4, V – 0.5/0.8, A – 444, V – 670	69-month follow-up with no threshold testing. Patient expired 70 months following initial MRI due to complications of ependymoma

EP = electrophysiology; MRI = magnetic resonance imaging.

did not experience any adverse events in our experience. Our ability to demonstrate the pacing thresholds of the leads when connected to a CIED generator before and after MRI helps advance our hypothesis that no significant endocardial damage took place during these exams.

With increased prevalence of CIEDs and expanding indications for MRI studies, clinical situations are likely to arise where removal of abandoned leads is less practical or a higher risk than proceeding with an MRI. Although our experience is small, the data support the feasibility and safety of MRI scanning in patients with abandoned CIED leads. Based on the patients we have evaluated, we would not empirically exclude any patient from MRI with a strong clinical indication on the basis of an abandoned lead. Systematic, multicenter, prospective protocols should be performed to evaluate the safety of MRI scans in patients with abandoned CIED leads. This could most practically be accomplished in previously established registries. Our results are best interpreted in light of the limitations of the study design. Multiple different lead

models were tested with potentially different MRI characteristics and grouped together for this report.

Limitations. The complexity of lead-MRI interactions has been previously described by Mattei et al.[17] The small number of patients and multiple lead models limits the generalizability of our results. While SAR values were held to 1.5 W/kg, the actual SAR data were not available for analysis in a majority of the studies. Additionally, only 1.5T magnets were used; these findings may not apply with stronger magnets. Our study is also limited by the retrospective nature of data retrieval and the loss of patients to follow-up once the issue precipitating the MRI scan was resolved. In addition, all of the patients studied lacked a generator with functioning leads in place in tandem with an abandoned lead. Theoretically, the presence of an abandoned lead adjacent to a functioning system during MRI may adversely impact the functioning system.

Conclusion

The use of MRI in patients with abandoned cardiac device leads appears feasible when performed under careful monitoring, although the experience is small. MRI did not significantly affect the function of leads that were subsequently reconnected to a cardiac device.

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