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Magnetic Resonance Imaging in Patients With Cardiac Implantable Electronic Devices With Abandoned Leads

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IMPORTANCE Magnetic resonance imaging (MRI) is the modality of choice for many conditions. Conditional devices and novel protocols for imaging patients with legacy cardiac implantable electronic devices (CIEDs) have increased access to MRI in patients with devices. However, the presence of abandoned leads remains an absolute contraindication.

OBJECTIVE To assess if the performance of an MRI in the presence of an abandoned CIED lead is safe and whether there are deleterious effects on concomitant active CIED leads.

DESIGN, SETTING, AND PARTICIPANTS This cohort study included consecutive CIED recipients undergoing 1.5-T MRI with at least 1 abandoned lead between January 2013 and June 2020. MRI scans were performed at the Hospital of the University of Pennsylvania. No patients were excluded.

EXPOSURES CIEDs were reprogrammed based on patient-specific pacing needs. Electrocardiography telemetry and pulse oximetry were monitored continuously, and live contact with the patient throughout the scan via visual and voice contact was performed if possible. After completion of the MRI, CIED evaluation was repeated and programming returned to baseline or to a clinically appropriate setting.

MAIN OUTCOMES AND MEASURES Variation in pre- and post-MRI capture threshold of 50% or more, ventricular sensing 40% or more, and lead impedance 30% or more, as well as clinical sequelae such as pain and sustained tachyarrhythmia were considered significant. Long-term follow-up lead-related data were analyzed if available.

RESULTS A total of 139 consecutive patients (110 men [79%]) with a mean (SD) age of 65.6 (13.4) years underwent 200 MRIs of various anatomic regions including the thorax. Repeat examinations were common with a maximum of 16 examinations for 1 patient. There was a total of 243 abandoned leads with a mean (SD) of 1.22 (0.45) per patient. The mean (SD) number of active leads was 2.04 (0.78) and 64 patients (46%) were pacemaker dependent. A transmit-receive radiofrequency coil was used in 41 patients (20.5%), all undergoing MRI of the brain. There were no abnormal vital signs or sustained tachyarrhythmias. No changes in battery voltage, power-on reset events, or changes of pacing rate were noted. CIED parameter changes including decreased right atrial sensing in 4 patients and decreased left ventricular R-wave amplitude in 1 patient were transiently noted. One patient with an abandoned subcutaneous array experienced sternal heating that subsided on premature cessation of the study.

CONCLUSIONS AND RELEVANCE The risk of MRI in patients with abandoned CIED leads was low in this large observational study, including patients who underwent examination of the thorax. The growing aggregate of data questions the absolute contraindication for MRI in patients with abandoned CIED leads.

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Invited Commentary

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agnetic resonance imaging (MRI) remains the test of choice for many conditions owing to its safety profile and excellent soft tissue contrast without associated exposure to iodinated contrast or ionizing radiation.¹One estimate is that 50% to 75% of patients with cardiac implantable electronic devices (CIEDs) will have an indication for MRI during their lifetime.² While the development of MRIconditional devices has the potential to enhance access to MRI for patients with such devices, there are a large number of patients with nonconditional or legacy devices. Recent data suggesting safety of scanning patients with these devices³⁻⁵ has led to supportive specialty society guidelines and expert consensus documents, as well as changes in Centers for Medicare & Medicaid Services (CMS) reimbursement policies for MRI in patients with legacy CIED systems.⁶⁻⁸ However, abandoned leads, which are theoretically associated with higher risk to adjacent structures including functional leads due to greater lead tip heating compared with leads attached to a generator,⁹ remain a contraindication to MRI examination in many institutions and are excluded from CMS reimbursement due to a paucity of safety data.

As the population of patients with CIEDs increases, so too does the number of patients with abandoned leads, making accurate risk assessment essential. Recent work has suggested safety of MRI with abandoned leads,^{10,11} but these data are from a single center. Additionally, there is a dearth of data regarding the safety of thoracic examination in these patients, where the theoretical risk for heating and current induction is greatest. We evaluated the safety of MRI examination in patients with abandoned CIED leads.

Methods

The study is a descriptive study of consecutive CIED recipients undergoing a 1.5-T MRI at the Hospital of the University of Pennsylvania. Those with abandoned CIED leads imaged between January 2013 and June 2020 formed the study cohort. Patients provided written consent for the procedure, and possible increased risk was discussed. The study was approved by the institutional review board at the Hospital of the University of Pennsylvania. All available imaging and other records were reviewed prior to the MRI to identify abandoned hardware including a discussion between the ordering health care professional and a radiologist in each case to assess the risks and benefits of MRI compared with alternative imaging modalities or other testing. An external defibrillator with capacity for cardiac pacing and a manufacturer-specific device programming system was maintained in the patient-holding area adjacent to the MRI control room while the patient was in the scanner. Physicians and mid-level health care professionals from radiology and cardiac electrophysiology were identified to oversee the safety of the MRI environment and all CIED-related issues, respectively. Prior to MRI, the CIED was interrogated with evaluation of baseline battery voltage, sensing, pacing thresholds, and lead impedances. Devices were reprogrammed based on patient-specific pacing needs, and tachyarrhythmia detection and therapies were deactivated. At-

Key Points

Question Can patients with abandoned cardiac implantable electronic device (CIED) leads safely undergo magnetic resonance imaging (MRI)?

Findings In this cohort study of 139 patients undergoing 200 MRIs of various anatomic regions including the thorax, no serious adverse events were noted. CIED parameter changes included transient decrease in lead sensing in 5 patients and subjective sternal heating in 1 patient with an abandoned subcutaneous array and sternal wires.

Meaning The findings of this study suggest that the presence of abandoned CIED leads should not necessarily preclude MRI, regardless of the anatomic region being studied.

tempts were made during reprogramming to avoid potential competition from an underlying rhythm and to minimize the risk of a pacing-mediated arrhythmia. Patients who were permanent pacemaker (PPM) dependent, defined as no significant intrinsic rhythm above 40 beats per minute, were reprogrammed to an asynchronous mode. Patients who were not PPM dependent were programmed to either a nontracking mode, programmed to an asynchronous mode, or pacing was turned off. Manufacturer-specific MRI conditional device programming was used for applicable devices, although the presence of an abandoned lead renders the system nonconditional and the protocol used for these patients was the same as used for those with legacy devices. During the time that the CIED was reprogrammed to accommodate the MRI environment, electrocardiography telemetry and pulse oximetry were monitored continuously. Live contact with the patient throughout the scan via visual and voice contact was performed if possible, and patients were instructed to report symptoms of any kind within the chest or device pocket during the study. Specialized medical personnel (advanced cardiac life support and a CIED-trained electrophysiology fellow, physician assistant, or physician) able to recognize and treat a significant change in cardiac rhythm or hemodynamic stability, perform advanced cardiac life support, and perform transcutaneous pacing or cardioversion/defibrillation, were present in the MRI control area throughout the scan. After completion of the MRI, CIED evaluation was repeated and programming returned to baseline or to a clinically appropriate setting.

Related adverse event criteria were based on the CMS decision memo for MRI in patients with CIEDs⁸ and defined as a variation in pre- and post-MRI capture threshold of 50% or more, sensing 40% or more, and lead impedance of 30% or more, as well as burning or pulling sensations in the chest or device pocket, sustained tachyarrhythmia during MRI, changes in vital signs determined to be attributed to MRI-related programming changes, power-on resets, or a change in the pacing rate. Long-term follow-up data were collected if present in the electronic heath record.

Continuous variables are expressed as means (SDs) or as medians with interquartile ranges. Categorical variables are expressed as numbers and percentages. Analyses were performed using JMP version 12 (SAS Institute). This study was Magnetic Resonance Imaging in Patients With Cardiac Implantable Electronic Devices With Abandoned Leads

Table 1. Patient Characteristics							
Characteristic	No. (%)						
No. of patients	139						
Age, mean (SD), y	64.8 (14.1)						
Male	110 (79)						
Active CIED systems							
Single-chamber PPM	5 (2.5)						
Dual chamber							
РРМ	43 (21.5)						
PPM EPI	1 (0.5)						
PPM with 1 EPI lead	2 (1)						
ICD							
Single chamber	39 (19.5)						
Dual chamber	42 (21)						
Biventricular							
PPM	1 (0.5)						
ICD	59 (29.5)						
ICD EPI	1 (0.5)						
Subcutaneous ICD	4 (2)						
None	3 (1.5)						
Abandoned leads							
Right atrial							
PPM	50 (21)						
PPM EPI	5 (2)						
Right ventricular							
PPM	70 (29)						
PPM EPI	18 (7)						
ICD	65 (27)						
ICD coil	8 (3)						
Pace-sense portion of ICD	11 (5)						
Coronary sinus	6 (2)						
Left ventricular							
Endocardial	1 (0.4)						
EPI	3 (1)						
Lead fragments	5 (2)						
PPM tip (lung)	1 (0.4)						
PPM (right ventricular)	2 (1)						
ICD (right ventricular)	2 (1)						
Subcutaneous array	1 (0.4)						

Abbreviations: CIED, cardiac implantable electronic device; EPI, epicardial; ICD, implantable cardioverter-defibrillator; PPM, permanent pacemaker.

a descriptive case series, and no statistical comparisons were made.

Results

Patient and CIED characteristics are presented in **Table 1**. From 2013 to 2020, 139 patients (110 men [79%]) with a mean (SD) age of 65.6 (13.4) years underwent 200 MRIs of multiple different anatomic regions including the brain (84 [42%]), heart

Region No. (%) Brain 84 (42) Heart 50 (25) Spine Lumbar 27 (13.5) Cervical 16 (8) Abdomen 11 (5.5) Thoracic spine 6(3) 4(2) Head Prostate 4(2) Pelvis 2(1)Knee 2(1) Shoulder 2(1) Foot 2(1) Rectum 2(1) Hip 2(1) Orbits 1 (0.5) Ankle 1 (0.5) 1 (0.5) Face 1 (0.5) Chest Neck 1 (0.5) No. of MRIs per patient 1 121 2 13 3 2 4 2 7 2 9 1 16 1

Table 2. Magnetic Resonance Imaging (MRI) Region and Frequency

(50 [25%]), lumbar spine (27 [14%]), cervical spine (16 [8%]), abdomen (11 [6%]), thoracic spine (6 [3%]), head (4 [2%]), prostate (4 [2%]), pelvis (2 [1%]), knee (2 [1%]), shoulder (2 [1%]), foot (2[1%]), rectum (2[1%]), hip (2[1%]), orbits (1[0.5%]), ankle (1[0.5%]), face (1[0.5%]), chest (1[0.5%]), and neck (1[0.5%]) (Table 2). There were a total of 219 anatomic regions included as 14 studies involving MRIs of multiple body parts including 2 regions (10 [71%]), 3 regions (3 [21%]), and 4 regions (1 [7%]). Thirteen patients (9%) underwent 2 separate MRIs, 2 patients (1%) had 3 studies, 2 patients (1%) had 4, 2 patients (1%) had 7, 1 patient had 9, and 1 patient (0.7%) underwent 16 MRIs. There were a total 243 abandoned leads with a mean (SD) of 1.22 (0.45) leads per patient (Figure 1). Thirty-seven patients (26.6%) had 2 abandoned leads, and 3 patients (2%) had 3 (Figure 2). Abandoned leads included right ventricular PPM (70 [29%]), implantable cardioverter-defibrillator (ICD) (65 [27%]), right atrial PPM (50 [21%]), right ventricular PPM epicardial (EPI) (18 [7%]), ICD coil (8 [3%]), pace-sense portion of ICD (11 [5%]), coronary sinus (6 [3%]), right atrial PPM EPI (5 [2%]), left ventricular endocardial PPM (1[0.4%]), left ventricular PPM EPI (3 [1%]), subcutaneous array (1 [0.4%]), and various lead fragments (5 [2%]) (including PPM tip in lung [1], partial ICD

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Figure 1. Cardiac Magnetic Resonance Images (MRIs) of 2 Patients With Active and Abandoned Implantable Cardioverter-Defibrillator (ICD) Leads Performed Prior to Ventricular Tachycardia Ablation Procedures

A Basal septal LV midmyocardial LGE MRI image

B Transmural LGE MRI image



A, Basal septal left ventricular (LV) midmyocardial late gadolinium enhancement (LGE) consistent with nonischemic cardiomyopathy. B, Transmural basal inferolateral and subendocardial anteroseptal LGE consistent with prior infarctions.

right ventricular lead tip [2], and partial right ventricular PPM lead tip [2]) (Table 2). There were no patients with abandoned CIED leads who were excluded from the study.

Active CIED systems included single-chamber PPM (5 [2.5%]), dual-chamber PPM (43 [21.5%]), dual-chamber PPM EPI (1 [0.5%]), dual-chamber PPM (with 1 EPI lead) (2 [1%]), single-chamber ICD (39 [19.5%]), dual-chamber ICD (42 [21%]), biventricular PPM (1 [0.5%]), biventricular ICD (59 [29.5%]), biventricular ICD (with 1 EPI PPM lead) (1 [0.5%]), subcutaneous ICD (4 [2%]), and no active system (3 [1.5%]) (Figure 2 and Table 1). The mean (SD) number of active leads was 2.04 (0.78), and 64 patients (46%) were PPM dependent. A transmit-receive radiofrequency coil was used in 41 studies (21%), all of which involved MRI of the brain, and 40 patients (29%) had history of sternotomy. There were no power-on resets, sustained tachyarrhythmias, or clinically relevant changes in vital signs, battery voltage, or pacing rates during MRI. All studies were performed in normal specific absorption rate mode and did not exceed 2.0 Watts per kg whole body or 3.2 Watts per kg during any study performed using the body coil for radiofrequency transmission.

There were 6 adverse events (**Table 3**), all occurring in men, including a significant decrease in right atrial sensing in 4 patients with a mean (SD) decrease in amplitude of 57.8% (7.8%). One patient was in permanent atrial fibrillation and was appropriately programmed to ventricular demand pacing mode. Three patients underwent appropriate sensitivity reprogramming without clinical sequelae. Sensing returned to normal in all 4 patients at the first available follow-up appointment (range, 5 days to 20 months). One patient had a 48% decrease in R-wave sensing of a coronary sinus lead from 6.0 to 3.1 millivolts, which improved to 5.0 millivolts the following day. One patient with an abandoned subcutaneous array experienced sternal heating that subsided on cessation of the study, representing the only study that was terminated prematurely. Long-term lead-related follow-up data were available for 83 patients after a total of 143 MRIs showing no adverse events throughout a mean (SD) of 15.77 (14.4) months.

Discussion

CIED leads have been shown to heat when exposed to a magnetic field in an MRI environment,^{12,13} potentially resulting in myocardial thermal injury, arrhythmias, damage to adjacent leads, and changes in capture thresholds and sensing parameters. As such, CIEDs have historically been considered a relative contraindication to MRI, to be done on a case-by-case and site-by-site basis with appropriate radiology and cardiology support, and in centers conducting or participating in clinical studies designed to assess the utility and safety of MRI exposure.¹⁴ The development of MRI-conditional devices, managed according to specific labeling requirements, has enhanced access to MRI when dedicated protocols are followed. However, imaging of patients with legacy devices, who make up the bulk of the CIED patients worldwide,¹³ has been restricted.

Recently, MRI protocols have been developed and tested showing safety in patients with legacy devices.¹⁵ This was

Figure 2. Representative Chest Radiographs of Patients With Abandoned Cardiac Implantable Electronic Device Leads B RA and RV PPM leads

A ICD lead





C Multiple RA PPM leads and an RV PPM lead

D ICD leads from right and left sides of the chest

E RA and RV epicardial PPM leads



F Disrupted ICD lead



A, An implantable cardioverter-defibrillator (ICD) lead (note the multiple lung masses). B, Right atrial (RA) permanent pacemaker (PPM) and right ventricular (RV) PPM leads. C, Multiple RA PPM leads and an RV PPM lead (note the additional leads attached to a contralateral PPM). D, ICD leads from the right

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and left sides of the chest. E, RA and RV epicardial PPM leads from the abdomen. F, A disrupted ICD lead including the superior vena cava high-voltage coil adjacent to a hemodialysis catheter.

Table 3. Related Adverse Events After MRI in Patients With CIEDs With Abandoned Leads

Patient No.	Age, y	Sex	MRI region	Active CIED	Abandoned lead	Adverse event	Follow-up result (first available)	
1	60s	М	Cardiac	DC PPM (EPI RV)	RV PPM	RA 0.3 to 0.1 mV	Normalization at 1 mo	
2	50s	Μ	Knee	DC ICD	RV PPM	RA 6 to 2.1 mV	Normalization at 9 mo	
3	50s	Μ	Brain	BiV ICD	RV PPM	RA 6 to 3 mV	Normalization at 20 mo	
4	80s	Μ	Entire spine	DC PPM (EPI RV)	RA and RV PPM	RA 2 to 1 mV	Normalization at 5 d	
5	50s	Μ	Cardiac	BiV ICD	CS	LV 6 to 3.1 mV	Improvement to 5 mV at 1 d	
6	60s	М	Cardiac	DC ICD	Subcutaneous array	Sternal burning	Subsided on cessation of MRI	

Abbreviations: BiV, biventricular; CIED, cardiac implantable electronic device; CS, coronary sinus; DC, dual-chamber; EPI, epicardial; ICD, implantable cardioverter-defibrillator; LV, left ventricle; M, male; MRI, magnetic resonance imaging; mV, millivolts; PPM, permanent pacemaker; RA, right atrial; RV, right ventricle

followed by larger multi-institutional observational studies that have replicated these safety findings including the Magna-Safe registry, which included 1500 patients with non-MRIconditional PPMs or ICDs who underwent nonthoracic MRIs at 1.5 T with appropriate reprogramming.¹⁶ A similar study by Nazarian et al⁴ of 1509 patients that included thoracic MRIs showed similar safety⁴ and has since been replicated on a smaller scale.¹⁷ These data ultimately led to refinement of guidelines and protocols for MRI, which eased restrictions on patients with legacy devices.^{6,7}

However, MRI in the setting of abandoned leads is theoretically associated with higher risk leading to exclusion of

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many of these patients from studies. In a cylindrical phantom model, for clinical lead lengths between 40 and 60 cm, abandoned leads exhibited greater lead tip heating compared with leads attached to a generator.⁹ In a similar study using a phantom human trunk simulator, abandoned leads were found to modify the radiofrequency-heating profile of adjacent MRIconditional leads, strongly dependent on the termination condition of the lead, with a maximum temperature rise of 17.6 °C of the active lead.¹⁸ Because of these data, access to MRI in this population has been limited, with patients and clinicians required to consider a different imaging modality or performance of transvenous lead extraction.¹⁹ As transvenous lead extraction carries both short-^{20,21} and long-term²² complication sequelae, this option has remained unappealing.

Recent studies have demonstrated clinical safety of MRIs in patients with abandoned leads, ^{10,11,23,24} the largest of which included 80 patients with 90 abandoned leads who underwent 97 MRIs with no clinical or electrical evidence of CIED dysfunction, arrhythmias, or pain. Additionally, preimaging and postimaging paired cardiac troponin T measurements showed no evidence of myocardial injury. In this study, 24% of the MRIs were thoracic. Similar data have been shown for MRIs of patients with CIED lead fragments.^{25,26} Our study adds to the accumulating safety data in patients with abandoned leads and represents the largest description thus far, including endocardial and epicardial PPM, ICD, subcutaneous highvoltage coils, and lead fragments. The 6 adverse events (3%) that were seen included mostly (5 of 6) reductions in lead sensing with the ability to successfully reprogram the sensitivity of the affected lead until normalization occurred. Of those 5 patients, 4 (2%) involved the right atrial lead, slightly higher than the 1% incidence of comparable events seen in the largest experience of patients undergoing MRI with legacy devices but without abandoned leads,²⁷ likely explained by the higher change in sensing threshold of 50% used in that study. One patient experienced subjective chest heating during the MRI that subsided after premature termination of the study. This patient had an abandoned subcutaneous array that coursed inferiorly and posteriorly around his back, distant from his pain. He also had sternal chest wires that presumably could have heated during the MRI. This phenomenon of chest burning or pulling, which was only seen in 1 of 41 patients with previous sternotomy in our study, has been reported before without a conclusive determination of cause.^{27,28}

This study also represents the largest cohort of patients with abandoned CIED leads undergoing MRI of the thoracic region with 57 total MRIs (28.5%) including 50 (25%) of the heart. As the device and leads reside within the isocenter of the magnetic field, the risk of lead heating increases.²⁹ Multiple studies have described the safety of thoracic MRI in this scenario, but the majority of these did not include abandoned

leads.^{5,28,30} Our study, with a heterogeneous population all with abandoned CIED leads, showed no serious adverse events, suggesting an overall positive safety profile in this scenario. The implications of these data relate to the utility of cardiac MRI for diagnostic and prognostic purposes in patients with cardiomyopathy³¹ (Figure 1) as well as prior to complex procedures, including ventricular tachycardia³²⁻³⁹ and atrial fibrillation⁴⁰⁻⁴² ablation.

Despite the relative safety seen in this study, appropriate monitoring precautions and protocols consistent with the 2017 Heart Rhythm Society Expert Consensus Statement on MRI and Radiation Exposure in Patients with CIEDs⁶ remains prudent. Other risk mitigation strategies have been proposed in patients with legacy devices with or without abandoned leads such as the use of a transmit-receive radiofrequency coil^{9,43} in patients undergoing MRI of the brain or extremities to avoid a central location of the leads in relation to the radiofrequency coil, as well as a change in the MRI landmark.⁴⁴

Limitations

This is a single-center observational study. All MRI scans were performed at 1.5 T, and thus, our results cannot be extrapolated to different MRI field strengths. While our adverse event criteria were guided by the widely accepted CMS decision document,⁸ a different threshold for CIED-related phenomena may have changed our findings. Although our patient population was heterogenous with a wide array of active and abandoned leads, this does not represent all available leads, and the extent of heating and current induction is likely a function of lead fragment length as well as the presence or absence of end caps. Although we specifically looked for evidence of abandoned leads during our MRI screening procedure, it is possible that some patients with abandoned leads were not known at the time of MRI. Finally, this cohort only includes a limited number of patients with abandoned leads without an active CIED because these were not tracked routinely in our CIED database. Therefore, we cannot draw definitive conclusions about MRIs in patients with abandoned leads but no active system, for example, after generator explant.

Conclusions

In this study of patients with abandoned CIED leads undergoing MRI, including those who underwent MRI of the thorax, a low rate of arrhythmia, patient symptoms, or change in device settings was observed. The growing aggregate of data calls into question current institutional and CMS reimbursement policies concerning MRI in patients with abandoned CIED leads.

ARTICLE INFORMATION

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