

MRI in Patients with Cardiovascular Implantable Electronic Devices and Fractured or Abandoned Leads

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Purpose: To examine the clinical effect of lead length and lead orientation in patients with cardiac implantable electronic devices (CIEDs) and lead fragments or abandoned leads undergoing 1.5-T MRI.

Materials and Methods: This Health Insurance Portability and Accountability Act–compliant retrospective study included patients with CIEDs and abandoned leads or lead fragments undergoing 1.5-T MRI from March 2014 through July 2020. CIED settings before and after MRI were reviewed, with clinically significant variations defined as a composite of the change in capture threshold of at least 50%, in sensing of at least 40%, or in lead impedance of at least 30% between before MRI and after MRI interrogation. Adverse clinical events were assessed at MRI and up to 30 days after. Univariable and multivariable analysis was performed.

Results: Eighty patients with 126 abandoned CIED leads or lead fragments underwent 107 1.5-T MRI examinations. Sixty-seven patients (median age, 74 years; IQR, 66–78 years; 44 male patients, 23 female patients) had abandoned leads, and 13 (median age, 66 years; IQR, 52–74 years; nine male patients, four female patients) had lead fragments. There were no reported deaths, clinically significant arrhythmias, or adverse clinical events within 30 days of MRI. Three patients with abandoned leads had a significant change in the composite of capture threshold, sensing, or lead impedance. In a multivariable generalized estimating equation analysis, lead orientation, lead length, MRI type, and MRI duration were not associated with a significant change in the composite outcome.

Conclusion: Use of 1.5-T MRI in patients with abandoned CIED leads or lead fragments of varying length and orientation was not associated with adverse clinical events.

Supplemental material is available for this article.

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Current guidelines provide inconsistent recommendations regarding MRI in patients with cardiac implantable electronic devices (CIEDs) and abandoned leads or lead fragments. In the United States, a consensus statement from the Heart Rhythm Society does not provide guidance on the appropriateness of MRI in this population because of insufficient data (1). On the other hand, European guidelines provide a class IIb recommendation for MRI if the benefits outweigh risks but do not define the probability or severity of harm (2).

Patients with abandoned leads or lead fragments are considered at risk because of the unpredictable effects of lead tip heating during MRI and, as a secondary consideration, the risk associated with the CIED (3). Despite these risks, patients with abandoned leads undergoing MRI do not demonstrate adverse events when imaged using prespecified protocols (4) or if the device generator has been removed (5). In addition, patients with abandoned CIED leads do not have biochemical evidence of myocardial injury after MRI (6).

Although in vitro studies suggest that the length and orientation of fractured or abandoned leads contribute to heating during MRI (7,8), the effect in a clinical setting

has not been reported. Additionally, it is unknown whether the length and orientation of abandoned leads or lead fragments affect CIED function in patients undergoing MRI. The primary objective of this study was to examine the effect of lead orientation and lead length on clinical outcomes for patients with pacemakers or implantable cardioverter defibrillators and abandoned leads or lead fragments undergoing 1.5-T MRI. Secondary objectives included quantifying changes to CIED function after 1.5-T MRI.

Materials and Methods

Study Design and Patient Selection

This was an institutional review board–approved, Health Insurance Portability and Accountability Act–compliant retrospective analysis of patients with CIEDs and abandoned leads (defined as intact leads no longer connected to a generator) or lead fragments undergoing a clinically indicated 1.5-T MRI at two academic medical centers within an integrated health care system. Consecutive patients from March 2014 through July 2020 were included in the analysis. The need for written informed consent was waived.

Abbreviation

CIED = cardiac implantable electronic device

Summary

MRI in the presence of abandoned cardiac implantable electronic device leads or lead fragments of varying length and orientation was not associated with adverse clinical events.

Key Points

- Eighty patients with 126 abandoned cardiac implantable electronic device (CIED) leads or lead fragments underwent 107 1.5-T MRI examinations.
- MRI studies included a broad range of body regions.
- Use of 1.5-T MRI in the presence of abandoned CIED leads or lead fragments of varying length and orientation was not associated with adverse clinical events.

Keywords

Cardiac Assist Devices, MRI, Cardiac Implantable Electronic Device

MRI was performed using 1.5-T Aera (Siemens Healthcare) or 1.5-T Signa HD (GE HealthCare) machines operating in normal mode (specific absorption rate <2 W/kg). Imaging parameters were adjusted at the discretion of the technologist to ensure specific absorption rate less than 2 W/kg (eg, reducing number of sections, using gradient-echo sequences instead of fast spin echo). Patient vital signs, pulse oximetry, and cardiac waveforms were monitored during the examination by a nurse or physician certified in advanced cardiac life support. Patients were instructed to notify the MRI technician immediately of any unexpected symptoms. Any adverse clinical event, patient concerns, or premature termination of MRI was recorded by a nurse or technician. After MRI, the CIED was reinterrogated and the device was reset to the before-MRI settings.

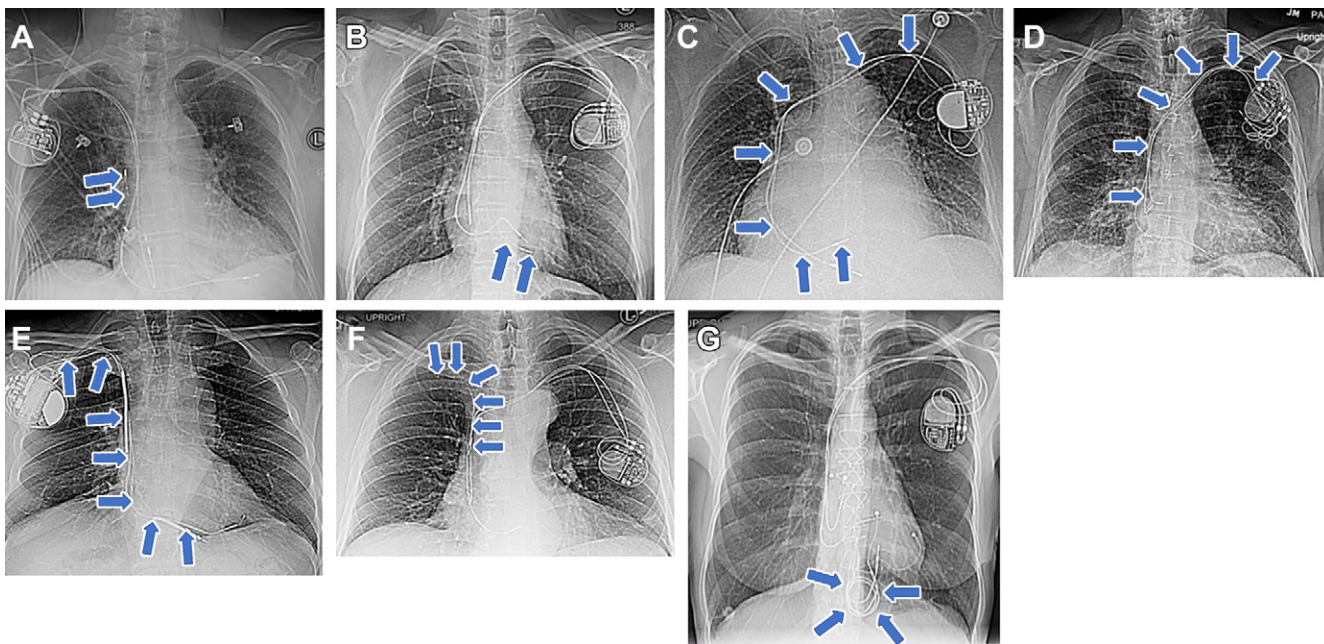
MRI Protocol

Patients with abandoned CIED leads or lead fragments were considered to have nonconditional CIEDs and underwent 1.5-T MRI using a predefined protocol for non-MRI conditional CIEDs (Fig S1). As part of the institutional protocol, chest radiography was performed before MRI to identify abandoned leads or lead fragments. Immediately before MRI, patients underwent CIED interrogation and device settings were recorded. CIEDs were then programmed into an asynchronous mode or nonpacing mode according to the predefined protocol on the basis of pacemaker dependence.

Chest Radiography

Chest radiographs in patients with CIEDs and abandoned leads or lead fragments were independently reviewed, with the reader blinded to patient outcomes. The proximal lead location and distal lead location were recorded. Abandoned lead length was obtained from the manufacturer's instructions for use. For lead fragments, lead length was measured on the radiograph using incorporated software tools in the picture archiving and communication system.

CIED lead implantation was categorized according to the radiographic appearance as vertical, horizontal, C-shaped, r-shaped, Z-shaped, 7-shaped, or coiled (Figure). Leads originating in the left chest wall were categorized as C-shaped if they terminated in the right ventricle or distal right atrium, or r-shaped if they terminated in the superior



Examples of abandoned or fractured lead orientation on frontal chest radiographs (arrows): **(A)** vertical fractured lead fragment in a 78-year-old female patient, **(B)** horizontal fractured lead fragment in a 47-year-old female patient, **(C)** C-shaped abandoned lead (terminating in the right ventricle) in a 79-year-old female patient, **(D)** r-shaped abandoned lead (terminating in the superior vena cava or right atrial junction) in a 75-year-old male patient, **(E)** Z-shaped abandoned lead (terminating in the right ventricle) in a 72-year-old male patient, **(F)** 7-shaped abandoned lead (terminating in the proximal right atrium) in a 58-year-old male patient, and **(G)** coiled abandoned lead in a 51-year-old female patient.

Table 1: Patient Characteristics and MRI Details

Variable	Abandoned Lead (<i>n</i> = 67)	Lead Fragment (<i>n</i> = 13)	<i>P</i> Value
Age (y)	74 (66–78)	66 (52–74)	.04
Female sex	23 (34)	4 (31)	>.99
Male sex	44 (66)	9 (69)	>.99
BMI (kg/m ²)	28.1 (25.1–35.2)	29.1 (24.4–34.5)	.97
Generator type			.86
Pacer	24 (36)	5 (38)	
ICD	43 (64)	8 (62)	
Pacemaker dependent	14 (32)	2 (22)	.71
MRI type*			<.001
Brain/neck/cervical spine	39 (40)	10 (35)	
Chest/cardiac	8 (8)	0	
Abdomen/pelvis	17 (18)	1 (3)	
Thoracic spine	8 (8)	0	
Lumbar spine	17 (18)	5 (17)	
Upper extremity	2 (2)	3 (10)	
Lower extremity	6 (6)	10 (35)	
MRI duration (min)	30 (21–43)	28 (22–33)	.33

Note.—Data are reported as frequencies, with percentages in parentheses; or medians, with IQRs in parentheses. BMI = body mass index (calculated as weight in kilograms divided by height in meters squared), ICD = implantable cardioverter defibrillator.
* Percentages based on MRI scans of 97 body regions (abandoned leads) or 29 body regions (lead fragments).

vena cava or proximal right atrium. Leads originating in the right chest wall were categorized as Z-shaped if they terminated in the right ventricle or distal right atrium and as 7-shaped if they terminated in the superior vena cava or proximal right atrium.

The lead manufacturer, model, date of implant, capped status, and type of passive or active fixation were obtained from the medical record or the vendor record. CIED settings before and after MRI were obtained from the medical record, with clinically significant variations defined as a composite of the change in capture threshold of at least 50%, in sensing of at least 40%, or in lead impedance of at least 30% between pre-MRI and post-MRI interrogation (5). Adverse clinical events were assessed by reviewing the medical record at the time of MRI and at 30 days.

Statistical Analysis

Descriptive statistics are used to summarize the data. Continuous variables are reported as medians and IQRs. Categorical variables are reported as frequencies and percentages. Continuous variables were compared using *t* test or Wilcoxon rank sum (Mann-Whitney) test, as appropriate. Normality of continuous variables was determined by the Shapiro-Wilk test. Categorical variables were compared using the Fisher exact test or χ^2 test. To account for complexity and repeated measures of the data, univariable and multivariable generalized estimating equations were used to assess the association of lead orientation, lead length, MRI

type (ie, anatomic region imaged), and MRI duration to the composite of change in capture threshold of at least 50%, sensing of at least 40%, or lead impedance of at least 30%. In patients who underwent more than one MRI examination, the first examination for each patient was used in the analysis. Stata software, version 17 (StataCorp), was used for statistical analysis. Two-sided *P* < .05 indicated statistical significance.

Results

Patient Characteristics

Eighty patients with abandoned CIED leads (*n* = 67; 44 male patients, 23 female patients) or lead fragments (*n* = 13; nine male patients, four female patients) underwent 107 1.5-T MRI examinations covering 126 body regions (Table 1). The median age for patients with abandoned leads was statistically significantly older than for patients with lead fragments (74 years [IQR, 66–78 years] vs 66 years [IQR, 52–74 years]; *P* = .04). Eight patients (10%) had more than one abandoned lead or lead fragment, and 16 patients (20%) underwent more than one MRI examination. MRI studies were stratified by body region, including brain, neck, and cervical spine (49 of 126; 38.9%); chest, cardiac, and thoracic spine (16 of 126; 12.6%); abdomen, pelvis, and lumbar spine (40 of 126; 31.7%); upper extremity (five of 126; 4.0%); and lower extremity (16 of 126; 12.7%). The distribution of MRI studies differed between patients

Table 2: Characteristics of Abandoned Leads and Fractured Leads

Parameter	Abandoned Lead (<i>n</i> = 97)	Lead Fragment (<i>n</i> = 29)	<i>P</i> Value
Lead manufacturer			.03
Medtronic	36 (37)	6 (21)	
St Jude	29 (30)	12 (41)	
Boston Scientific	19 (20)	1 (3)	
Biotronic	6 (6)	6 (21)	
Sorin	2 (2)	0	
Oscor	2 (2)	0	
Greatbatch Medical	0	1 (3)	
Unknown	3 (3)	3 (10)	
Year of lead implant (range)	2014 (1996–2019)	2016 (2000–2018)	.15
Lead type			.002
Pacer	67 (69)	21 (72)	
ICD	27 (28)	2 (7)	
Epicardial	3 (3)	6 (21)	
Lead origin, left side	91 (93.8)	15 (51.7)	<.001
Lead termination			<.001
Left chest wall	3 (3)	14 (48)	
Superior vena cava	3 (3)	4 (14)	
Right atrium	8 (8)	0	
Right ventricle	82 (85)	11 (38)	
Coronary sinus	1 (1)	0	
Lead orientation			<.001
Vertical	0	3 (10)	
Horizontal	0	17 (59)	
C-shaped	79 (81)	3 (10)	
r-shaped	11 (11)	2 (7)	
Z-shaped	4 (4)	0	
7-shaped	1 (1)	4 (14)	
Coiled	2 (2)	0	
Lead length (cm) (IQR)	57 (52–60)	5.3 (4.1–8.6)	<.001
Lead fixation			.66
Passive	21 (46)	3 (60)	
Active	25 (54)	2 (40)	
Capped lead	38 (95)	3 (75)	.25

Note.—Data are frequencies, with percentages in parentheses; medians, with IQRs in parentheses; or medians, with ranges in parentheses. Lead fixation available for 51 of 126 (40%) leads. Capped lead data available for 41 of 126 (33%) leads. ICD = implantable cardioverter defibrillator.

with abandoned leads and those with lead fragments ($P < .01$); however, no evidence showed a difference in MRI duration between groups (30 vs 28 minutes; $P = .33$). There was no evidence of differences in generator type (pacemaker vs implantable cardioverter defibrillator) or frequency of pacemaker dependence.

MRI Examinations

MRI examinations were performed on a total of 126 leads, including 97 abandoned leads and 29 lead fragments (Table 2). Of the abandoned leads, 67 were pacemaker leads, 27 were trans-

venous implantable cardioverter defibrillator leads, and three were epicardial implantable cardioverter defibrillator leads. Of the lead fragments, 21 were pacemaker lead fragments, two were transvenous implantable cardioverter defibrillator lead fragments, and six were epicardial implantable cardioverter defibrillator lead fragments. The distribution of lead type significantly differed between patients with abandoned leads and lead fragments ($P < .002$). Lead length was significantly longer with abandoned leads than with lead fragments (57 cm vs 5.3 cm; $P < .001$). The distribution of lead origin ($P < .001$), lead termination ($P < .01$), and lead orientation ($P < .001$) also sig-

Table 3: Univariable and Multivariable Generalized Estimating Equation Models for Association of Lead Orientation, Lead Length, MRI Type, and MRI Duration with Change in CEID Function

Variable	Univariable Model		Multivariable Model	
	OR (95% CI)	P Value	OR (95% CI)	P Value
Lead orientation				
Vertical	
Horizontal	
C-shaped	0.98 (0.09, 10.58)	.99	0.92 (0.04, 20.99)	.96
r-shaped	4.34 (0.35, 53.09)	.25	5.86 (0.29, 117.52)	.25
Z-shaped	
7-shaped	
Coiled	
Lead length	1.01 (0.95, 1.06)	.84	0.89 (0.72, 1.10)	.29
MRI type				
Brain/neck/cervical spine	2.73 (0.24, 30.98)	.42	2.10 (0.16, 28.40)	.58
Thoracic/cardiac/thoracic spine	
Abdomen/pelvis/lumbar spine	1.26 (0.11, 14.41)	.85	1.53 (0.09, 25.89)	.77
Upper extremity	
Lower extremity	
MRI duration	0.97 (0.90, 1.06)	.54	0.95 (0.85, 1.06)	.37

Note.—Data in parentheses are 95% CIs. Change in CEID function defined as a composite of change in capture threshold of $\geq 50\%$, sensing of $\geq 40\%$, or lead impedance of $\geq 30\%$. CEID = cardiac implantable electronic device, OR = odds ratio.

nificantly differed in patients with abandoned leads compared with those with lead fragments. The type of lead fixation and frequency of capped leads did not differ between patients with abandoned leads and those with lead fragments.

Outcomes

There were no reported deaths, clinically significant arrhythmias, or adverse clinical events within 30 days of 1.5-T MRI in all patients. Immediate post-MRI device interrogation data were available for 80 of 107 MRI examinations (Fig S1). There were no power-on resets. Three patients with abandoned leads had a significant change in the composite of capture threshold, sensing, or lead impedance: One patient with a pacemaker and C-shaped lead had a 40% decrease in atrial sensing, one patient with an implantable cardioverter defibrillator and C-shaped lead had a 50% decrease in both atrial threshold and right ventricular threshold, and one patient with a pacemaker and an r-shaped lead had a 63% reduction in atrial sensing. These changes in lead parameters were managed by device reprogramming. The multivariable generalized estimating equation analysis showed that lead orientation, lead length, MRI type, and MRI duration were not associated with a significant change in the composite of capture threshold, sensing, or lead impedance (Table 3).

Discussion

MRI in patients with CIEDs and abandoned leads or lead fragments in phantom models demonstrates the potential

for lead tip heating to cause patient harm (9). Two important factors influencing the risk of lead tip heating in vitro at MRI are lead length and lead configuration (10). To our knowledge, this is the first study to specifically demonstrate that in vivo variations in the length and configuration of abandoned CIED leads or lead fragments at 1.5-T MRI are not associated with adverse clinical events. These results are consistent with previously published case series, which showed that patients with abandoned leads or lead fragments have a favorable safety profile at MRI (4,11,12).

Although variations in lead length and configuration are important drivers for lead tip heating, several theoretical factors may contribute to the overall risk profile, such as lead type (endocardial vs epicardial) (13), lead termination condition (14), and lead location relative to isocenter (15). Because of the complexity of these interactions, 1.5-T MRI in patients with abandoned leads or lead fragments may present risks that have not been defined.

Discrepancies between in vitro and in vivo studies regarding the effect of lead tip heating during MRI may be explained by the lack of a uniform radiofrequency field in vivo (16), the dissipation of heat due to flowing blood (13), and the effects of electromagnetic coupling from adjacent leads reducing deposited radiofrequency energy (17). In clinical practice, minimizing the potential interaction between abandoned leads or lead fragments and the MRI field can be achieved by lowering specific absorption rate, using transmit-receive coils where feasible, and imaging at a non-chest landmark (18).

In addition to the risk of lead tip heating, MRI can also impact CIED function (19). In our study, significant changes in CIED settings occurred after three MRI examinations (2.8%), without adverse clinical events. These patients were managed by CIED reprogramming, and no patients required lead or device revision. Changes in CIED function were not associated with lead orientation, lead length, MRI type, or MRI duration in a multivariate model.

The study had limitations. This retrospective study may not have captured all adverse events during the 30-day follow-up period, although the broad geographic coverage of our integrated health care system makes this less likely. Post-MRI device interrogation data were available for only 80 MRI examinations (75%). The 2.8% rate for significant change in CIED function is like that shown in previous reports with abandoned leads (4), and we expect that missing post-MRI interrogation data would not substantially alter this. Incomplete data were available for lead fixation and capped leads and were not included in the multivariable model. Lead heating was not directly evaluated; thus, subclinical myocardial injury may not have been detected. However, it has been reported previously (6) that troponin T values do not significantly change in patients with abandoned leads undergoing MRI. Finally, the study did not assess outcomes for patients with abandoned leads or lead fragments in whom the CIED had been removed.

An increasing number of patients with CIEDs can expect to be referred for MRI during their lifetime (20). Patients with abandoned CIED leads or lead fragments and a clinical indication for advanced imaging have limited options for MRI because of insurance reimbursement exclusions (21). In many instances, alternatives to MRI provide suboptimal diagnostic information (22). Alternatively, removing leads solely to facilitate MRI exposes patients to risks of morbidity and mortality (23,24). This retrospective analysis of patients with 126 abandoned CIED leads or lead fragments varying in length and orientation undergoing 1.5-T MRI found no adverse clinical outcomes, supporting the consideration of 1.5-T MRI in this historically contraindicated population. Larger prospective registries are warranted to confirm the feasibility of MRI in this patient population.

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