Radiology: Cardiothoracic Imaging

RESEARCH LETTER

Outcome of MRI in Patients with Nonconditional Devices with Mismatch between Manufacturer of Leads and Generator

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Despite the increasing number of patients with MRI-conditional cardiac implantable electronic devices (CIEDs), there is still a substantial number of patients with non–MRI-conditional CIEDs. Several studies have demonstrated the safety of performing MRI scans in patients with non–MRI-conditional CIEDs by using different protocols (1–4). Most CIED manufacturers have applied for MRI-conditional status for some of their legacy leads, making these patients eligible to receive an MRI-compatible system at the time of generator replacement, provided that the generator and leads are from the same manufacturer. However, there are times when a generator from a different manufacturer is chosen at the time of generator replacement or upgrade from an implantable cardioverter-defibrillator (ICD) to a cardiac resynchronization therapy defibrillator (CRT-D) because of certain features, which renders the device non–MRI conditional. To our knowledge, no study has examined the outcomes of patients undergoing MRI scans with non–MRI-conditional CIED where there is a mismatch between the manufacturer of the leads and generators.

Materials and Methods

We created an institutional review board–approved registry at our institution entitled Patient Registry of Magnetic Resonance Imaging in Non-Approved DEvices (PROMeNADe) (ClinicalTrials.gov identifier: NCT 03081364), the details of which were published previously (4). The registry included patients who had undergone thoracic and nonthoracic MRI studies as well as patients who were pacemaker dependent and patients with abandoned leads. All MRI examinations were performed with a 1.5-T scanner (Optima MR450 W; GE Healthcare) according to standard MRI protocols. No protocol adjustments were made to reduce specific absorption rate. All patients were screened prior to the scan and monitored during the scan via the protocol described previously. No special accommodation was made for mismatched devices.

Results

From September 2015 to June 2019, a total of 35 scans were performed in 29 patients (51% female; mean age, 69 years) who had a mismatch between the manufacturer of the CIED generator and one or more of the leads (Table 1). Two patients (6%) were pacemaker dependent. The most common MRI scans were spinal (13 scans), brain (eight scans), and cardiac (seven scans). An ICD (46%) was the most common CIED, followed by CRT-D (34%). The average number of leads per patient was 2.0. The right ventricular lead was the most common mismatched lead (83%), commonly a result of a single-chamber ICD that was replaced with a different manufacturer generator. The most common device manufacturer in this series was Medtronic (66%), followed by St Jude/Abbott (20%). The most common lead manufacturer in this series was Boston Scientific/Guidant (37%), followed by St Jude/Abbott (34%). One patient had a cardiac resynchronization therapy pacemaker with a Medtronic generator, St Jude/Abbott right atrial and right ventricular leads, and a Boston Scientific coronary sinus lead and had undergone MRI without problems. All CIEDs were checked before and after the MRI, and the patients were followed up in a device clinic per protocol. One patient had a minor change in lead impedance after MRI. Two other patients had minor physiologic changes that resolved by the end of the MRI (Table 2).

Discussion

In this cohort of patients with non–MRI-conditional devices and a mismatch between the manufacturer of generators and leads who underwent MRI scans, no adverse events were noted. To our knowledge, this is the only study to date to report this finding. A limitation of this finding was that it is from a retrospective, single-center study with a small sample size. However, we included patients from a broad variety of manufacturers of devices and leads and did not exclude any patients. This study demonstrates that performing MRI scans in nonconditional devices with a mismatch between the manufacturer of generators and leads may be safe, a finding that would need to be confirmed by future studies.

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Abbreviations

CIED = cardiac implantable electronic device, CRT-D = cardiac resynchronization therapy defibrillator, ICD = implantable cardioverter-defibrillator

Summary

In a series of 35 MRI examinations with non–MRI-conditional devices with a mismatch between the manufacturer of the device generators and leads, there were no adverse events.

Keywords

MRI, Cardiac, Safety

Table 1: Characteristics and Scan and Device Information of Patients Undergoing MRI Scans with Mismatch between Manufacturer of Generator and Leads

Parameter	No.	Percentage
Characteristic		
No. of patients/no. of scans	29/35	
Mean age (y)	69	
Female sex	18	51%
Pacemaker dependent	2	6%
Mean leads per patient	2	
Types of scans		
Abdomen	2	6%
Cervical spine	3	9%
Cardiac	7	20%
Head	8	23%
Thoracic or lumbar spine	10	29%
Hip/knee	5	14%
Device type		
Pacemaker	4	11%
ICD	16	46%
CRT-P	2	6%
CRT-D	12	34%
Other	1	3%
Device manufacturer		
Biotronik	3	9%
Boston Scientific	2	6%
Medtronic	23	66%
St Jude/Abbott	7	20%
Mismatched lead type		
Right atrium	13	37%
Right ventricle	29	83%
Left ventricle/coronary sinus	6	17%
Other	1	3%
Lead manufacturer		
Biotronik	2	6%
Boston Scientific/Guidant	13	37%
Medtronic	7	20%
St Jude/Abbott	12	34%
Other	2	6%

Note.—CRT-D = cardiac resynchronization therapy defibrillator, CRT-P = cardiac resynchronization therapy pacemaker, ICD = implantable cardioverter-defibrillator.

Table 2: Subjective and Objective Patient Outcomes and Changes in Device Function

Primary Outcome	No. of Patients
Change in device function	
Lead impedance change > 10%	1
Lead sensing change > 20%	0
Lead threshold change > 10%	0
Battery voltage change > 10%	0
Subjective and objective patient outcomes	
Observed change in patient rhythm	0
Change in oxygen saturation	1
Change in heart rate	1
Change in blood pressure	0
Reported symptoms of chest pain/burning, near syncope	0
Syncope	0
Cardiac arrest	0
Death	0

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